UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 40-F

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934**

☒ **ANNUAL REPORT PURSUANT TO SECTION 13(A) OR 15(D) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2023
Commission File Number 001-41923

EUPRAXIA PHARMACEUTICALS INC.
(Exact name of registrant as specified in its charter)

British Columbia	**2834**	**Not Applicable**
(Province or other jurisdiction of incorporation or organization)	**(Primary standard industrial classification code number, if applicable)**	**(I.R.S. Employer Identification No., if applicable)**

201-2067 Cadboro Bay Road
Victoria, British Columbia, Canada V8R 5G4
Telephone: (250) 590-3968
(Address and telephone number of registrant's principal executive offices)

Corporation Service Company
19 West 44th Street, Suite 200
New York, NY 10036
(800) 927-9800
(Name, address (including zip code) and telephone number (including area code) of agent for service in the United States)

Securities registered pursuant to Section 12(b) of the Act: None

Securities registered pursuant to Section 12(g) of the Act: None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: common shares

For annual reports, indicate by check mark the information filed with this form:

☒ **Annual Information Form** ☒ **Audited Annual Financial Statements**

Indicate the number of outstanding shares of the issuer's classes of capital or common stock as of the close of the period covered by the annual report: 27,282,165 Common Shares (as at December 31, 2023).

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Exchange Act during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes ☐ No ☒

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (s.232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 12b-2 of the Exchange Act. Emerging growth company. ☒

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act. ☐

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Auditor Name: KPMG LLP Auditor Location: Vancouver, Canada Auditor Firm ID: 85

PRINCIPAL DOCUMENTS

The following documents are filed as part of this Annual Report on Form 40-F:

A. Annual Information Form

For the Registrant's Annual Information Form for the year ended December 31, 2023, see Exhibit 99.1 of this Annual Report on Form 40-F ("***AIF***").

B. Audited Annual Financial Statements

For the Registrant's Audited Consolidated Financial Statements as of and for the years ended December 31, 2023 and 2022 (the "***2023 Financial Statements***"), including the Independent Auditor's Report with respect thereto, see Exhibit 99.2 of this Annual Report on Form 40-F.

C. Management's Discussion and Analysis

For the Registrant's Management's Discussion and Analysis of Financial Condition and Results of Operations for the year ended December 31, 2023 ("***MD&A***"), see Exhibit 99.3 of this Annual Report on Form 40-F.

CONTROLS AND PROCEDURES

A. Certifications

The required disclosure is included in Exhibits 99.5, 99.6, 99.7 and 99.8 of this Annual Report on Form 40-F.

B. Disclosure Controls and Procedures

The information provided under the heading "Disclosure Controls and Procedures and Internal Controls Over Financial Reporting" contained in the MD&A, filed as Exhibit 99.3 to this Annual Report on Form 40-F, is incorporated by reference herein.

C. Management's Annual Report on Internal Control over Financial Reporting and Attestation Report of the Registered Public Accounting Firm

This annual report does not include a report of management's assessment regarding internal control over financial reporting or an attestation report of the company's registered public accounting firm due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

D. Changes in Internal Control over Financial Reporting

The information provided under the heading "Disclosure Controls and Procedures and Internal Controls Over Financial Reporting" contained in the MD&A, filed as Exhibit 99.3 to this Annual Report on Form 40-F, is incorporated by reference herein.

AUDIT COMMITTEE FINANCIAL EXPERT

The Registrant's Board of Directors has determined that each member of the Audit Committee, John Montalbano, Simon Pimstone and Paul Geyer, are "independent" (as defined by Rule 10A-3 of the Exchange Act and Nasdaq Rule 5605(a)(2)) and that each of Mr. Montalbano and Dr. Pimstone are "audit committee financial experts" (as that term is defined in paragraph 8(b) of General Instruction B to Form 40-F). For a description of Mr. Montalbano's and Dr. Pimstone's relevant experience in financial matters, see the biographical descriptions for each under "Directors and Executive Officers" in the AIF, which is filed as Exhibit 99.1 to this Annual Report on Form 40-F.

The SEC has indicated that the designation or identification of a person as an audit committee financial expert does not make such person an "expert" for any purpose, impose any duties, obligations or liability on such person that are greater than those imposed on members of the audit committee and the board of directors who do not carry this designation or identification, or affect the duties, obligations or liability of any other member of the audit committee or board of directors.

CODE OF ETHICS

The Board of Directors of the Registrant (the "Board") has adopted a written code of business conduct and ethics (the "Code") which emphasizes the importance of matters relating to honest and ethical conduct, full, fair, accurate, timely, and understandable disclosure in reports that the Registrant files with, or submits to, the Securities and Exchange Commission (the "Commission") and in other public communications, compliance with applicable laws, rules and regulations, the prompt internal reporting of violations of the Code and accountability for adherence to the Code. All individuals representing the Registrant, including the Registrant's principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, are expected to abide by all applicable provisions of the Code and adhere to its principles and values when representing the Registrant to the public or performing services for, or on behalf of, the Registrant. The Board will review the effectiveness of the Code on an ongoing basis to ensure that the Registrant's business activities are conducted in accordance with the principles and rules set out therein. A copy of the Code can be obtained from the Registrant's website at www.eupraxiapharma.com/investors.

PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information provided under the heading "Audit Committee Information — External Auditor Fees" by Category contained in the AIF, filed as Exhibit 99.1 to this Annual Report on Form 40-F, is incorporated by reference herein.

AUDIT COMMITTEE PRE-APPROVAL POLICIES AND PROCEDURES

The information provided under the heading "Audit Committee Information — Pre-Approval Policies and Procedures" contained in the AIF, filed as Exhibit 99.1 to this Annual Report on Form 40-F, is incorporated by reference herein.

OFF-BALANCE SHEET ARRANGEMENTS

The information provided under the heading "Off-Balance Sheet Arrangements" contained in the MD&A, filed as Exhibit 99.3 to this Annual Report on Form 40-F, is incorporated by reference herein.

CONTRACTUAL OBLIGATIONS

The information provided under the heading "Contractual Obligations" contained in the MD&A, filed as Exhibit 99.3 to this Annual Report on Form 40-F, is incorporated by reference herein.

IDENTIFICATION OF THE AUDIT COMMITTEE

The information provided under the heading " Audit Committee Information — Audit Committee" contained in the AIF, filed as Exhibit 99.1 to this Annual Report on Form 40-F, is incorporated by reference herein.

DIFFERENCES IN NASDAQ AND CANADIAN CORPORATE GOVERNANCE REQUIREMENTS

The Registrant is a foreign private issuer and has applied to list its common shares on the Nasdaq Capital Market ("***Nasdaq***").

Nasdaq Rule 5615(a)(3) permits a foreign private issuer to follow its home country practice in lieu of the requirements of the Rule 5600 Series, the requirement to disclose third party director and nominee compensation set forth in Rule 5250(b)(3), and the requirement to distribute annual and interim reports set forth in Rule 5250(d), provided, however, that such a Company shall: comply with the Notification of Noncompliance requirement (Rule 5625), the Voting Rights requirement (Rule 5640), the Diverse Board Representation Rule (Rule 5605(f)), the Board Diversity Disclosure Rule (Rule 5606), have an audit committee that satisfies Rule 5605(c)(3), and ensure that such audit committee's members meet the independence requirement in Rule 5605(c)(2)(A)(ii).

The Registrant does not follow Rule 5620(c) regarding minimum quorum for meetings of shareholders and instead follows its home country practice. The Nasdaq minimum quorum requirement under Rule 5620(c) for a shareholder meeting is 33-1/3% of the outstanding shares of a company's common voting stock. In addition, a registrant listed on Nasdaq is required to state its quorum requirement in its by-laws. Under the Registrant's articles, quorum for a meeting of the Registrant's shareholders is at least one person who is, or who represents by proxy, one or more shareholders who, in the aggregate, hold at least 5% of the issued shares of the Registrant entitled to be voted at the meeting. The Business Corporations Act (British Columbia) ("***BCBCA***") defers to the quorum requirements in a corporation's articles. The primary market for the Registrant's common shares in Canada is the Toronto Stock Exchange (the "TSX"). The rules of the TSX do not contain quorum requirements. As a result, the Registrant's quorum requirements in respect of shareholder meetings are not prohibited by the BCBCA or the rules of the TSX.

FORWARD-LOOKING STATEMENTS

Certain statements in this Annual Report on Form 40-F are forward-looking statements within the meaning of Section 21E of the Exchange Act and Section 27A of the Securities Act of 1933, as amended. Please see "CAUTION REGARDING FORWARD-LOOKING STATEMENTS AND RISK FACTORS" in the AIF, filed as Exhibit 99.1 to this Annual Report on Form 40-F for a discussion of risks, assumptions, uncertainties and other factors that could cause actual results to vary from those forward-looking statements.

INCORPORATION BY REFERENCE

This Annual Report is incorporated by reference into the Registrant's Registration Statement on Form F-10 (File No. 333- 276586).

UNDERTAKING

The Registrant undertakes to make available, in person or by telephone, representatives to respond to inquiries made by the ***Commission*** staff, and to furnish promptly, when requested to do so by the Commission staff, information relating to the securities in relation to which the obligation to file an annual report on Form 40-F arises or transactions in said securities.

BOARD DIVERSITY MATRIX

The table below reports self-identified diversity statistics for the Board of Directors of the Registrant as of December 31, 2023, as required by Nasdaq Rule 5606.

Board Diversity Matrix	Eupraxia Pharmaceuticals Inc.	(As of	04/01/2024	)
Country of Principal Executive Offices	Canada			
Foreign Private Issuer	Yes			
Disclosure Prohibited Under Home Country Law	No			
Total Number of Directors	6			
	Female	**Male**	**Non-Binary**	**Did Not Disclose Gender**
Part I: Gender Identity				
Directors	0	6	0	0
Part II: Demographic Background				
Underrepresented Individual in Home Country Jurisdiction	0			
LGBTQ+	0			
Did Not Disclose Demographic Background	1			

CONSENT TO SERVICE OF PROCESS

The Registrant has previously filed a Form F-X in connection with the class of securities in relation to which the obligation to file this report arises.

Any change to the name or address of the Registrant's agent for service shall be communicated promptly to the Commission by amendment to Form F-X referencing the file number of the Registrant.

Exhibit Index

Exhibit No.	Document
97.1	Compensation Recovery Policy of the Registrant.
99.1	Annual Information Form of the Registrant for the fiscal year ended December 31, 2023.
99.2	Consolidated Financial Statements as of and for the years ended December 31, 2023 and 2022.
99.3	Management's Discussion and Analysis of Financial Condition and Results of Operations for the year ended December 31, 2023
99.4	Consent of KPMG LLP, dated April 1, 2024.
99.5	Certification of Chief Executive Officer (Principal Executive Officer) pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
99.6	Certification of Chief Financial Officer (Principal Financial Officer) pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
99.7	Certification of Chief Executive Officer (Principal Executive Officer) under Section 906 of the Sarbanes-Oxley Act of 2002.
99.8	Certification of Chief Financial Officer (Principal Financial Officer) under Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document.
101.SCH	Inline XBRL Taxonomy Schema Linkbase Document.
101.CAL	Inline XBRL Taxonomy Calculation Linkbase Document.
101.DEF	Inline XBRL Taxonomy Definition Linkbase Document.
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	Inline XBRL Taxonomy Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

SIGNATURES

Pursuant to the requirements of the Exchange Act, the Registrant certifies that it meets all of the requirements for filing on Form 40-F and has duly caused this report to be signed on its behalf by the undersigned, thereto duly authorized.

Date: April 1, 2024

Eupraxia Pharmaceuticals Inc.

By: /s/ James A. Helliwell
Name: James A. Helliwell
Title: Chief Executive Officer

Exhibit 97.1

EUPRAXIA PHARMACEUTICALS INC.

COMPENSATION RECOVERY POLICY

As adopted on December 21, 2023 and effective
as of the effective date of the Company's Form 8-A
filed with the Securities and Exchange Commission

Eupraxia Pharmaceuticals Inc. (the "**Company**") is committed to strong corporate governance. As part of this commitment, the Company's Board of Directors (the "**Board**") has adopted this clawback policy called the Compensation Recovery Policy (the "**Policy**"). The Policy is intended to further the Company's pay-for-performance philosophy and to comply with applicable laws by providing rules relating to the reasonably prompt recovery of certain compensation received by Covered Executives in the event of an Accounting Restatement. The application of the Policy to Covered Executives is not discretionary, except to the limited extent provided below, and applies without regard to whether a Covered Executive was at fault. Capitalized terms used in the Policy are defined below, and the definitions have substantive impact on its application so reviewing them carefully is important to your understanding.

The Policy is intended to comply with, and will be interpreted in a manner consistent with, Section 10D of the Securities Exchange Act of 1934 (the "**Exchange Act**"), with Exchange Act Rule 10D-1 and with the listing standards of the national securities exchange (the "**Exchange**") on which the securities of the Company are listed, including any official interpretive guidance.

Persons Covered by the Policy

The Policy is binding and enforceable against all "**Covered Executives**." A Covered Executive is each individual who is or was ever designated as an "officer" by the Board in accordance with Exchange Act Rule 16a-1(f) (a "**Section 16 Officer**"). The Committee may (but is not obligated to) request or require a Covered Executive to sign and return to the Company an acknowledgement that such Covered Executive will be bound by the terms and comply with the Policy. The Policy is binding on each Covered Executive whether or not the Covered Executive signs and/or returns any acknowledgment.

Administration of the Policy

The Compensation Committee (the "**Committee**") of the Board has full delegated authority to administer the Policy. The Committee is authorized to interpret and construe the Policy and to make all determinations necessary, appropriate, or advisable for the administration of the Policy. In addition, if determined in the discretion of the Board, the Policy may be administered by the independent members of the Board or another committee of the Board made up of independent members of the Board, in which case all references to the Committee will be deemed to refer to the independent members of the Board or the other Board committee. All determinations of the Committee will be final and binding and will be given the maximum deference permitted by law.

Accounting Restatements Requiring Application of the Policy

If the Company is required to prepare an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected

in the current period or left uncorrected in the current period (an "**Accounting Restatement**"), then the Committee must determine the Excess Compensation, if any, that must be recovered. The Company's obligation to recover Excess Compensation is not dependent on if or when restated financial statements are filed.

Compensation Covered by the Policy

The Policy applies to certain **Incentive-Based Compensation** (certain terms used in this Section are defined below) that is **Received** on or after October 2, 2023 (the "**Effective Date**"), during the **Covered Period** while the Company has a class of securities listed on a national securities exchange. Such Incentive-Based Compensation is considered "**Clawback Eligible Incentive-Based Compensation**" if the Incentive-Based Compensation is Received by a person after such person became a Section 16 Officer and the person served as a Section 16 Officer at any time during the performance period for the Incentive-Based Compensation. "**Excess Compensation**" means the amount of Clawback Eligible Incentive-Based Compensation that exceeds the amount of Clawback Eligible Incentive-Based Compensation that otherwise would have been Received had such Clawback Eligible Incentive-Based Compensation been determined based on the restated amounts. Excess Compensation must be computed without regard to any taxes paid and is referred to in the listing standards of the Exchange as "erroneously awarded compensation."

To determine the amount of Excess Compensation for Incentive-Based Compensation based on stock price or total shareholder return, where it is not subject to mathematical recalculation directly from the information in an Accounting Restatement, the amount must be based on a reasonable estimate of the effect of the Accounting Restatement on the stock price or total shareholder return upon which the Incentive-Based Compensation was Received and the Company must maintain documentation of the determination of that reasonable estimate and provide that documentation to the Exchange.

"**Incentive-Based Compensation**" means any compensation that is granted, earned, or vested based wholly or in part upon the attainment of a Financial Reporting Measure. For the avoidance of doubt, no compensation that is potentially subject to recovery under the Policy will be earned until the Company's right to recover under the Policy has lapsed.

"**Financial Reporting Measures**" are measures that are determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measures that are derived wholly or in part from such measures. Stock price and total shareholder return are also Financial Reporting Measures. A Financial Reporting Measure need not be presented within the financial statements or included in a filing with the Securities and Exchange Commission.

Incentive-Based Compensation is "**Received**" under the Policy in the Company's fiscal period during which the Financial Reporting Measure specified in the Incentive-Based Compensation award is attained, even if the payment, vesting, settlement or grant of the Incentive-Based Compensation occurs after the end of that period. For the avoidance of doubt, the Policy does not apply to Incentive-Based Compensation for which the Financial Reporting Measure is attained prior to the Effective Date.

"**Covered Period**" means the three completed fiscal years immediately preceding the Accounting Restatement Determination Date. In addition, Covered Period can include certain transition periods resulting from a change in the Company's fiscal year.

"**Accounting Restatement Determination Date**" means the earliest to occur of: (a) the date the Board, a committee of the Board, or one or more of the officers of the Company authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the Company is required to prepare an Accounting Restatement; and (b) the date a court, regulator, or other legally authorized body directs the Company to prepare an Accounting Restatement.

Repayment of Excess Compensation

The Company must recover Excess Compensation reasonably promptly and Covered Executives are required to repay Excess Compensation to the Company. Subject to applicable law, the Company may recover Excess Compensation by requiring the Covered Executive to repay such amount to the Company by direct payment to the Company or such other means or combination of means as the Committee determines to be appropriate (these determinations do not need to be identical as to each Covered Executive). These means include (but are not limited to):

(a) requiring reimbursement of cash Incentive-Based Compensation previously paid;

(b) seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer, or other disposition of any equity-based awards (including, but not limited to, time-based vesting awards), without regard to whether such awards are Incentive-Based Compensation or vest based on the achievement of performance goals;

(c) offsetting the amount to be recovered from any unpaid or future compensation to be paid by the Company or any affiliate of the Company to the Covered Executive, including (but not limited to) payments of severance that might otherwise be due in connection with a Covered Executive's termination of employment and without regard to whether such amounts are Incentive-Based Compensation;

(d) cancelling outstanding vested or unvested equity awards (including, but not limited to, time-based vesting awards), without regard to whether such awards are Incentive-Based Compensation; and/or

(e) taking any other remedial and recovery action permitted by law, as determined by the Committee.

The repayment of Excess Compensation must be made by a Covered Executive notwithstanding any Covered Executive's belief (whether or not legitimate) that the Excess Compensation had been previously earned under applicable law and therefore is not subject to clawback.

In addition to its rights to recovery under the Policy, the Company or any affiliate of the Company may take any legal actions it determines appropriate to enforce a Covered Executive's obligations to the Company or to discipline a Covered Executive. Failure of a Covered Executive to comply with their obligations under the Policy may result in (without limitation) termination of that Covered Executive's employment, institution of civil proceedings, reporting of misconduct to appropriate governmental authorities, reduction of future compensation opportunities or change in role. The decision to take any actions described in the preceding sentence will not be subject to the approval of the Committee and can be made by the Board, any committee of the Board, or any duly authorized officer of the Company or of any applicable affiliate of the Company. For avoidance of doubt, any decisions of the Company or the Covered Executive's employer to discipline a Covered Executive or terminate the employment of a Covered Executive are independent of determinations under this Policy. For example, if a Covered Executive was involved in activities that led to an Accounting Restatement, the Company's decision as to whether to not to terminate such Covered Executive's employment would be made under its employment arrangements with such Covered Executive and the requirement to apply this no-fault and non-discretionary clawback policy will not be determinative of whether any such termination is for cause, although failure to comply with the Policy might be something that could result in a termination for cause depending on the terms of such arrangements.

Limited Exceptions to the Policy

The Company must recover the Excess Compensation in accordance with the Policy except to the limited extent that any of the conditions set forth below is met, and the Committee determines that recovery of the Excess Compensation would be impracticable:

(a) The direct expense paid to a third party to assist in enforcing the Policy would exceed the amount to be recovered. Before reaching this conclusion, the Company must make a reasonable attempt to recover such Excess Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange;

(b) Recovery would violate a law in the country where the Company was incorporated that was adopted prior to November 28, 2022. Before making this determination, the Company must obtain an opinion of home country counsel, acceptable to the Exchange, that recovery would result in such a violation, and must provide such opinion to the Exchange; or

(c) Recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the legal requirements as such.

Other Important Information in the Policy

The Policy is in addition to the requirements of Section 304 of the Sarbanes-Oxley Act of 2002 that are applicable to the Company's Chief Executive Officer and Chief Financial Officer, as well as any other applicable laws, regulatory requirements, rules, or pursuant to the terms of any existing Company policy or agreement providing for the recovery of compensation.

Notwithstanding the terms of any of the Company's organizational documents (including, but not limited to, the Company's bylaws), any corporate policy or any contract (including, but not limited to, any indemnification agreement), neither the Company nor any affiliate of the Company will indemnify or provide advancement for any Covered Executive against any loss of Excess Compensation. Neither the Company nor any affiliate of the Company will pay for or reimburse insurance premiums for an insurance policy that covers potential recovery obligations. In the event that the Company is required to recover Excess Compensation pursuant to the Policy from a Covered Executive who is no longer an employee, the Company will be entitled to seek recovery in order to comply with applicable law, regardless of the terms of any release of claims or separation agreement that individual may have signed.

The Committee or Board may review and modify the Policy from time to time.

If any provision of the Policy or the application of any such provision to any Covered Executive is adjudicated to be invalid, illegal or unenforceable in any respect, such invalidity, illegality or unenforceability will not affect any other provisions of the Policy or the application of such provision to another Covered Executive, and the invalid, illegal or unenforceable provisions will be deemed amended to the minimum extent necessary to render any such provision or application enforceable.

The Policy will terminate and no longer be enforceable when the Company ceases to be a listed issuer within the meaning of Section 10D of the Exchange Act.

ACKNOWLEDGEMENT

- I acknowledge that I have received and read the Compensation Recovery Policy (the "**Policy**") of Eupraxia Pharmaceuticals Inc. (the "**Company**").
- I understand and acknowledge that the Policy applies to me, and all of my beneficiaries, heirs, executors, administrators or other legal representatives and that the Company's right to recovery in order to comply with applicable law will apply, regardless of the terms of any release of claims or separation agreement I have signed or will sign in the future.
- I agree to be bound by and to comply with the Policy and understand that determinations of the Committee (as such term is used in the Policy) will be final and binding and will be given the maximum deference permitted by law.
- I understand and agree that my current indemnification rights, whether in an individual agreement or the Company's organizational documents, exclude the right to be indemnified for amounts required to be recovered under the Policy.
- I understand that my failure to comply in all respects with the Policy is a basis for termination of my employment with the Company and any affiliate of the Company as well as any other appropriate discipline.
- I understand that neither the Policy, nor the application of the Policy to me, gives rise to a resignation for good reason (or similar concept) by me under any applicable employment agreement or arrangement.
- I acknowledge that if I have questions concerning the meaning or application of the Policy, it is my responsibility to seek guidance from .
- I acknowledge that neither this Acknowledgement nor the Policy is meant to constitute an employment contract.

Please review, sign and return this form to .

Covered Executive

_____
(*print name*)

_____
(*signature*)

_____
(date)

EUPRAXIA PHARMACEUTICALS INC.
ANNUAL INFORMATION FORM

Dated April 1, 2024

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INTRODUCTION

In this annual information form (this "**AIF**"), unless the context requires otherwise, references to the "Company", "Eupraxia", "we", "us", "our" and similar words refer to Eupraxia Pharmaceuticals Inc. or any predecessor thereto, as the context requires. The information in this AIF is presented as of December 31, 2023, unless otherwise indicated. All dollar amounts in this AIF are in Canadian dollars, except where otherwise indicated.

All regulatory filings to-date and communication from the Company have been made referencing EP-104IAR. In the interest of greater clarity for investors, the Company will use EP-104IAR when referring to the product candidate that is intended for intra-articular ("**IAR**") injections for indications such as osteoarthritis ("**OA**"), EP-104GI when referring to the product candidate that is intended for submucosal injections in the GI tract for indications such as eosinophilic esophagitis ("**EoE**"), and simply refer to the product candidate as EP-104 in conjunction with topics that are related to both EP-104IAR and EP-104GI.

CAUTION REGARDING FORWARD-LOOKING STATEMENTS AND RISK FACTORS

Certain statements and information in this AIF contain forward-looking statements or forward-looking information under applicable securities legislation that may not be based on historical fact, including, without limitation, statements containing the words "may," "might," "will," "likely", "could," "would," "should," "expect," "intend," "plan," "objective," "goal," "outlook," "anticipate," "believe," "estimate," "predict," "project," "forecast," "estimate," "potential," "target," "seek," "contemplate," "continue," "design," and "ongoing," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words and similar expressions. Forward-looking statements include estimates, plans, expectations, opinions, forecasts, projections, targets, guidance or other statements that are not statements of fact. Such forward-looking statements are made as of the date of this AIF.

Forward-looking statements are necessarily based on estimates and assumptions made by us in light of our experience and perception of historical trends, current conditions and expected future developments, as well as factors that we believe are appropriate. Forward-looking statements in this AIF include, but are not limited to, statements relating to:

- the Company's business strategies and objectives, including current and future plans, expectations and intentions;
- the Company's intent to use capital resources previously identified for EP-104IAR to continue the development of EP-104GI;
- the Company's intention to evaluate funding alternatives for the continued development of EP-104IAR, including potential partnership opportunities;
- the Company's ability to obtain sufficient funding for our operations, including funding for research, development and commercial activities;
- the Company's projected operating expenses and capital expenditures;
- the Company's ability to achieve profitability;
- projected revenues, future trends, opportunities and growth in the Company's industry and the drug development markets;
- the Company's ability to maintain and enhance its competitive advantages and technological advantages;
- the entry into commercial partnerships and commercialization of our technology;
- the Company's ability to enter into definitive agreements with its contract research organizations ("**CROs**");
- the Company's ability to enter into co-development and/or collaborative partnerships;
- the Company's clinical development programs and activities and the estimated timing thereof;
- the timing, status and results of clinical trials, including with respect to patient recruitment and data readout;
- the success of regulatory submissions;
- the obtaining of potential regulatory approval;
- the hiring of additional research and development team members;
- the potential for the Company's technology to impact the drug delivery process;
- the development of additional intellectual property, ability to patent or otherwise protect such developed intellectual property and licenses with third parties for intellectual property;
- the ability of patents and notices of allowance to provide protection over intellectual property in applicable jurisdictions;
- the Company's ability to protect, expand upon and exploit its existing intellectual property;
- the entry into sponsored research agreements and the benefits therefrom;
- the competitive advantages of the Company and its technology;

- the Company's product candidates and results gathered from studies thereof;
- the development of products from the Company's competitors;
- the application of regulations and standards to the Company's future products and services or research and development activities;
- the Company's retention of funds or payment of dividends;
- the translation of the Company's technologies and expansion of its offerings into clinical applications;
- the benefits to patients from Eupraxia's platforms;
- the value of the strategic relationship to Eupraxia's clients and investors;
- the Company's engagement with legal and regulatory authorities in various jurisdictions;
- the Company's anticipated use of proceeds from the Offering (as defined herein) and its existing cash and cash equivalents and the related estimated cash runway;
- the sufficiency of the Company's existing cash and cash equivalents to fund its future operating expenses and capital expenditure requirements;
- the Company's application for approval to list its common shares (the "Common Shares") on the Nasdaq Capital Market (the "Nasdaq");
- the Company's ability to successfully refinance the Debt Agreement (as defined herein) with Silicon Valley Bank ("**SVB**") and SVB Innovation Credit Fund VIII, L.P.;
- the demand and commercial viability of the Company's technology; and
- the demand and market acceptance for products developed by the Company.

Forward-looking statements and information involve significant risks, assumptions, uncertainties and other factors that may cause actual future results or anticipated events to differ materially from those expressed or implied in any forward-looking statements or information and, accordingly, should not be read as guarantees of future performance or results. These risks and factors include, but are not limited to:

- we have a limited operating history and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability;
- we will require substantial additional financing to achieve our goals and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts;
- we are substantially dependent on the success of our lead product candidates EP-104GI, which is currently being studied in an open label Phase 1b/2a clinical study, and EP-104IAR, for which we are evaluating funding alternatives for the continued development, including potential partnership opportunities. If we are unable to complete development of, obtain approval for and commercialize EP-104GI or EP-104IAR, alone or through a potential partnership, in a timely manner, our business will be harmed;
- if we breach any of the agreements under which we license rights to our product candidates or technology from third parties, we could lose license rights that are important to our business. Our current license agreement may not provide an adequate remedy for its breach by the licensor;
- adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and our financial condition and results of operations;
- clinical trials are expensive, time consuming and difficult to design and implement and may fail to demonstrate adequate safety and efficacy of our product candidates. Furthermore, the results of previous preclinical studies and clinical trials may not be predictive of future results, and the results of our current and planned clinical trials may not satisfy the requirements of the U.S. Food and Drug Administration (the "**FDA**") or comparable non-U.S. regulatory authorities or provide the basis for regulatory approval;
- our lead product candidates may not be successful for their intended use;
- our current and future product candidates will require regulatory approval, which is costly, and we may not be able to obtain it and we may fail to obtain regulatory approvals or only obtain approvals for limited uses or indications;
- the clinical trials of our product candidates may not demonstrate safety and efficacy to the satisfaction of the FDA, European Medicine Agency ("**EMA**") or other comparable foreign regulatory authorities or otherwise produce positive results;
- we completely rely on third parties to provide supplies and inputs required for our products;
- we rely on CROs to provide clinical and non-clinical research services; if such CROs do not successfully carry out their contractual duties including to comply with applicable laws and regulations or meet expected deadlines, our business could be substantially harmed;
- the manufacture of drugs is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented;
- our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor or other third party will discover them or that our trade secrets will be misappropriated or disclosed;

- the outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, EMA or other comparable foreign regulatory authorities. Terminating the development of any of our product candidates could materially harm our business and the market price of our Common Shares;
- interim, initial, "top-line", and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data;
- any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could seriously harm our business;
- our current or future product candidates may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other products that may result in a safety profile that could inhibit regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences;
- where appropriate and applicable, we may seek approval from the FDA or comparable foreign regulatory authorities through the use of expedited approval pathways, such as Fast Track designation or orphan drug designation. Even if we receive Fast Track designation or other designation, we can provide no assurance that we will be able to obtain FDA approval sooner or if at all;
- if we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our drug candidates, if approved, we may be unable to generate any product revenue;
- we have a novel technology with uncertain market acceptance;
- if we experience delays or difficulties in the enrollment and/or maintenance of patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected;
- the FDA, EMA and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction;
- obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions;
- if the market opportunity for any product candidate that we or our strategic partners develop is smaller than we believe, our revenue may be adversely affected and our business may suffer;
- even if our product candidates receive regulatory approval, we will be subject to significant post marketing regulatory requirements and oversight;
- FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates;
- the FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses;
- disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business;
- we rely on key personnel;
- we may not be able to successfully execute our business strategy;
- we are in a highly competitive industry which is continuously evolving with technological changes;
- our future success will depend on our ability to continually enhance and develop our product candidates;
- we may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success;
- changes in methods of product candidate manufacturing or formulation may result in additional costs or delay;
- if we are unable to differentiate EP-104 from existing therapies or if the FDA or other applicable regulatory authorities approve additional, and potentially less costly, therapies that compete with EP-104, our ability to successfully commercialize EP-104GI or EP-104IAR would be adversely affected;
- a variety of risks associated with potential international business relationships could materially adversely affect our business;
- collaboration arrangements we may enter into in the future may not be successful;
- provisions of our existing and any future debt instruments may restrict our ability to pursue our business strategies;
- we may acquire businesses or products, or form strategic alliances in the future, and we may not realize the benefits of such acquisitions or alliances;
- we have traditionally relied on key collaborations and grants;
- we are subject to evolving global laws and regulations relating to privacy, data protection and information security, which may require us to incur substantial compliance costs, and any failure or perceived failure by us to comply with such laws and regulations may harm our business and operations;

- our business and operations could suffer in the event of an actual or perceived information security incident such as a cybersecurity breach, system failure, or other compromise of our systems or those of a third-party or other contractor or vendor;
- we may fail to manage our growth successfully, which may adversely impact our operating results;
- we use hazardous chemicals and biological materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly;
- if product liability lawsuits are brought against us, then we may incur substantial liabilities and may be required to limit commercialization of EP-104, if approved, for any indication, and any other future products;
- our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading, which could significantly harm our business;
- we may be subject to securities litigation, which is expensive and could divert management attention;
- our directors and executive officers may be affiliated with other biotech companies and may have conflicts of interest;
- our business may be affected by macroeconomic conditions;
- our business may be affected by global geopolitical risks;
- we may be responsible for corruption and anti-bribery law violations;
- we are subject to foreign exchange risks;
- we are subject to taxation risks and changing rules by different tax authorities;
- we are subject to a number of risks and hazards and may not be sufficiently insured for all of them;
- we will devote significant resources to regulatory compliance as a public entity;
- changes in accounting standards from IFRS to U.S. GAAP can be difficult to predict and could adversely impact how we record and report our financial condition and results of operations;
- in the past, we have had to restate our previously issued consolidated financial statements and as part of that process identified a material weakness in our disclosure controls and procedures and internal control over financial reporting as of December 31, 2022. If we are unable to develop and maintain effective disclosure controls and procedures and internal control over financial reporting, we may not be able to accurately report our financial results in a timely manner, which may adversely affect investor confidence in us and may adversely affect our business, financial condition and results of operations;
- our success depends on our ability to protect our intellectual property and our proprietary technologies;
- if the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected;
- intellectual property rights do not necessarily address all potential threats to our competitive advantage;
- our patent rights may prove to be an inadequate barrier to competition;
- our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts;
- we may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses;
- we may be involved in lawsuits to protect or enforce our patents or our future licensors' patents, which could be expensive, time consuming, and unsuccessful. Further, our issued patents or our current or future licensors' patents could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad;
- intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our Common Shares to decline;
- derivation proceedings may be necessary to determine priority of inventions, and an unfavorable outcome may require us to cease using the related technology or to attempt to license rights from the prevailing party;
- we may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products and product candidates;
- changes in U.S. patent law, or laws in other countries, or their interpretation could diminish the value of patents in general, thereby impairing our ability to protect our product candidates;
- we may be subject to claims challenging the inventorship or ownership of our patents, the patents we license, and other intellectual property;
- patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time;
- we may not be able to protect or enforce our intellectual property rights throughout the world;

- obtaining and maintaining our patent protection depends on compliance with various procedural, documentary submission, fee payment and other requirements imposed by regulations and governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements;
- if our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected;
- if we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected, harming our business and competitive position;
- we may be subject to claims that we or our employees, independent contractors, or consultants have wrongfully used or disclosed alleged confidential information or trade secrets;
- we may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees, independent contractors, or consultants have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers;
- we may be subject to claims challenging the inventorship of our patents and other intellectual property;
- our rights to develop and commercialize our technology and product candidates may be subject, in part, to the terms and conditions of any future licenses granted to us by others;
- if we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our future licensors, we could lose license rights that are important to our business;
- the patent protection and patent prosecution for some of our product candidates may be dependent on third parties;
- coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if approved, which could make it difficult for us to sell any product candidates or therapies profitably;
- our relationships with healthcare providers and physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings;
- our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements;
- our research and development activities could be affected or delayed as a result of possible restrictions on animal testing;
- ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations;
- the market price of the Common Shares may be volatile;
- investors may lose their entire investment;
- we have no history of dividends;
- our existing executive officers and directors own a significant percentage of Common Shares and may have a significant impact over matters submitted to our shareholders for approval;
- future sales of Common Shares by our existing shareholders could cause our share price to decline;
- we will need to raise additional financing in the future which may dilute our share capital;
- if securities or industry analysts either do not publish research about us or publish inaccurate or unfavorable research about us, our business or our market, or if they adversely change their recommendations regarding our Common Shares, the trading price or trading volume of our Common Shares could decline;
- any issuance of preferred shares could make it difficult for another company to acquire us or could otherwise adversely affect holders of our Common Shares, which could depress the price of our Common Shares;
- our constating documents permit us to issue an unlimited number of Common Shares without additional shareholder approval;
- raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates;
- we have warrants, convertible debt, and shares of a subsidiary exchangeable for Common Shares outstanding, which in each case, if exercised, converted or exchanged, respectively, could cause dilution to existing shareholders;
- our Common Shares may have limited liquidity;

- even if our Common Shares are approved for listing, we cannot assure you that an active market will develop for Common Shares on the Nasdaq;
- United States investors may not be able to obtain enforcement of civil liabilities against us;
- as a foreign private issuer, we are subject to different U.S. securities laws and rules than a domestic U.S. issuer, which may limit the information publicly available to our U.S. shareholders;
- we may lose our foreign private issuer status in the future, which could result in significant additional costs and expenses to us;
- U.S. holders of our Common Shares may suffer adverse tax consequences if we are characterized as a passive foreign investment company; and
- if a U.S. holder is treated as owning at least 10% of our Common Shares, such U.S. holder may be subject to adverse U.S. federal income tax consequences.

Such forward-looking statements reflect our current views with respect to future events, are subject to risks and uncertainties and are necessarily based upon a number of estimates and assumptions that, while considered reasonable by Eupraxia as of the date of such statements, are inherently subject to significant medical, scientific, business, economic, competitive, political and social uncertainties and contingencies. Many factors could cause our actual results, performance, or achievements to be materially different from any future results, performance, or achievements that may be expressed or implied by such forward-looking statements. In making the forward-looking statements included in this AIF, the Company has made various material assumptions, including but not limited to (i) the Company's ability to attract and retain skilled staff; (ii) future research and development plans for the Company proceeding substantially as currently envisioned; (iii) industry growth trends, including with respect to projected and actual industry sales; (iv) the Company's ability to obtain positive results from the Company's research and development activities, including clinical trials; (v) sufficient working capital and the Company's ability to control costs and raise additional financing going forward; (vi) obtaining regulatory approvals and the potential benefits of our products, if approved; (vii) general business and economic conditions; (viii) the Company's ability to achieve profitability; (ix) the Company's ability to successfully commercialize its current product candidates, enter into commercial partnerships and develop new products; (x) the availability of financing on reasonable terms; (xi) market competition; (xii) the products and technology offered by the Company's competitors; (xiii) the Company's ability to protect patents and proprietary rights; and (xiv) the availability and cost of personnel, materials and supplies.

In evaluating forward-looking statements, current and prospective shareholders should specifically consider various factors, including the risks outlined herein under the heading "*Risk Factors*". Should one or more of these risks or uncertainties, or a risk that is not currently known to us materialize, or should assumptions underlying those forward-looking statements prove incorrect, actual results may vary materially from those described herein. These forward-looking statements are made as of the date of this AIF and we do not intend, and do not assume any obligation, to update these forward-looking statements, except as required by applicable securities laws. Investors are cautioned that forward-looking statements are not guarantees of future performance and are inherently uncertain. Accordingly, investors are cautioned not to put undue reliance on forward-looking statements.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements.

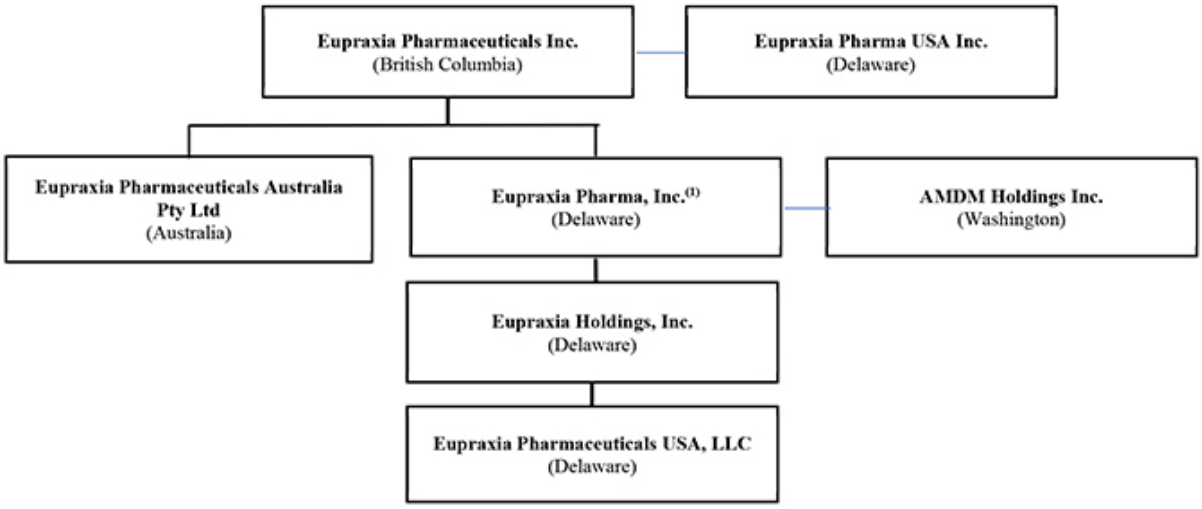
CORPORATE STRUCTURE

General

The Company was incorporated under the name "Plaza Capital Partners Inc." pursuant to the *Business Corporations Act* (Alberta) on May 12, 2011. On May 11, 2012, the Company was continued to British Columbia under the *Business Corporations Act* (British Columbia) (the "**BCBCA**"), with the name "Eupraxia Pharmaceuticals Inc.". Our registered and records office is located at Suite 3500, 1133 Melville Street, The Stack, Vancouver, British Columbia, Canada, V6E 4E5. Our head office is located at 201 - 2067 Cadboro Bay Road, Victoria, British Columbia, Canada V8R 5G4.

Intercorporate Relationships

The chart below illustrates the Company's inter-corporate relationships of its subsidiaries as at the date hereof. All ownership is 100% unless otherwise stated.



Notes:

(1) Amanda Malone, the Chief Scientific Officer of the Company, holds 225 non-voting Class B shares (the "**Class B Shares**") of Eupraxia Pharma Inc. ("**Eupraxia Pharma**"), representing 5% of the outstanding securities of Eupraxia Pharma. The Company holds the remaining 95% of such securities, which consists of 4,275 voting Class A shares. Each Class B Share is exchangeable into Common Shares based on an exchange rate of 2,500 Common Shares for each Class B Share, subject to adjustments upon the occurrence of certain events, for a total of 562,500 Common Shares. The Class B Shares are exchangeable by Dr. Malone at her election, provided that the Company may force the exchange of the Class B Shares into Common Shares at any time on or after January 31, 2031, or on or after January 31, 2026, if the Company is listed on a stock exchange and is a reporting issuer in Canada at such time. The Company may also force the exchange of the Class B Shares into Common Shares if there is a change of control transaction involving the Company, a change in law which makes the exchange necessary or desirable or if there are a *de minimis* number of Class B Shares outstanding. If the Company is listed on a stock exchange at the time of the applicable exchange, the Company may elect to pay Dr. Malone cash in lieu of issuing Common Shares, with such cash amount to be determined based on the then current market price of the Common Shares.

GENERAL DEVELOPMENT OF THE BUSINESS

Three-Year History

2024

On January 30, 2024 the Company announced positive data from a Magnetic Resonance Imaging ("**MRI**") exploratory sub-study in its Phase 2 SPRINGBOARD trial evaluating the safety and efficacy of EP-104IAR for the treatment of osteoarthritis of the knee.

On February 1, 2024 the Company announced summary results from the End-of-Phase 2 meeting with the FDA and the initiation of the Phase 3 Development program for EP-104IAR.

On February 5, 2024 the Company announced updated positive clinical trial data in its EP-104GI RESOLVE trial for the treatment of Eosinophilic Esophagitis.

On February 5, 2024, the Company filed and obtained a receipt for a final short form base shelf prospectus (the "**Shelf Prospectus**"). The Shelf Prospectus replaced the Company's 2023 Shelf Prospectus filed in June 2023. The Shelf Prospectus will allow the Company and certain of its securityholders to qualify the distribution of up to US$200 million of Common Shares, preferred shares, debt securities, warrants, subscription receipts, and units, or any combination thereof during the 25-month period that the Shelf Prospectus is effective, in amounts, at prices and on terms based on market conditions at the time of any offering, and set forth in an accompanying shelf prospectus supplement.

On March 15, 2024 the Company announced the closing of an overnight marketed offering (the "**Offering**") of Common Shares. The Company issued 8,260,435 Common Shares at a price of CDN$4.10 per Common Share for gross proceeds of CDN$33,867,784, which included the issuance of 943,435 Common Shares upon partial exercise of the over-allotment option.

2023

On May 18, 2023, the Company announced the appointment of Dr. Mark Kowalski to the role of Chief Medical Officer. This new position reports directly to the Chief Executive Officer ("CEO") and is responsible for advancing clinical trials and pipeline development.

On June 8, 2023, the Company announced the dosing of the first patient in an open label Phase 1b/2a clinical study (RESOLVE) using EP-104GI in EoE. The RESOLVE study will be conducted in up to 24 adult patients with a confirmed diagnosis and active EoE symptoms. Primary outcomes for safety, PK and efficacy will be collected at various points over a 12-week total period, with a subsequent follow up at six (6) months. Initial low-dose cohorts presented early signals of efficacy, and we anticipate ongoing safety, efficacy and PK readouts from subsequent dose-escalation cohorts throughout 2024. The RESOLVE protocol is active at sites in Canada, the Netherlands and Australia. Additional sites and jurisdictions will be added as necessary to complete target recruitment.

On June 13, 2023, the Company announced that it had received U.S. Fast Track designation for EP-104IAR in the treatment of OA. This process is designed to facilitate the development and expedite the review of drugs that treat serious conditions and fill an unmet medical need.

On June 22, 2023, the Company filed and obtained a receipt for a final short form base shelf prospectus (the "**2023 Shelf Prospectus**"). The 2023 Shelf Prospectus replaced the Company's 2022 Shelf Prospectus filed in January 2022.

On June 26, 2023, the Company announced positive results from its Phase 2b clinical trial of EP-104IAR for pain associated with knee OA. EP-104IAR met its primary endpoint with a clinically meaningful and statistically significant (p=0.004) improvement over vehicle-placebo in WOMAC Pain at 12 weeks.

On August 18, 2023, the Company announced the closing of a non-brokered private placement. The Company issued 3,183,875 Common Shares at a price of CDN$7.00 per Common Share for gross proceeds of CDN$22,287,125.

On September 7, 2023, the Company announced the appointment of KPMG LLP as the auditor of the Company, effective August 30, 2023. Concurrently, Baker Tilly WM, LLP resigned as the Company's auditor. There were no reportable events involving Baker Tilly WM, LLP.

On October 11, 2023, the Company announced the initiation of a second cohort in its Phase 1b/2a clinical trial in EoE.

On December 12, 2023 the Company announced positive clinical data in its EP-104GI RESOLVE trial.

2022

On January 10, 2022, the Company filed a final short form base shelf prospectus with the securities regulatory authorities in each of the provinces and territories of Canada (the "**2022 Shelf Prospectus**"). The 2022 Shelf Prospectus allowed the Company and certain of its securityholders to qualify the distribution of up to CDN$30 million of common shares, preferred shares, debt securities, warrants, subscription receipts, and units, or any combination thereof during the 25-month period that the 2022 Shelf Prospectus is effective, in amounts, at prices and on terms based on market conditions at the time of any offering, and set forth in an accompanying shelf prospectus supplement.

On April 20, 2022, the Company announced that it had closed an overnight marketed public offering (the "**2022 Offering**"). Pursuant to the 2022 Offering, Eupraxia issued 7,150,550 units of the Company (the "**Units**") at a price of CDN$2.05 per Unit and 181,000 common share purchase warrants of the Company (the "**Warrants**") at a price of CDN$0.30 per Warrant for aggregate gross proceeds of approximately CDN$14.7 million. The completion of the 2022 Offering satisfied the requirement to raise CDN$10 million in additional net new capital under the terms of a contingent convertible debt agreement (the "**Debt Agreement**") with SVB.

On September 26, 2022, the Company announced the grant of a patent and a notice of allowance for EP-104. The grant of European Patent EP2976062B1 provides compositional and method of use coverage for EP-104 and covers major European markets of commercial significance. The Company believes the new European patent offers strong protection for EP-104 in key European markets until 2034, pending any adjustments or extensions.

On September 26, 2022, the Company also announced the grant of a Brazilian notice of allowance, which will provide compositional and method-of-use coverage for EP-104. The Company believes this grant will provide extensive protection for EP-104 in the Brazilian market until 2034, also pending any adjustments or extensions.

On October 11, 2022, the Company provided the following updates to its Phase 2 OA trial:

- The study successfully completed all Data Safety Monitoring Board reviews, with no drug-related serious adverse events noted and was observed to be well tolerated.
- The inclusion criteria were expanded to include diagnosed diabetic patients.
- MRIs were added as an elective assessment for remaining patients to be enrolled in the study.

On October 12, 2022, the Company announced the initiation of the Phase 1b/2a trial of EP-104GI for EoE. Eupraxia has received regulatory and ethics committee clearance to begin the trial in Canada, Australia and the Netherlands, and data from the open label trial is anticipated to start reading out in the first half of 2023.

On November 2, 2022, the Company announced the appointment of Mr. Paul Brennan to the role of Chief Business Officer. This new position reports directly to the CEO and is responsible for advancing partnership opportunities for the Company.

On December 7, 2022, the Company announced that it had completed enrollment, randomization and dosing of the last patient, in its Phase 2 trial that is evaluating the efficacy and safety of EP-104IAR for the treatment of OA of the knee.

2021

On January 31, 2021, the Company entered into a contribution agreement with Amanda Malone, the Chief Scientific Officer of the Company, and certain of the Company's subsidiaries (the "**Contribution Agreement**"). Pursuant to the Contribution Agreement, the Company acquired AMDM Holdings Inc., a corporation wholly owned by Ms. Malone, which held 5% of the equity interest in the Company's subsidiary, Eupraxia Pharmaceuticals USA, LLC ("**Eupraxia USA**"). In exchange, the Company issued to Ms. Malone 225 non-voting Class B Shares in Eupraxia Pharma, representing 5% of the outstanding securities of Eupraxia Pharma. The Company holds the remaining 95% of such securities, which consists of 4,275 voting Class A shares.

On March 3, 2021, the Company obtained a receipt for its final prospectus filed with the securities regulatory authorities in each of the provinces of Canada, other than Québec, in connection with the initial public offering (the "**IPO**") of 5,125,000 Units at a price of CDN$8.00 per Unit (the "**IPO**") for gross proceeds of CDN$41,000,000. Each Unit

consisted of one common share in the Company and one-half of one Warrant. Each Warrant is exercisable into one common share of the Company (each, a "**Warrant Share**") at an exercise price of CDN$11.20 per Warrant Share at any time prior to 5:00 p.m. (Toronto time) on the date that is five years following the closing of the IPO, subject to adjustment in certain events. The Warrants include an acceleration provision, exercisable at the Company's option, if the Company's daily volume weighted average share price is greater than CDN$22.40 for five consecutive trading days. The closing of the IPO occurred on March 9, 2021. The Company was listed on the Toronto Stock Exchange ("**TSX**") with the listing of both the Common Shares and the Warrants under the symbols "EPRX" and "EPRX.WT", respectively.

On March 9, 2021, upon the closing of the IPO, (i) the CDN$6,690,000 aggregate principal amount of convertible notes issued from June 19, 2018 to May 23, 2019 (collectively, the "**Convertible Notes (10%)**"), plus accrued and unpaid interest of CDN$1,457,086; (ii) the CDN$831,000 aggregate principal amount of convertible notes issued from June 1, 2020 to January, 2021 (collectively, the "**Convertible Notes (30%)**", and together with the Convertible Notes (10%), the "**Convertible Notes**"), plus accrued and unpaid interest CDN$50,918; and (iii) 857,500 special warrants (collectively, the "**Special Warrants**"), were automatically converted into 1,103,886 Common Shares and 157,501 Common Shares and exercised into 298,798 Common Shares, respectively.

On April 14, 2021, the Company entered into an agreement with Nordic Bioscience Clinical Development A/S ("**NBCD**"), a CRO dedicated to clinical drug development and research in OA, to conduct Eupraxia's EP-104IAR Phase 2 clinical trial (protocol EP-104IAR-201). The randomized, placebo-controlled trial evaluates the safety, efficacy and pharmacokinetics ("**PK**") of a single 25 mg injection into the knees of 300 subjects with knee OA. NBCD agreed to make a $500,000 USD investment in the Company on the same terms as the IPO (the "**Equity Investment**"). NBCD's subscription for the Equity Investment was satisfied by setting off $500,000 USD of service fees otherwise payable by Eupraxia to NBCD and allowed Eupraxia to expand enrollment in its EP-104IAR Phase 2 clinical trial from the original 240 to 300 patients.

On April 29, 2021, the Company issued to NBCD 78,456 Units at a price of CDN$8.00 per Unit, with each Unit consisting of one Common Share and one-half of one common share purchase warrant of the Company (each whole common share purchase warrant, a "**Nordic Warrant**"). Each Nordic Warrant is exercisable into one Common Share at an exercise price of CDN$11.20 per share at any time prior to 5:00 p.m. on the date that is five years from the date of issuance, subject to adjustment in certain events. The Nordic Warrants include the same acceleration provision as the Warrants under the IPO, which is exercisable at the Company's option if the Company's daily volume weighted average share price is greater than CDN$22.40 for five consecutive trading days. The Nordic Warrants are transferable but are not listed on the TSX.

On May 3, 2021, the Company announced the appointment of Bruce Cousins as the Company's new President and Chief Financial Officer, replacing Alex Rothwell.

On May 18, 2021, the Company offered existing lenders the opportunity to convert their outstanding principal and accrued interest into Common Shares at a conversion price equal to CDN$4.6106 per Common Share. Principal and interest totaling CDN$5,987,642 was subsequently converted into 1,298,664 Common Shares on June 8, 2021. Accrued interest totaling CDN$180,197 was paid in cash to lenders.

On June 21, 2021, the Company entered into the Debt Agreement with SVB and concurrently drew down in full the CDN$10 million principal amount under the Debt Agreement. The Debt Agreement has a term of 36 months or 48 months on SVB's election. The Debt Agreement accrues interest at the greater of 2.45% and the Canadian prime rate, requiring monthly interest payments. An additional payment in kind will accrue at a rate of 7% per annum, which will be settled on maturity or conversion. Subject to the terms and conditions of the Debt Agreement, SVB may elect to convert the principal amount of the convertible debt and the accrued and unpaid interest thereon into Common Shares at a conversion price equal to CDN$5.68 per Common Share. The Company has agreed to grant SVB a security interest in all of its assets, excluding its patents and other intellectual property, as security for its obligations under the Debt Agreement. The Company is required, on or prior to June 30, 2022, to raise additional net new capital, as defined in the Debt Agreement, in the aggregate amount of CDN$10 million. This net new capital can originate from, but is not restricted to, a variety of sources as outlined in the Debt Agreement and can include up to CDN$5 million in reduced project expenses. This obligation has been fully satisfied.

On July 19, 2021, the Company announced that it had received authorization from the Danish Medicines Agency to initiate the EP-104IAR Phase 2 clinical trial. This was followed by central ethics approval on September 1, 2021. On September 14, 2021, the Company announced that it had initiated patient screening. Successful candidates were subsequently enrolled and dosed in the last quarter, with patient recruitment completed in 2022.

On September 16, 2021, the Company announced the publication of EP-104IAR Phase 1 results in *Osteoarthritis and Cartilage Open*. The article, entitled, "Safety and Pharmacokinetics of EP-104IAR (sustained-release fluticasone propionate) in Knee Osteoarthritis: A Randomized, Double-Blind, Placebo-Controlled Phase 1 Trial," was made available to all readers through the medical journal's website.[1] On this date, the Company also announced receipt of a Notice of Allowance from the Israel Patent Office with respect to its patent application "Injectable Sustained Release Composition and Method of using the Same for Treating Inflammation in Joints and Pain Associated Therewith."

On November 4, 2021, the Company announced receipt of advisory services and funding of up to CDN$700,000 from the National Research Council of Canada Industrial Research Assistance Program (NRC-IRAP) to support a research and development project to further develop the Company's polymer-based proprietary drug delivery technology.

On December 2, 2021, the Company announced its intent to increase the number of clinical research sites and modify patient enrollment criteria in the EP-104IAR Phase 2 trial to facilitate patient recruitment.

On December 3, 2021, the Company amended its stock option plan (the "**Amended Plan**") to: (i) amend the maximum number of Common Shares that may be reserved and available for issuance upon exercise of stock options ("**Options**"), from 15% of the aggregate of the Company's issued and outstanding Common Shares to 18.5% of the total number of issued and outstanding Common Shares (on a non-diluted basis) at the relevant time; and (ii) remove the overall Common Share limitation for all security based compensation arrangements contained in the Company's existing amended and restated stock option plan.

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1 Amanda Malone, James Price, Nicola Price, Vik Peck, Alan Getgood, Robert Petrella, James Helliwell. Safety and pharmacokinetics of EP-104 (sustained-release fluticasone propionate) in knee osteoarthritis: A randomized, double-blind, placebo-controlled Phase 1 trial, *Osteoarthritis and Cartilage Open*, Volume 3, Issue 4,2021,100213, ISSN 2665-9131, https://doi.org/10.1016/j.ocarto.2021.100213.

DESCRIPTION OF THE BUSINESS

Overview of the Company

We are a clinical-stage biotechnology company seeking to leverage our proprietary Diffusphere technology to optimize drug delivery for applications with significant unmet medical need. Each of our product candidates are designed to improve patient benefit by providing more prolonged activity than currently available treatments, combined with an improved pharmacokinetics ("PK") and related safety profile and precisely targeted local delivery. We believe a product with this profile could offer the dual potential of providing long-lasting treatment while minimizing tolerability complications in target and non-target tissues. Our strategy is to develop a portfolio of product candidates based on this delivery technology.

We currently have two distinct clinical development programs, one targeting EoE and the second targeting chronic OA pain in the knee. Currently, both programs are broadly based upon the same drug candidate (EP-104). The injectable drug is dispensed together with a "vehicle" diluent specifically designed for the target delivery modality and co-administered with the active pharmaceutical ingredient ("API"). For our ongoing clinical studies we are using the same underlying API and extended-release formulation. In the future, we anticipate that therapeutic targets will be differentiated by dosing levels, vehicle and delivery methods and will be distinct product candidates. The product candidate that is being developed specifically for submucosal injections in the GI tract with an initial indication of EoE is referred to as EP-104GI, and the product candidate that is being developed for intra-articular ("IA") injections with an initial indication of knee OA is referred to as EP-104IAR. EP-104 is intended to refer to the extended-release Diffusphere technology, which is used in the formulation of both EP-104GI and EP-104IAR.

We have successfully completed a Phase 2b trial with EP-104IAR in knee OA, and in January 2024 held a meeting with the FDA to determine the preclinical and clinical requirements for an NDA submission and approval in the United States. We believe that the future success of the product will be dependent on late phase development and commercialization expertise, and will require significant resources. We are currently evaluating funding alternatives for the continued development of EP-104IAR, including potential partnership opportunities and intend to modulate investment levels pending the outcomes. We intend to undertake certain preclinical and manufacturing activities as well as Phase 3 planning and preparation related to EP-104IAR to ensure continuity of the project, but we intend to wait until we have funding needs further sorted before committing to additional significant spend for this program. We intend to use our capital resources previously identified for EP-104IAR development to continue development of EP- 104GI.

We are currently conducting a Phase 1b/2a clinical trial with EP-104GI. We intend to continue development of EP-104GI through the ongoing clinical trial and any subsequent trials required by the FDA to obtain commercial approval. We intend to evaluate the possibility of identifying a corporate partner to help with the development of EP-104GI.

Product Candidates

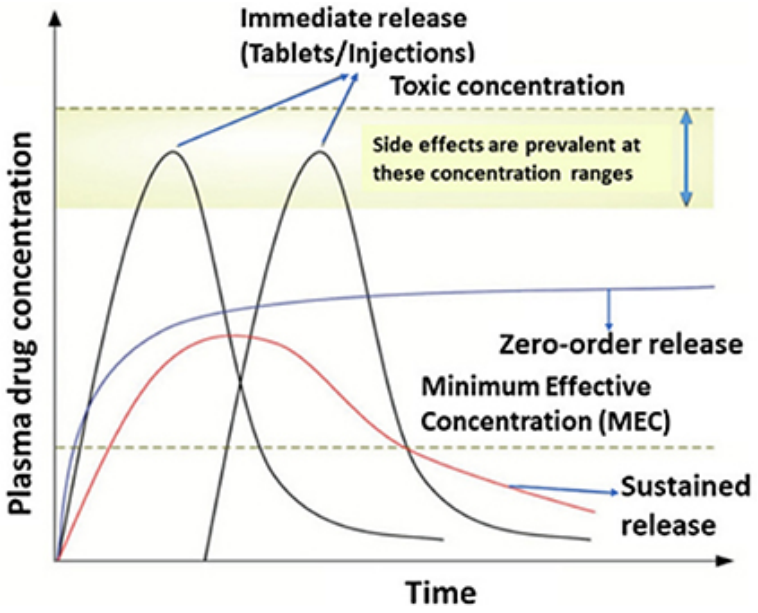
The primary active ingredient of the EP-104 product candidates consists of a solid core of fluticasone propionate ("FP") coated with an outer layer of polyvinyl alcohol ("PVA"). FP is a synthetic trifluorinated corticosteroid with potent anti-inflammatory activity and a well-established systemic safety record in the form of widely used inhaled, intranasal, and topical agents. It has been shown to be locally active, and FP that is systemically absorbed is rapidly metabolized. Relative to other corticosteroids (including triamcinolone acetonide or "TCA"), FP has a high affinity for the glucocorticoid receptor, low solubility, a low rate of dissociation, and a comparatively long half-life. It is currently approved by the FDA, Health Canada, European Medicines Agency and many other regulatory agencies around the world. PVA is a biocompatible polymer with numerous biomedical applications and a 30-year safety record in various human tissues. We believe these characteristics make EP-104 a promising candidate for prolonged anti-inflammatory use.

EP-104 technology is designed to work through the diffusion of the drug particles through a microns-thin polymer membrane. When the particles are injected at the disease site, extracellular fluid diffuses across the polymer membrane and into the particles themselves, dissolving some of the solid drug core and creating a saturated drug solution inside

the microsphere with relatively low drug concentrations in the outside microenvironment. Steady-state diffusion of FP across the polymer membrane and into the extracellular space then delivers the drug candidate to the intended area at a prolonged and steady release rate with close to constant drug levels. This rate can be controlled by changing the size of the drug core and the properties of the polymer membrane, creating a target drug release profile designed to maximize disease treatment and reduce systemic and local side effects often accompanying drugs having conventional release profiles.

The following figure illustrates the differences between immediate release drugs, standard extended-release drugs and the release profile intended by EP-104. Immediate-release drugs release high initial drug levels into the blood (which can result in side effects), followed by rapid drug clearance. Standard extended-release profiles tend to blunt the early peak effects but still decline at a rapid rate. EP-104 is designed to prevent early peak concentrations associated with side effects and extend the duration of FP residence time in the intended area of administration to achieve prolonged activity.

Drug Plasma Levels and Release Profiles



Another key feature differentiating EP-104 from other extended-release IA corticosteroid formulations is that more than 90% by weight of EP-104 is the active FP component in the investigational drug product, compared to less than 20% in other polymer based extended release products using degradation.

FP, although approved by the FDA, Health Canada, EMA and other regulatory agencies, is not currently approved for use in any formulation for the treatment of symptoms in either EoE or OA. To our knowledge, EP-104GI and EP-104IAR are the only extended-release formulations of FP in development for these conditions. We believe that the EP-104 drug delivery technology platform has the potential to have a beneficial application for EoE, given the already-established efficacy of oral immediate release of FP in this indication. The drug delivery technology platform also has the potential to be an effective treatment for OA based on the proven efficacy of other corticosteroids for this condition. The potential for an improved treatment of EoE and OA with our proprietary formulations of EP-104 is further supported by a continually expanding library of data supporting the value of extended-release steroids.

EP-104GI for Eosinophilic Esophagitis

Overview

EP-104 is being developed for the treatment of EoE, a rare immune-mediated disease recognized by the U.S. National Organization for Rare Disorders ("NORD"). Adaptations to the original formulation of EP-104 will result in the creation of EP-104GI for this specific indication, including modifications to the carrier vehicle and dose.

EoE is characterized by inflammation and the accumulation of large numbers of eosinophils (a type of white blood cells) within the epithelial lining of the esophagus. In adults, EoE leads to dysphagia and food impaction. In children, it often presents with irritability, nausea and vomiting. Patients with EoE frequently develop esophageal strictures, a narrowing or tightening of the esophagus, accompanied by proliferations of fibrotic tissue.

Market Size

According to NORD criteria, EoE is categorized as a rare disease. US population-based studies have shown that the incidence is increasing by approximately 10 cases per 100,000 persons annually. As a result, the most accurate estimates of the incidence and prevalence of EoE are the most recently published studies. In 2021 Kamat et al., performed a retrospective analysis via the MarketScan claims database covering 19-21 million US patients to identify patients diagnosed with EoE according to ICD-9/10 codes from 2015 to 2018. The authors reported prevalence of 117 patients per 100,000 in 2018. Using a ~2.9% annual prevalence growth rate since the data was collected, we estimate that EoE has a U.S. prevalence of 451,000 patients in 2023.

Patients with EoE often experience debilitating impacts from both symptoms and interventions, leading to mental health issues and compounding the overall disease burden on the health care system and the individual. Approximately US$1 billion is spent annually in hospitalizations, endoscopic procedures and medications to treat EoE, and a significant unmet medical need exists for cost-effective and less burdensome long-term treatment options.

Current Treatments

Current EoE treatment guidelines aim to lower eosinophil counts and improve symptoms. Recommended treatment progresses from strict dietary protocols to pharmacological intervention (proton pump inhibitors, swallowed corticosteroids) to mechanical intervention (endoscopic dilation for established strictures). The American Gastroenterological Association and the Joint Task Force on Allergy-Immunology Practice recommend the use of topical corticosteroids (budesonide, swallowed fluticasone) over systemic steroids for long-term EoE management.

There are two approved treatments for EoE in the U.S. – Dupixent (dupilumab), a monoclonal antibody (mAb) marketed by Sanofi and Regeneron, and Takeda's recently-approved Eohilia, a twice-daily oral suspension of budesonide approved for up to 12 weeks of use. Dupixent was originally approved in March 2017 for atopic dermatitis and was approved for EoE in May 2022. The U.S. list price is US$3,803 per carton. Each carton contains two injections; prescribing information for EoE indicates either a once weekly or twice-monthly injection by weight, thus the expected annual list cost to a patient is up to US$91,000. In 2023, Dupixent was also approved for EoE in Canada and Europe.

Jorveza is an effervescent orodispersible budesonide tablet available in the European Union and Canada. The Canadian list price is CDN$3,413 per annum to maintain remission; however, the Canadian Agency for Drugs and Technologies in Health (CADTH) reports that "the cost-effectiveness of budesonide is highly uncertain due to the sponsor's pharmacoeconomic model" and that insufficient evidence exists for maintenance of remission vs relapse past the 6-12-week remission induction window.

Future Competitive Landscape

Several pharmaceuticals in development are lifecycle extensions of currently marketed products:

- AstraZeneca's Tezspire (tezepilumab) has an annual cost of US$52,789 based on their list price and recommended frequency of administration.
- AstraZeneca's Fasenra (benralizumab) has an annual cost of US$44,091 based on their list price and recommended frequency of administration.

- Pfizer's Velsipity (etrasimod), approved for ulcerative colitis, recently demonstrated proof of concept in a Phase 2 trial. Currently Velsipity is marketed as a once daily oral formulation with a wholesale cost of US$6,164 for a 30-day bottle (amounting to approximately US$75,000 per year).

Other products in late-stage development include:

- Ellodi's APT-1011 (FP), an orodispersable tablet in Phase 3 development for adult subjects. Clinical and histological response noted at week 12 and sustained until follow-up at week 52. Studies found increased response with increased dosage but recommends taking once daily to optimize risk-benefit profile.
- EsoCap's ESO-101, a capsule with a rolled up mucoadhesive film containing the cortiscosteroid mometasone furoate. On December 5, 2023, EsoCap announced positive results from a Phase 2 study.
- Bristol Myer's Squibb's cendakimab, a mAb in Phase 3 development

Manufacturing

EP-104 consists of a vial of EP-104 powder and a separate vial of liquid (referred to as the "Vehicle"). Before injection, the Vehicle is mixed with the dry powder to suspend the EP-104 particles; this enables the EP-104 powder to be injected into the patient. In an ongoing stability study, the powder has proven stable for 48 months when stored at room temperature. Batches of EP-104 are currently manufactured at the projected initial batch scale required for launch. We expect to use the same coated and cured FP particles from our EP-104IAR program for EP-104GI. However, we anticipate refinements to both the dose and vehicle to optimize patient outcomes in EoE.

Clinical Studies

We commenced dosing patients in the second quarter of 2023 for an open label Phase 1b/2a clinical study (RESOLVE) using EP-104GI in EoE. The RESOLVE study will be conducted in up to 24 adult patients with a confirmed diagnosis and active EoE symptoms. Primary outcomes for safety, PK and efficacy will be collected at various points over a 12-week total period, with a subsequent follow up at six (6) months. Initial low-dose cohorts presented early signals of efficacy, and we anticipate ongoing safety, efficacy and PK readouts from subsequent dose-escalation cohorts throughout 2024. The RESOLVE protocol is active at sites in Canada, the Netherlands and Australia. Additional sites and jurisdictions will be added as necessary to complete target recruitment.

Subsequent steps in the research program will be determined following analysis of results as well as interaction with key opinion leaders and regulatory authorities. To seek marketing approval for EP-104GI, we expect to carry out at least one Phase 3 study assessing both efficacy (reduced eosinophils and improved symptoms) and safety of EP-104GI in this indication.

EP-104IAR for Osteoarthritis

EP-104IAR Target Product Profile for Knee OA

Durable pain relief	Better tolerability than existing steroids
Long-term repeat dose potential	Cartilage sparing versus existing steroids
Bilateral dosing potential	Supported by major treatment guidelines
Safe for use by diabetics	Room temperature storage

OA is a chronic progressive disease characterized by deterioration of joint cartilage and inflammation, which results in pain and stiffness, usually in the morning or after a period of inactivity; and loss of joint function which limits daily activities. In normal joints, cartilage acts as a cushion between bones and provides a smooth gliding surface for

movement. In OA, the inflammatory processes integral to disease progression damages the cartilage, and over time cartilage wears away, causing bone to rub directly against bone resulting in joint damage, severe pain and disability.

Globally, OA is a leading cause of disability in older adults. Estimates of prevalence and incidence vary according to the definition of OA used (i.e., radiographic (X-Ray) versus symptomatic) and the joints assessed. The global prevalence of knee OA is estimated at approximately 23% in adults over the age of 40. According to a report by the Centers for Disease Control and Prevention, OA is estimated to affect more than 32.5 million adults in the United States alone. A 2018 report estimated there were 14 million people with symptomatic knee OA. OA is also often associated with depression and loss of sleep which can greatly affect quality of life.

Current evidence-based OA treatment guidelines aim to manage signs and symptoms, with the goal of slowing progression if possible. Recommended pharmacological interventions include topical and oral non-steroidal anti-inflammatory drugs, and IA corticosteroids. IA corticosteroid injections have been used for decades to manage pain and stiffness associated with inflammation in knee OA and have been approved by regulatory authorities as safe and effective. However, IA corticosteroid injections often result in suboptimal patient outcomes because of their short duration of activity and systemic side effects such as flushing, glucose alterations and cortisol suppression due to the high peak exposures required to maintain efficacious concentrations for prolonged durations. Evidence is also emerging regarding the risk of adverse joint findings and/or OA progression following frequent/repeated immediate release IA corticosteroid injections.

Market Opportunity

Arthritis has profound societal and economic impacts. According to a 2013 U.S. survey, the financial burden from arthritis totaled US$304 billion (US$140 billion in medical costs and US$164 billion in lost wages). OA is the most common joint disorder and the leading cause of chronic disability in older adults, affecting approximately 30 million adults in the United States. OA is the second most expensive condition treated in US hospitals, accounting for US$16.5 billion or 4.3% of aggregate hospital costs in 2013.

The market for OA therapeutics is large and growing. The estimated 2020 global market size for knee OA therapeutics was just over US$5.6 billion and is expected to grow to US$8.7 billion by 2025 (representing a 10% compound annual growth rate for this period). This represents approximately 80% of the US$7.3 billion global OA market. Geographically, about 34.2% of the global spend is attributed to North America, 37.6% to Europe, 21.3% to Asia Pacific and 6.9% to the rest of the world. In the United States, the estimated market for knee OA therapeutics was US$1.8 billion in 2020, and this number is expected to grow to US$2.9 billion by 2025.

Current Treatments

Current OA treatments aim to manage signs and symptoms, in combination with therapy to slow disease progression. There are several international evidence-based guidelines for OA management, each promoting similar treatment escalation paradigms. These approaches are typically stepwise and dictated by patient symptoms, disease severity and comorbidities. They range from general lifestyle measures (e.g., exercise, weight loss, etc.) to physiotherapy, orthopedic aids and orthoses for patients with milder symptoms, followed by pharmacotherapy, and finally surgery and rehabilitation in the most severe patients. The American Association of Orthopedic Surgeons reported 1,168,826 total knee replacement surgeries from 2012 and 2020 and this number is expected to reach 1,921,000 by 2030.

The most recently published OA treatment guidance is the 2019 American College of Rheumatology (“ACR”)/Arthritis Foundation guidelines for OA management. The only pharmacotherapy treatments strongly recommended for knee OA in these guidelines are topical and oral NSAIDs and IA corticosteroids (see below). Tramadol-based opioids and duloxetine are conditionally recommended in specific circumstances and usually in late-stage disease just before total joint replacement is considered. A broad range of other non-pharmaceutical therapies are also available, such as hyaluronic acid/hyaluronate, platelet rich plasma or mesenchymal stem cells. Many of the major treatment guidelines do not recommend these non-pharmaceutical therapies primarily due to a lack of proven efficacy from well-controlled clinical trials.

Overview of ACR / Arthritis Foundation Recommended Pharmacotherapies for Knee OA

ACR/Arthritis Foundation Recommendation	Pharmacotherapy
Strongly Recommended	Oral / topical NSAIDs IA Steroids
Conditionally Recommended	Acetaminophen, Tramadol, Duloxetine, Topical Capsaicin
Conditionally Against	IA Hyaluronic Acid, IA Botulinum Toxin, Prolotherapy, Colchicine, Non-Tramadol Opioids, Fish Oil, Vitamin D
Strongly Against	Bisphosphonates, Glucosamine, Hydroxychloroquine, Methotrexate, TNF Inhibitors, IL-1 Receptor Antagonists, Platelet Rich Plasma, Stem Cell Injection, Chondroitin

Source: 2019 American College of Rheumatology/Arthritis Foundation Guideline for the Management of Osteoarthritis of the Hand, Hip, and Knee.

OA pharmacotherapy typically starts with oral NSAIDs (over-the-counter or prescription). Oral NSAIDs provide short-term, moderate pain relief but come with systemic toxicity concerns such as gastrointestinal, cardiovascular, and renal side effects and potential drug interactions. For example, the oral prescription NSAID celecoxib is approved to treat OA pain but has a boxed warning that highlights the increased risk of cardiovascular events associated with the product. Topical NSAIDs provide a moderate degree of efficacy relative to oral NSAIDs, with side effects being less pronounced due to their lower systemic exposures.

IA corticosteroids are strongly recommended in the ACR guidelines. IA corticosteroid injections for managing pain and stiffness associated with inflammation in OA patients have been used for decades. They have been approved by regulatory authorities as safe and effective with a rapid onset of action. However, injections of currently approved instant-release corticosteroids often result in suboptimal patient outcomes due to their short duration of efficacy and systemic side effects as a result of the steroid reaching the circulation from the knee. These include flushing, glucose alterations and cortisol suppression due to the high peak exposures required to maintain efficacious concentrations for prolonged durations. The local safety of frequent, repeated doses of currently approved instant release IA steroids has also not been conclusively established.

The label of the only approved extended-release corticosteroid for knee OA in the U.S. market states that “the efficacy and safety of multiple doses has not been demonstrated.” Comments from the non-clinical reviewer in the FDA’s Summary Basis of Approval state that the drug “caused a dose-dependent loss of cartilage with peak effects at 3 months following administration.” It also stated that animals treated with the drug “showed clear increases in microscopic changes to the local tissue and more severe cartilage loss relative to control and immediate-release TCA, and these local responses were not fully reversed at the end of the 9-month recovery period.”

We believe the current range of available pharmacotherapies suggests a need for a product with rapid onset, prolonged duration, a chronic dosing paradigm, minimal side effects and no impact on cartilage. Further, an improved safety profile would potentially enable dosing of multiple joints, which would greatly benefit the approximately 70% of knee OA patients who are thought to develop OA in both knees.

Market Overview

IA treatments comprise approximately half of the global market share for OA therapeutics, with the other half shared by NSAIDs (31.2%) and analgesics (18.9%) as of 2020.

Oral and topical NSAIDs are typically used as the first-line pharmacotherapy in OA treatment. The majority of NSAIDs are over-the-counter products; however, prescription products are also used. We estimate that oral analgesics accounted for approximately US$397 million in 2019 in the United States.

As of 2020, market share for IA treatments is dominated by corticosteroids and HA injections, with HA injections leading in market volume. Within North America, corticosteroids accounted for approximately US$272 million in 2020 and are expected to grow to US$452 million by 2025 (representing a compound annual growth rate of 10.7% for this timeframe).

Zilretta (extended-release TCA) is currently the only marketed extended-release corticosteroid for OA. Zilretta demands a premium list price (US$691 per dose) as compared to generic instant-release TCA, which is generally available in the United States for under US$20 per 40 mg dose. Assuming four injections per year, we estimate an annual Zilretta per-patient cost of US$2,764. The continued growth of Zilretta highlights the considerable need for effective OA pain relief.

While corticosteroids lead the market in volume, branded HA injections lead in value. HA is produced naturally by the body as a lubricant and has a generally favorable safety profile. Considered medical devices, HA treatments are subject to different regulatory requirements than pharmaceutical drugs. Costing on average US$1,128 per treatment course, they represent the highest annual treatment cost for OA other than knee replacement surgery. At this cost, we estimate that the annual per-patient cost for HA is approximately US$2,256 (based on 2 injections/year). Despite IA HA being conditionally recommended *against* in the ACR guidelines, North American sales for HA preparations were estimated at US$991 million in 2020, and this segment is projected to grow to US$1.6 billion by 2025 (representing a compound annual growth rate of 10.3%).

Market Feedback

We believe that there is an unmet need for a product that has the efficacy of a steroid, provides sustained relief, and approaches the safety of HA treatment. Such a treatment could promote IA corticosteroid treatment in earlier stages of the disease, allow long-term multi-dose therapy and provide an alternative option to systemic treatments for patients with bilateral knee OA.

To assess market reception to EP-104IAR's target product profile, we sponsored a market research study involving 80 U.S. and European rheumatologists, orthopedists, orthopedic surgeons and sports medicine specialists.

Results supported a new therapeutic with EP-104IAR's proposed characteristics:

- A large majority (86%) of respondents indicated they would probably or definitely prescribe a drug with EP-104IAR's target characteristics.
- Corticosteroid injections were generally preferred over HA injections (32% versus 25%).
- The preferred duration of pain relief for an IA therapy varies but averages six months, aligning with the target duration of effect for EP-104IAR.
- The potential for cartilage damage is a key safety concern for any new or existing OA therapeutics.

Future Competitive Landscape

As of the date of this AIF, there is no known cure for knee OA, short of knee replacement surgery. Current therapy focuses on a combination of nonpharmacologic (e.g., exercise, weight loss) and pharmacologic approaches to reduce pain and improve function. Marketed pharmacologic therapies include NSAIDs, HA preparations, instant and extended-release corticosteroid injections, opioids and topical capsaicin. Despite these options, there exists unmet medical need for safe and long-term relief of knee OA pain. See "*Current OA Treatments."*

Several companies are engaged in late-stage development for OA treatments. A summary of their current status is provided below:

- On January 17, 2023, Ampio Pharmaceuticals, Inc. confirmed in a letter to stakeholders that it had discontinued its program for Ampion (a low molecular weight fraction of human serum albumin).
- The Taiwan Liposome Company presented late-breaking results from its Phase 3 EXCELLENCE study comparing TLC599 (liposomal dexamethasone sodium phosphate) at the 2023 ACR congress. The abstract stated that TLC599 met its primary endpoint (change in WOMAC Pain versus placebo at 12 weeks) for single dose and showed numerical superiority to placebo upon second dose out to 52 weeks.
- Centrexion Therapeutics Corp. also presented Phase 3 results at ACR 2023 for CNTX-4975-05, a purified form of capsaicin. The drug failed to meet its primary endpoint of pain upon walking at 12 weeks using a numerical pain rating scale.
- Grunenthal is currently recruiting in a global Phase 3 program of resiniferatoxin (RTX), a capsaicin analogue found in the succulent plant *Euphorbia resinifera*.
- On November 13, 2023 Biosplice Therapeutics, Inc. presented interim results from its long-term extension trial of Lorecivivint (SMO4690) – a small molecule Wnt inhibitor. The OA-7 trial was a two-year extension trial, which enrolled patients who completed OA-11 (a prior 12-month Phase 3 trial). Although final results are not anticipated until late 2024, patients completing 3 annual injections to date support the potential for multiple injections of lorecivivint to delay structural progression and provide symptomatic benefit.
- Kolon TissueGene, Inc. is moving forward with its U.S. Phase 3 program for Invossa – an IA injection of normal and modified chondrocytes that claims to modify disease progression. As of January 2024, clinicaltrials.gov lists two recruiting Phase 3 studies in degenerative knee OA. A Phase 2 study in symptomatic early hip OA is listed as “not yet recruiting.”
- On December 13, 2023, Levicept Ltd, announced it had completed recruitment in its Phase 2 clinical trial of LEVI-04, a neurotrophin-modulating biological agent. Top line data are expected to be announced in late first half of 2024.
- On April 11, 2023, Paradigm Pharmaceuticals Ltd. announced that six-month results from its Phase 2 trial of injectable pentosan polysulfate sodium (iPPS) suggests it may slow progression of knee OA. Twelve-month data were expected by the end of the year. As of January 2024, clinicaltrials.gov lists active recruitment in a phase 2/3 trial of iPPS as well as a Phase 3 trial that is not yet recruiting.
- On November 1, 2022, Anika Therapeutics Inc. announced that Cingal, a combination of HA and instant release triamcinolone hexacetonide (TH) met its primary endpoint and demonstrated superiority over TH alone at 25 weeks. This is the product’s third Phase 3 trial. Cingal is already marketed in multiple countries outside of the U.S.
- TrialSpark acquired Sprifermin from Merck KGaA in January 2022. This recombinant form of human fibroblast growth factor 18 has been evaluated in over 800 patients.

Development Program

Manufacturing

EP-104 consists of a vial of EP-104 powder and the Vehicle. Just before injection, the Vehicle is mixed with the dry powder to suspend the EP-104 particles; this enables the EP-104 powder to be injected into the patient’s knee. In an ongoing stability study, the powder has proven stable for 48 months when stored at room temperature. Batches of EP-104 are currently manufactured at the projected initial batch scale required for launch.

Non-clinical Studies

We have completed multiple non-clinical investigations with EP-104, including a large IND-enabling non-clinical study in dogs. Non-clinical data have indicated that after a single high-dose IA injection of EP-104 to the knees of dogs, FP was released locally for greater than ten months with moderate exposure in the plasma. There was no evidence of cartilage damage in dogs over the ten-month follow-up period at any administered doses. In this study, a low dose of EP-104 released FP locally for longer than eight months with minimal systemic exposure. This dose was used to justify the dose selection in our Phase 2 clinical trial. Both U.S. and European competent authorities have reviewed our non-clinical safety data and deemed this information suitable to support clinical research studies.

Several non-clinical studies are underway to support the Phase 3 and registration program. These activities include safety and biocompatibility evaluations of EP-104 excipients as well as non-clinical studies to provide information needed to support the continued clinical investigation of EP-104 product candidates in humans.

Clinical Studies

EP-104IAR has been evaluated in two clinical studies in OA patients. The first clinical study was a Phase 1, double-blind, placebo-controlled clinical study (protocol EP-104-101) to assess safety, PK and preliminary efficacy in 32 knee OA patients at three sites in Canada. The single 15 mg dose was generally well tolerated and showed predictable PK. The study was not powered to detect efficacy; however, patient-reported outcome measures were collected and analyzed to evaluate pain and symptom relief. Despite the limitations of this study (small size, low dose, significant underdosing in nine subjects, and high placebo response), we believe it provides promising tolerability and PK data and preliminary clinical activity data that support future development of EP-104IAR. Results of the study have been published in *Osteoarthritis and Cartilage Open*.

The second clinical study was SPRINGBOARD – a Phase 2, double-blind, placebo-controlled clinical study (protocol EP-104IAR-201) that assessed the efficacy, safety and PK of a single 25 mg dose of EP-104IAR in 318 patients with moderate knee OA. The trial was conducted at 12 sites in Denmark, Poland and Czech Republic, with the last patient visit announced on May 25, 2023. Top-line data readout was announced on June 26, 2023.

EP-104IAR-201 met its primary endpoint with a clinically meaningful and statistically significant ($p=0.004$) improvement over vehicle-placebo in Western Ontario and McMaster Universities Osteoarthritis (“WOMAC”) Pain at 12 weeks in the Intent to Treat population.

EP-104IAR-201 also showed statistically significant improvement over placebo at 12 weeks in three of four secondary endpoints: WOMAC Function ($p=0.014$), OMERACT-OARSI strict responders ($p=0.011$) and Area Under the Curve (“AUC”) for WOMAC Pain ($p<0.001$). Importantly, statistical significance with OMERACT-OARSI strict responders to 15 weeks and AUC for WOMAC Pain to 24 weeks was also seen in the Phase 2b study, highlighting a strong and durable response. The secondary endpoint of the difference in change from baseline in the WOMAC Pain subscale at 24 weeks was not met, delivering statistical significance to 14 weeks.

We also performed pre-specified analyses in the moderate sub-population which comprised 68% of the study population (n=214). Statistically significant efficacy was seen for WOMAC Pain (17 weeks) and OMERACT-OARSI strict responders (22 weeks). Additionally, 40% of moderate patients achieved near complete pain relief (WOMAC Pain score of ≤ 2) which was statistically significant for 22 weeks.

EP-104IAR was well tolerated, with adverse events similar to placebo, and no withdrawals due to drug side effects. Changes in cortisol were minimal and transient and there were no differences in blood glucose levels between treatment groups, including diabetics. We believe these safety data and the observed pharmacokinetic profile support our goal of developing a product that can be used for repeat and bilateral dosing, and in certain at-risk populations.

In parallel to the main study, MRI, with macrocyclic gadolinium-based contrast agent, was obtained from participating patients who received EP-104IAR (n=6) or placebo (n=6). Scans were performed at baseline and weeks 12, 24 and 52 (or on early exit). The data obtained in the MRI sub-study demonstrated the following results:

- Treatment with EP-104IAR resulted in a decrease in inflammation at weeks 12 and 24 when compared to placebo. The two groups were similar at one year as the clinical effect of the single EP-104IAR injection had waned by one year.
- A correlation between reduction in inflammation and a reduction in WOMAC Pain scores was observed.
- A trend of equivalent or improved T2 relaxation times was observed in the EP-104IAR treated group compared to the placebo group at 12 weeks and that trend held steady, or improved, at 24 weeks and 52 weeks. These data suggest a trend of potential improvement in cartilage quality and morphology in the treated group.

Regulatory

We participated in a pre-IND meeting with the FDA regarding the OA program before submission and subsequent clearance of an IND, allowing evaluation of the product candidate under the SPRINGBOARD Phase 2 OA protocol.

In June 2023, EP-104IAR received Fast Track designation from the FDA. The Fast Track process is designed to facilitate and potentially expedite the development review of drugs to treat serious conditions and fill an unmet medical need. The designation recognizes both the seriousness of knee OA pain and the potential for EP-104IAR to fill the need for extended-release pain relief for this indication.

We believe our planned development pathway for EP-104IAR is supported by several key factors:

- following our recent End-of-Phase 2 meeting with the FDA in January 2024, we believe we have alignment on the required endpoints for our Phase 3 clinical trials in order to support an NDA submission;
- an open Investigational New Drug (IND) application with the FDA;
- an abbreviated New Drug Application (NDA) regulatory pathway under the FDCA, Section 505(b)(2);
- FDA Fast Track designation, recognizing the potential of EP-104IAR to meet an unmet medical need in a serious condition such as OA pain;
- a corticosteroid (FP) with a well-established record of clinical use that supports anti-inflammatory effects, and a well-characterized systemic tolerability profile;
- no evidence of cartilage damage at the therapeutic concentrations intended for humans in the IND-enabling preclinical study; and
- preliminary evidence of rapid and extended pain reduction versus placebo in both Phase 1 and Phase 2 clinical trials.

End-of-Phase-2 Meeting with FDA for EP-104IAR

In January 2024, we engaged with the FDA in an End-of-Phase-2 meeting to discuss results from the SPRINGBOARD study and to discuss planned clinical and non-clinical activities to support a New Drug Application (“NDA”) for EP-104IAR. Based on these interactions, we believe that the following clinical trials will be required in support of a future NDA submission for EP-104IAR:

- PROMENADE 1 – A Phase 3 trial in approximately 740 knee OA patients to confirm the safety and efficacy of a single dose of EP-104IAR for six months post-dose. We anticipate that a subset of patients will be followed for one year.
- PROMENADE 2 – A Phase 3 trial in approximately 300 patients to evaluate the safety and durability of response after a second dose of EP-104IAR. We anticipate that the trial will be run in parallel with PROMENADE 1 and patients will be followed for a maximum of nine months after the second injection.
- A Phase 1 study carried out in approximately 30 patients comparing the pharmacokinetics of EP-104IAR and Flovent® HFA.

In addition to the anticipated clinical trials described above, we anticipate that we or a potential partner would need to conduct additional non-clinical work to support repeat dosing of EP-104IAR and the characterization of PVA in-line with the FDA's feedback.

We anticipate that we or a potential partner would submit the NDA for EP-104IAR under Section 505(b)(2) of the FDCA to obtain FDA approval, which is required before marketing a new drug in the United States. A 505(b)(2) NDA would rely in part on non-clinical studies and clinical trials conducted by us or a potential partner, and in part on the FDA's prior findings of safety and efficacy for the active ingredient for which we do not have a right of reference or which have been established in the scientific literature in the public domain. We intend to, either alone or with a partner, pursue marketing approval and commercialization of EP-104 in the U.S. and additional ex-U.S. geographies along with the potential partner.

Lifecycle Opportunities for EP-104 Products

Corticosteroids are broadly used for various indications that may benefit from a targeted delivery and extended-release profile with minimal side effects. Natural lifecycle extensions for EP-104 products could include other joints affected by OA, other inflammatory arthropathies, or other inflammatory conditions.

Near-Term Research Activities

Our focus over the 24 months following the date of this AIF will be the execution of the EP-104 development program.

EP-104GI Program:

- Continued dose escalation and completed enrollment of the Phase 1b/2a RESOLVE clinical study to evaluate the safety and effectiveness of EP-104GI in EoE;
- Engage with the FDA in a Pre-IND meeting to discuss clinical and non-clinical topics related to the development program;
- Manufacture material to support EP-104GI clinical trials;
- Following feedback from the FDA, initiate Phase 1b/2a clinical study to evaluate the safety and effectiveness in EP-104GI preventing the recurrence of benign strictures; and
- Initiate a Phase 2 / 3 trial to demonstrate the effectiveness and safety of EP-104GI in EoE.

EP-104IAR Program:

- Complete non-clinical studies to support NDA filing that would enhance the EP-104IAR label and evaluate the safety and biocompatibility of all excipients; and
- Further development of the EP-104IAR program would be determined in conjunction with additional funding opportunities including a potential collaboration partner.
- Continue to strengthen the IP portfolio around the EP-104 technology;
- Continue to evaluate portfolio options for EP-104 and the Diffusphere technology platform; and
- Continued development of the manufacturing process to support both programs.

Where appropriate, we may use strategic collaborations or partnerships to accelerate development and maximize the commercial potential of our development programs. In parallel, we intend to seek out licencing, co-development or marketing partners for its technology, with the potential to expand and exploit its application fully. It is our intention to put in place conditions and resources, including the potential use of licensing partnerships, that support the success of the development program, marketing authorization(s) and commercialization across multiple jurisdictions, as well as exploitation of any opportunities for lifecycle and patent extension. Depending on market conditions, this may take the form of co-development or commercialization partnerships, transactional opportunities and/or public financing options.

Pipeline programs are another area of potential growth in the next 24 months. Our technology is potentially compatible with various drugs and therapeutic indications. The pipeline strategy focuses on modulating the release of existing drugs to achieve better clinical outcomes in areas of high medical need. The technology has the potential to be particularly suitable for diseases requiring precisely targeted and controlled localized therapy where broader tissue or systemic exposure should be avoided (e.g., tumour oncology). We have previously investigated indications involving post-surgical pain (EP-105) and post-surgical site infections (EP-201). While both programs demonstrated preclinical evidence of supporting our technology, these programs are currently paused so we can remain focused on the other programs described previously in this AIF.

We currently have several pipeline candidates in development with a goal to add a pipeline product candidate over the next 24 months to allow for sustained corporate growth. We expect this to involve a multidisciplinary review of candidate drugs, formulation development, *in vitro* screening to identify the most promising lead candidates and non-clinical proof-of-concept studies. Information generated from these inquiries will determine whether we should proceed with further development.

Specialized Skill and Knowledge

We have extensive knowledge in scientific research and clinical development of locally delivered, extended-release alternatives to existing pharmaceuticals. By enlisting the support of experienced preclinical, clinical trial, regulatory and legal consultants, we are able to use expert knowledge to assist in the development of its products and the protection of its intellectual property. We continually evaluate our internal resources and may add talented senior professionals to our team as needed to support growth.

Employees

As of December 31, 2023, we had 29 full-time employees.

Our employees are not governed by a collective bargaining agreement. We depend on certain key members of its management and scientific staff and the loss of services of one or more of these persons could adversely affect us.

Facilities

Our head office is located in Victoria, British Columbia, Canada. The nature of the space is immaterial to our operations as operating activities related to our pipeline product candidates are primarily outsourced to contractors.

Patents and Proprietary Information

IP strategy

We strive to protect our product candidates and other proprietary technologies, processes, and know-how through a variety of methods. Our policy is to pursue, maintain and defend patent rights in strategic areas, whether developed internally or licensed from third parties, and to protect the technology, inventions and improvements that are commercially important to the development of our business. We also rely on trade secrets and other proprietary know how that may be important to the development of our business.

As of February 1, 2024, we have licensed from Auritec Pharmaceuticals, Inc. ("**Auritec**") one issued patent in the United States generally covering the EP-104 technology, which is expected to expire in 2029 with patent term adjustments.

In addition to the licensed Auritec patent, as of February 1, 2024, we have filed our own patent applications covering the EP-104 composition, among other things, which has resulted in two issued patents in the United States (US9987233, US11219604), one granted patent in Europe (EP2976062), and granted patents in more than ten foreign jurisdictions. These patents covering the EP-104 composition are expected to expire in 2034, absent any patent term adjustments or extensions. We have also filed our own patent applications covering a method of manufacturing the EP-104 composition, which is pending in the United States, Europe, and more than ten foreign jurisdictions outside the United States. These patent applications, if issued, could provide additional patent protection for EP-104 until 2040, absent any patent term adjustments or extensions. In addition, we have filed an international patent application directed to various methods of use of EP-104 in the treatment of inflammation of the gastrointestinal tract, such as EoE. Patents that issue from this international patent application could provide additional patent protection for the use of EP-104 in the treatment of EoE until 2043, absent any patent term adjustments or extensions.

We also seek to protect our intellectual property in part by entering into confidentiality agreements with companies with whom we share proprietary and confidential information in the course of business discussions, and by having confidentiality terms in our agreements with our employees, consultants, scientific advisors, clinical investigators, and other contractors and also by requiring our employees, commercial contractors, and certain consultants and investigators, to enter into invention assignment agreements that grant us ownership of any discoveries or inventions made by them while in our employ.

In addition to patent protection, we also rely on trademark registration, trade secrets, know how, other proprietary information to develop and maintain our competitive position. We seek to protect and maintain the confidentiality of proprietary information of our business that is not amenable to, or that we do not consider appropriate for, patent protection. We take steps to protect our proprietary information, including trade secrets and unpatented know-how, by entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors. We believe that the combination of patent protection and trade secrets will inhibit entry of generics into the market. However, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets and unpatented know-how, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. For more information regarding the risks related to our intellectual property, see "Risk Factors—Risks Related to Our Intellectual Property.

License Agreement with Auritec

Auritec is a privately held clinical-stage drug delivery company that holds patents in the field of extended-release delivery of drug products utilizing its proprietary drug delivery platform (the "**Plexis Platform**"). We, through our subsidiary, Eupraxia USA, are a party to an amended and restated license agreement dated effective October 9, 2018 (as further amended, the "**Amended and Restated License Agreement**") with Auritec.

Under the terms of the Amended and Restated License Agreement, Auritec has granted Eupraxia USA an exclusive license (including the right to sublicense to its affiliates and third parties) under the licensed patents owned or controlled by Auritec and for all the technical information and know-how relating to the technology claimed in such patents or possessed by Auritec with respect to the use of the Plexis Platform for the delivery of fluticasone in all medical fields (except for (a) otolaryngology and (b) the prevention, treatment and control of all diseases, disorders and conditions of the eye and its adnexa ((a) and (b) collectively, the "**Excluded Fields**")), to develop, make, have made, manufacture, use, commercialize, sell, sub-license, offer for sale, import, and have imported products for the delivery of fluticasone drug products using the Plexis Platform in all medical fields except the Excluded Fields (such field, the "**Eupraxia Field**" and such products, the "**Products**").

Pursuant to the terms of the Amended and Restated License Agreement, in consideration for the rights and exclusive license granted to Eupraxia USA, Eupraxia USA paid an upfront payment of US$5,000,000 (the "**Upfront Fee**"). All other licensing payments under the Amended and Restated License Agreement will come due as set forth in the table below.

In addition to the Upfront Fee, pursuant to the Amended and Restated License Agreement, Eupraxia USA has agreed to pay Auritec up to US$30 million upon achievement of certain regulatory and commercial milestones related to Products as well as a royalty of 4% of net sales of Products by Eupraxia USA or its affiliates, subject to certain reductions.

The following table summarizes the milestone payment schedule:

Milestone Event	**Milestone Payment (USD)**
Successful Completion of a Phase 2b Study	5,000,000
First OA Regulatory Approval	5,000,000
Second OA Regulatory Approval	5,000,000
Non-OA Indication Regulatory Approval	10,000,000
First calendar year in which aggregate net sales by Eupraxia USA, its affiliates and sublicensees exceed US$500,000,000	5,000,000
Maximum milestones payable	30,000,000

Eupraxia USA also agreed to pay to Auritec 20% of royalties or other consideration based on net sales of Products received by Eupraxia USA or its affiliates pursuant to a sublicensing transaction. Eupraxia USA further agreed to pay Auritec a percentage of Non-Royalty Monetization Revenue (as defined in the Amended and Restated License Agreement), which includes payments received for a sale of Eupraxia USA or its assets or sale or sublicense of a Product, which percentage ranges from 30% to 10% depending on the development stage of the most-advanced Product, up to a maximum of US$100 million. The following table summarizes the Non-Royalty Monetization Revenue percentage schedule:

Date of Execution	Percentage of Non-Royalty Monetization Revenue
Prior to Successful Completion of a Phase 2b Study (as defined in the Amended and Restated License Agreement)	30%
After Successful Completion of a Phase 2b Study but prior to Successful Completion of a Phase 3 Study (as defined in the Amended and Restated License Agreement)	20%
After Successful Completion of a Phase 3 Study but prior to Regulatory Approval (as defined in the Amended and Restated License Agreement) of a Product in the Eupraxia Field from FDA in the United States	15%
After Regulatory Approval of a Product in the Eupraxia Field from FDA in the United States	10%

Either party may terminate the Amended and Restated License Agreement in the event of the other party's bankruptcy, liquidation, or dissolution. Auritec may also terminate upon a material breach of the Amended and Restated License Agreement by Eupraxia USA that is not cured within 60 days (15 days in the case of a payment breach). Further, if Eupraxia USA directly or indirectly challenges any claim in any Auritec patent licensed under the Amended and Restated License Agreement, or assist a third party in doing so, Auritec may immediately terminate the Amended and Restated License Agreement. If Auritec directly or indirectly challenges any Eupraxia patent contemplated in the Amended and Restated License Agreement other than as reasonably required to defend Auritec patents as a basis for such challenge, or assists a third party in doing so, we may immediately terminate the Amended and Restated License Agreement.

Manufacturing Agreements

Since we do not have our own manufacturing facilities, all manufacturing activities are contracted out to Good Manufacturing Practices ("GMP") compliant facilities. All of the contract manufacturers used to date are under master service agreements and quality agreements and are compensated with cash and not shares of the Company. We share our proprietary knowhow to complete any manufacturing campaign with external contract manufacturers; however, all intellectual property associated with our proprietary know-how is retained by us.

Government Regulation

Government authorities in the United States, at the federal, state, and local level, and other countries extensively regulate, among other things, the research, development, non-clinical and clinical testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing, and export and import of products such as those we are developing. Generally, before a new drug can be marketed, considerable data must be generated, which demonstrate the drug's quality, safety, and efficacy. Such data must then be organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority.

Drug approval laws in the United States, Canada and Europe generally require licensing of manufacturing facilities, carefully controlled research and testing of products, government review of results and approval prior to marketing and sale of drug products. In addition, they require adherence to best practices as defined by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, as well as national guidelines. The process for pharmaceutical development and approval are subject to inherent risks, described in *"Risk Factors."*

The principal steps generally required for drug approval in the United States, Canada and Europe are described below.

Non-clinical Toxicology Studies

Non-clinical studies are conducted *in vitro* and in animals to evaluate toxicokinetics and PK to provide evidence of the safety and bioavailability of the drug candidate prior to its administration to humans in clinical studies and throughout development. Such studies have been completed, are underway or are planned for EP-104. See *"Non-clinical Studies."*

Human Testing

The process of conducting clinical trials with an investigational new drug generally cannot begin until a company has submitted to the appropriate regulatory authorities an application to do so and the required number of days have lapsed without objection from the applicable regulatory authority. (In certain jurisdictions, a no objection letter or approval may be required before the clinical trial can proceed). In the United States, this application is called an IND, and in Canada and most European countries, a clinical trial application ("CTA").

For the United States, the Sponsor must submit the results of the non-clinical tests, manufacturing information, analytical data and available clinical data or literature, within the IND, to the FDA. Some information, as is the case for EP-104, may be omitted from the IND in instances where prior FDA findings of safety or efficacy of a drug product are being relied upon. Even after the IND is submitted, non-clinical testing may continue to occur. An IND becomes effective automatically 30 days after receipt by the FDA, unless within that time the FDA raises concerns or questions, in which case a clinical hold may be put in place until the concerns are adequately addressed by the Sponsor with the FDA. As a result, a submission of an IND may not result in the FDA allowing clinical trials to commence. Similar regulations apply in Canada and in other foreign jurisdictions in which we may seek authorization to conduct a clinical trial.

Two key factors influencing the rate of progression of clinical trials are the rate at which patients can be enrolled to participate in the research program and whether effective treatments are currently available for the disease that the drug is intended to treat. Patient enrollment is largely dependent upon the incidence and severity of the disease, the treatments available and the potential side effects of the drug to be tested and any restrictions for enrollment that may be imposed by regulatory agencies. For further information see "*Risk Factors."*

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs (as defined below), which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site and must monitor the study until completed. Regulatory authorities, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk or that the clinical trial is unlikely to meet its stated objectives. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which may review data and endpoints at designated check points, make recommendations or halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There are also requirements governing the reporting of ongoing clinical studies and clinical study results to public registries.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

Phase 1 Clinical Trials

Phase 1 clinical trials are typically conducted on a small number of individuals (healthy volunteers or patients) to determine safety, dose limiting toxicities, tolerability, PK and to determine dose ranging for Phase 2 clinical trials in humans.

Phase 2 Clinical Trials

Phase 2 clinical trials typically involve a larger patient population than is required for Phase 1 and are conducted to evaluate the safety and efficacy of a drug candidate in patients having the disease for which the drug is indicated. This phase also serves to identify possible common short-term side effects and risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

Phase 3 Clinical Trials

Phase 3 clinical trials typically involve tests in a much larger population of patients suffering from the targeted condition or disease. These studies involve controlled and/or uncontrolled testing in an expanded patient population (several hundred to several thousand patients) at geographically dispersed test sites to establish clinical safety and effectiveness. These trials also generate information from which the overall risk-benefit relationship relating to the drug can be determined.

Post-approval clinical trials, sometimes referred to as Phase 4 studies, may be conducted after initial marketing approval. These clinical trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

The FDA or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts organized by the sponsor, known as a data safety monitoring board or committee. Depending on its charter, this group may determine whether a clinical trial may move forward at designated check points based on access to certain data from the clinical trial.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to submission of an IND, at the end of Phase 2, and before an NDA is submitted. Meetings at other times may be requested. These meetings can provide an opportunity for the sponsor to share information about the data gathered to date, for the FDA to provide advice, and for the sponsor and the FDA to reach agreement on the next phase of development. Sponsors typically use the meetings at the end of the Phase 2 clinical trial to discuss Phase 2 clinical results and present plans for the pivotal Phase 3 clinical trials that they believe will support approval of the new drug.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the drug and finalize a process for manufacturing the product in commercial quantities in accordance with cGMP (as defined below) requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, the manufacturer must develop methods for testing the identity, strength, quality, and purity of the final drug. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

While the IND is active and before approval, progress reports summarizing the results of the clinical trials and non-clinical studies performed since the last progress report must be submitted at least annually to the FDA, and written IND safety reports must be submitted to the FDA and investigators for serious and unexpected suspected adverse events, findings from other studies suggesting a significant risk to humans exposed to the same or similar drugs, findings from animal or in vitro testing suggesting a significant risk to humans, and any clinically important increased incidence of a serious suspected adverse reaction compared to that listed in the protocol or investigator brochure.

Marketing Application

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development non-clinical and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees; a waiver of such fees may be obtained under certain limited circumstances. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication. The FDA reviews an NDA to determine, among other things, whether a product is safe and effective for its intended use and whether its manufacturing is cGMP-compliant to assure and preserve the product's identity, strength, quality, and purity. Under the Prescription Drug User Fee Act, or PDUFA, guidelines that are currently in effect, the FDA has a goal of ten months from the date of "filing" of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes 12 months from the date the NDA is submitted to FDA because the FDA has approximately two months to make a "filing" decision after the application is submitted. The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application is also subject to review before the FDA accepts it for filing.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before the applicable regulatory authority approves the marketing application, they will initiate an inspection of the facility or facilities where the product is manufactured. Products will not be approved unless there is compliance with GMP. Approval may occur if the inspection is satisfactory and if the marketing application contains data providing substantial evidence that the drug is safe and effective in the studied indication. In addition to manufacturing inspections, the regulatory authority will typically inspect one or more clinical sites to assure compliance with Good Clinical Practices ("GCP").

If the FDA determines that the application, manufacturing process, or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and often will request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

After the FDA evaluates an NDA, it will issue an approval letter or a Complete Response Letter. An approval letter authorizes commercial marketing of the drug with prescribing information for specific indications. A Complete Response Letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A Complete Response Letter usually describes the specific deficiencies in the NDA identified by the FDA and may require additional clinical data, such as an additional pivotal Phase 3 clinical trial or other significant and time-consuming requirements related to clinical trials, non-clinical studies, or manufacturing. If a Complete Response Letter is issued, the sponsor must resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the NDA does not satisfy the criteria for approval.

The testing and approval process for a new drug candidate requires substantial time, effort and financial resources, and may take several years to complete. Data obtained from non-clinical and clinical testing are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Approval may not be granted on a timely basis, or at all.

Even if a regulatory authority approves a product candidate, the relevant authority may limit the approved indications for use, require specific contraindications, warnings or precautions be included in the product label, including a boxed warning, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's

safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms. For example, the FDA may require a Risk Evaluation and Mitigation Strategy ("REMS"), (also known as a Risk Management Plan ("RMP") in Europe) as a condition of, or following, approval to mitigate any identified or suspected serious risks and ensure safe use of the drug. The REMS or RMP could include medication guides, physician communication plans, assessment plans, and elements to assure safe use, such as restricted distribution methods, patient registries or other risk minimization tools. A REMS or RMP could materially affect the potential market and profitability of the product. A regulatory authority may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional label claims, are subject to further testing requirements, notification, and regulatory authority review and approval. Further, should new safety information arise, additional testing, product labeling or regulatory notification may be required.

The FDA also may offer conditional approval subject to, among other things, changes to proposed labeling or the development of adequate controls and specifications. Once approved, the FDA may withdraw the product approval if compliance with pre- and post-marketing requirements is not maintained or if problems occur after the product reaches the marketplace. In addition, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could impact the timeline for regulatory approval or otherwise impact ongoing development programs.

Expedited Development and Review Programs

The FDA has a fast track designation program that is intended to expedite or facilitate the process for reviewing new drug products that meet certain criteria. Specifically, new drugs are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. With regard to a fast track product, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

Any product submitted to the FDA for approval, including a product with a fast track designation, may also be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. A product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis, or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug designated for priority review in an effort to facilitate the review. The FDA endeavors to review applications with priority review designations within six months of the filing date as compared to ten months for review of new molecular entity NDAs under its current PDUFA review goals.

In addition, a product may be eligible for accelerated approval. Drug products intended to treat serious or life-threatening diseases or conditions may be eligible for accelerated approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform adequate and well-controlled post-marketing clinical trials. In addition, the FDA currently requires pre-approval of promotional materials as a condition for accelerated approval, which could adversely impact the timing of the commercial launch of the product.

The Food and Drug Administration Safety and Innovation Act established a category of drugs referred to as "breakthrough therapies" that may be eligible to receive breakthrough therapy designation. A sponsor may seek FDA designation of a product candidate as a "breakthrough therapy" if the product is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the fast track program features, as well as more intensive FDA interaction and guidance.

The breakthrough therapy designation is a distinct status from both accelerated approval and priority review, which can also be granted to the same drug if relevant criteria are met. If a product is designated as breakthrough therapy, the FDA will work to expedite the development and review of such drug.

Fast track designation, priority review, accelerated approval, and breakthrough therapy designation do not change the standards for approval, but may expedite the development or approval process. Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened. We may explore some of these opportunities for our product candidates as appropriate. The Food and Drug Omnibus Reform Act made several changes to the FDA's authorities and its regulatory framework, including, among other changes, reforms to the accelerated approval pathway, such as requiring the FDA to specify conditions for post-approval study requirements and setting forth procedures for the FDA to withdraw a product on an expedited basis for non-compliance with post-approval requirements.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug intended to treat a rare disease or condition affecting fewer than 200,000 individuals in the United States, or in other limited cases. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process, though companies developing orphan drugs are eligible for certain incentives, including tax credits for qualified clinical testing. In addition, an NDA for a product that has received orphan drug designation is not subject to a prescription drug user fee unless the application includes an indication other than the rare disease or condition for which the drug was designated.

If a product that has orphan drug designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same active moiety for the same indication for seven years, except in limited circumstances, such as another drug's showing of clinical superiority over the drug with orphan exclusivity. Competitors, however, may receive approval of different active moieties for the same indication or obtain approval for the same active moiety for a different indication. In addition, doctors may prescribe products for off-label uses and undermine our exclusivity. Orphan drug exclusivity could block the approval of one of our products for seven years if a competitor obtains approval for the same active moiety for the same indication before we do, unless we are able to demonstrate that our product is clinically superior. In response to the court decision in *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), in January 2023, the FDA published a notice in the Federal Register to clarify that while the agency complies with the court's order in *Catalyst*, FDA intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the *Catalyst* order – that is, the agency will continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. It is unclear how future litigation, legislation, agency decisions, and administrative actions will impact the scope of the orphan drug exclusivity. We cannot guarantee that we will obtain orphan drug designation for any products in any jurisdiction. Even if we are able to obtain orphan drug designation for a product, we cannot be sure that such product will be approved, that we will be able to obtain orphan drug exclusivity upon approval, if ever, or that we will be able to maintain any exclusivity that is granted.

Post-Approval Requirements

Any products manufactured or distributed by us pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There are continuing, annual program fees for any marketed products. Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP (as defined below), which impose certain procedural and documentation requirements upon us and our third-party manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and

correction of any deviations from cGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters, or untitled letters;
- clinical holds on post-approval or Phase IV clinical studies, if applicable;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment, or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases, and other communications containing warnings or other safety information about the product; or
- injunctions or the imposition of civil or criminal penalties.

The FDA closely regulates the marketing, labeling, advertising, and promotion of drug products. A company can make only those claims relating to safety and efficacy that are approved by the FDA and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising, and potential civil and criminal penalties. Physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, restrict manufacturer's communications on the subject of off-label use of their products. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined companies from engaging in off-label promotion. The FDA and other regulatory agencies have also required that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labelling.

Marketing Exclusivity

Market exclusivity provisions authorized under the FDCA can delay the submission and approval of certain marketing applications for products containing the same active ingredient. The FDCA permits patent term restoration of up to five years as compensation for a patent term lost during product development and FDA regulatory review process to the first applicant to obtain approval of an NDA for a new chemical entity in the United States. Patent-term restoration, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. A

drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not approve or even accept for review an abbreviated new drug application, or ANDA, or an NDA submitted under Section 505(b)(2), or a 505(b)(2) NDA, submitted by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication, where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FDCA alternatively provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages, or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active agent for the original indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to any non-clinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Pediatric exclusivity is another type of marketing exclusivity available in the United States. Pediatric exclusivity provides for an additional six months of marketing exclusivity attached to another period of exclusivity if a sponsor conducts clinical trials in children in response to a written request from the FDA. The issuance of a written request does not require the sponsor to undertake the described clinical trials. In addition, orphan drug exclusivity, as described above, may offer a seven-year period of marketing exclusivity, except in certain circumstances.

Other Healthcare Laws

Pharmaceutical manufacturers are subject to additional healthcare laws, regulation, and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation, U.S. federal anti-kickback, anti-self-referral, false claims, transparency, including the federal Physician Payments Sunshine Act, consumer fraud, pricing reporting, data privacy, data protection, and security laws and regulations as well as similar foreign laws in the jurisdictions outside the U.S. Similar state and local laws and regulations may also restrict business practices in the pharmaceutical industry, such as state anti-kickback and false claims laws, which may apply to business practices, including but not limited to, research, distribution, sales, and marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, or by patients themselves; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information; state and local laws which require the tracking of gifts and other remuneration and any transfer of value provided to physicians, other healthcare providers and entities; and state and local laws that require the registration of pharmaceutical sales representatives; and state and local laws governing the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The risk of our being found in violation of these or other laws and regulations is increased by the fact that many have not been fully interpreted by the regulatory authorities or the courts and their provisions are open to various interpretations. These laws and regulations are subject to change, which can increase the resources needed for compliance and delay drug approval or commercialization. Any action brought against us for violations of these laws or regulations, even successfully defended, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Also, we may be subject to private "qui tam" actions brought by individual whistleblowers on behalf of the federal or state governments. Actual or alleged violation of any such laws or regulations may lead to investigations and other claims and proceedings by regulatory authorities and in certain cases, private actors, and violation of any of such laws or any other governmental regulations that apply may result in penalties, including, without limitation, significant administrative, civil and criminal penalties, damages, fines, additional reporting obligations, and oversight if we become subject to a corporate integrity agreement or other

agreement to resolve allegations of non-compliance with these laws, the curtailment or restructuring of operations, exclusion from participation in government healthcare programs and imprisonment. See *"Risk Factors – Risks Relating to Marketing, Reimbursement, Healthcare Regulations and Ongoing Regulatory Compliance"* for a list of laws that may affect our ability to operate.

Coverage and Reimbursement

In the United States, Canada, and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage and establish adequate reimbursement levels for the product. In the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

In international markets, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies. For example, the European Union provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. Pharmaceutical products may face competition from lower-priced products in foreign countries that have placed price controls on pharmaceutical products and may also compete with imported foreign products. Furthermore, there is no assurance that a product will be considered medically reasonable and necessary for a specific indication, that it will be considered cost-effective by third-party payors, that an adequate level of reimbursement will be established even if coverage is available, or that the third-party payors' reimbursement policies will not adversely affect the ability for manufacturers to sell products profitably.

U. S. Healthcare Reform

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of products have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

There have been a number of proposals during the last few years regarding the pricing of pharmaceutical products, limiting coverage and the amount of reimbursement for drugs and other medical products, government control and other changes to the healthcare system in the United States. For example, in March 2010, the United States Congress enacted the Affordable Care Act (the "ACA"), which, among other things, includes changes to the coverage and payment for products under government health care programs. Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. For example, in June 2021 the U.S. Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case on procedural grounds without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. It is possible that the ACA will be subject to judicial or Congressional challenges in the future.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, the American Rescue Plan Act of 2021 eliminated the statutory Medicaid drug rebate cap manufacturers pay to state Medicaid programs, elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, the Centers for Medicare & Medicaid Services ("CMS") may develop new payment and delivery models, such as bundled payment models. Recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their products. Such scrutiny has resulted in several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. In August 2022, Congress passed the Inflation Reduction Act of 2022, or IRA, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Various industry stakeholders, including certain pharmaceutical companies and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. The impact of these judicial challenges, legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the government on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved.

In addition, individual states in the United States have also become increasingly active in implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures and, in some cases, mechanisms to encourage importation from other countries and bulk purchasing. A number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws once we begin commercialization after obtaining regulatory approval for any of our products. Further, FDA recently authorized the state of Florida to import certain prescription drugs from Canada for a period of two years to help reduce drug costs, provided that Florida's Agency for Health Care Administration meets the requirements set forth by the FDA. Other states may follow Florida. Furthermore, there has been increased interest by third party payors and governmental authorities in reference to pricing systems and publication of discounts and list prices. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

Government Regulation Outside of the U.S.

In addition to regulations in the U.S., we will be subject to a variety of regulations in other jurisdictions governing, among other things, research, development, testing, manufacture, quality control, controlled substances, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drugs, and reimbursement requirements. Generally, before a new drug can be marketed, considerable data demonstrating its quality, safety and efficacy must be obtained, organized into a format specific for each regulatory authority, submitted for review and approved by the regulatory authority. Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical studies or marketing of the product in those countries. Certain countries outside of the U.S. have a similar process that requires the submission of a clinical study application much like the IND prior to the commencement of human clinical studies. In the EU, for example, a CTA must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and the IRB, respectively. Once the CTA is approved in accordance with a country's requirements, clinical study development may proceed. Similar requirements regarding a CTA and ethics approval exist in Canada.

The requirements and process governing the conduct of clinical studies, product licensing, coverage, pricing and reimbursement vary from country to country. In all cases, the clinical studies are conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki. The EU clinical trials legislation currently is undergoing a transition process mainly aimed at harmonizing and streamlining clinical-trial authorization, simplifying adverse-event reporting procedures, improving the supervision of clinical trials and increasing their transparency.

For other countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical studies, product and establishment licensing, coverage, data protection, pricing and reimbursement vary from country to country.

If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, inability to import or export, seizure of products, operating restrictions and criminal prosecution.

RISK FACTORS

Investing in our securities involves a high degree of risk. Before deciding to invest in our securities, you should carefully consider the risks described below, together with other information included in or incorporated by reference into this AIF and filed on SEDAR+ at www.sedarplus.ca. If any of the following risks materialize, the business, financial condition, results of operation and future prospects of the Company will likely be materially and adversely affected. This could cause actual future events to differ materially from those described in forward-looking statements and may cause the trading price of our securities to decline. Our Risk Factors are not guarantees that no such conditions exist as of the date of this report and should not be interpreted as an affirmative statement that such risks or conditions have not materialized, in whole or in part. The following discussion highlights some of the risks and uncertainties facing the Company.

Risks Relating to Our Limited Operating History, Financial Position and Capital Requirements

We have a history of negative operating cash flow and may continue to experience negative operating cash flow.

Since our incorporation in May 2011, we have generated negative operating cash flows. We anticipate that we will continue to have negative cash flow and we expect to continue to incur losses for the foreseeable future as we continue to research and develop, and seek regulatory clearances for, our current product candidate and other potential product candidates. To the extent that we have negative operating cash flow in future periods, we may need to allocate a portion of our cash reserves to fund such negative cash flow. We may also be required to raise additional funds through the issuance of equity or debt securities. There can be no assurance that we will be able to generate a positive cash flow from our operations, that additional capital or other types of financing will be available when needed or that these financings will be on terms favourable to us.

If we are not successful in refinancing the Debt Agreement with Silicon Valley Bank, we will be required to repay amounts due in full, which could have an adverse effect on our business and financial condition.

In June 2021, we entered into the Debt Agreement with SVB and SVB Innovation Credit Fund VIII, L.P., and concurrently drew down, in full, the CDN$10,000,000 principal amount. The Debt Agreement has a term of 36 months (or 48 months at SVB's election). Interest accrues monthly in arrears at a rate per annum equal to the greater of (i) 2.45% and (ii) the Canadian prime rate. In addition, payment in kind interest accrues at a rate of 7.0% per annum, compounded monthly, and is payable on the maturity date. The Debt Agreement is secured by a security interest on substantially all of our assets, but excluding our patents and other intellectual property. As of February 28, 2024, an aggregate of approximately CDN$12 million in principal and accrued interest is currently outstanding under the Debt Agreement.

Subject to the terms and conditions of the Debt Agreement, SVB may elect to convert the principal amount of the convertible debt and the accrued and unpaid interest thereon into Common Shares at a conversion price equal to CDN$5.68 per Common Share. The conversion price of the accrued and unpaid interest will be subject to the minimum pricing requirements of the TSX, to the extent applicable, at the time of conversion. We have the right to call the convertible debt by paying to SVB an amount equal to 150% of the principal amount of the convertible debt (less principal amounts previously repaid). If any amounts due under the Debt Agreement are converted into Common Shares, our then holders of Common Shares will experience dilution.

In March 2023, SVB was closed and placed into receivership, and its holdings were subsequently transferred to Silicon Valley Bridge Bank, N.A ("**Bridge Bank**") being operated by the U.S. Federal Deposit Insurance Corporation ("**FDIC**"). The Ontario Superior Court of Justice subsequently granted a winding up order and have appointed a third party to begin an orderly, court-supervised process to restructure the branch to ensure an orderly transition of SVB's Canadian branch to Bridge Bank.

Due to SVB's receivership, we expect the Debt Agreement will mature on June 21, 2024. We are exploring various options to refinance the Debt Agreement. However, any such refinancing may not be successfully completed by June 21, 2024, on terms commercially attractive to us or at all. If any refinancing is insufficient to repay amounts owed under the Debt Agreement in full, we may need to use a portion of the proceeds from the Offering to repay the Debt Agreement, which could have an adverse effect on our business and financial condition and reduce our anticipated cash runway following the Offering by at least a full quarter.

Under the terms of the Debt Agreement, in the event that we become subject to the reporting requirements of the United States Securities Exchange Act of 1934 (the "**Exchange Act**") and list our Common Shares for trading on any U.S. stock exchange or inter-dealer quotation system, we have agreed to promptly thereafter enter into a registration rights agreement with the applicable holders under the Debt Agreement, pursuant to which such holders will have customary demand and "piggyback" registration rights with respect to Common Shares issued or issuable upon conversion of the debt. If our Common Shares become listed on the Nasdaq, this obligation will be triggered. Due to SVB's receivership and the resulting complexities, it may be difficult for us to meet our obligations to enter into the registration rights agreement. If we are able to enter into the registration rights agreement, it could result in additional sales of our Common Shares by the holders if the outstanding debt is converted to Common Shares before maturity.

Risks Relating to the Company's Business

We have a limited operating history and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.

We are a clinical stage biotechnology company with limited operating history and in particular, no history of earnings; we have not paid any dividends and we are unlikely to pay any dividends in the immediate or foreseeable future. Our success will depend to a large extent on the expertise, ability, judgement, discretion, integrity and good faith of our management.

We have no products approved for commercial sale in any jurisdiction and have not generated any revenue from product sales. To date, we have devoted substantially all of our resources and efforts to organizing and staffing our company, business planning, discovering, identifying and developing potential product candidates, securing related intellectual property rights and conducting preclinical studies and clinical trials of our product candidates. We have not yet demonstrated our ability to obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult for you to accurately predict our future success or viability.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by clinical stage pharmaceutical companies in rapidly evolving fields. We also may need to transition from a company with a research focus to a company capable of supporting commercial activities, or enter into strategic partnerships with one or more companies with such capability. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

We expect to spend a significant amount of capital to fund research and development. As a result, we expect that our operating expenses will increase significantly and, consequently, we will need to generate significant revenues to become profitable. Even if we do become profitable, we may not be able to sustain or increase profitability on a quarterly or annual basis. We cannot predict when, if ever, we will be profitable. There can be no assurances that we will be capable of producing our products in commercial quantities at reasonable costs or that we will successfully market them.

We will require substantial additional financing to achieve our goals and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts.

As of September 30, 2023, we had CDN$33.2 million of cash and cash equivalents. Based upon our current operating plan, we estimate that our cash and cash equivalents as of September 30, 2023 are insufficient for us to fund operating, investing, and financing cash flow needs for twelve months following September 30, 2023, the date of our unaudited condensed interim consolidated financial statements for the most recently completed financial period, and accordingly, we have determined that there is substantial doubt about our ability to continue as a going concern. We believe that we will continue to expend substantial resources for the foreseeable future as we continue the development of EP-104. Additionally, we expect to expend resources as we develop additional product candidates, if any, launch clinical trials and pursue commercialization of such product candidates, if approved. In addition, other unanticipated costs may arise. Because the outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of product candidates. Our costs will increase if we suffer any delays in our planned clinical trials for our current product candidates. Our forecast of the period of time through which our financial reserves will adequately support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "Risk Factors" section. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect.

Our future capital requirements will depend on many factors, including:

- the timing of, and the costs involved in, obtaining regulatory approvals for product candidates if clinical trials are successful;
- the scope, progress, results and costs of developing and advancing product candidates through clinical trials and researching and discovering new product candidates;
- our ability to establish and maintain strategic partnerships, licensing or other arrangements and the financial terms of such agreements;
- the cost of manufacturing product candidates for clinical trials in preparation for regulatory approval and in preparation for commercialization;
- the amount of revenue from an approved product candidate, if any; and
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation.

The ongoing economic slowdown and downturn of global capital markets has generally made the raising of capital by equity or debt financing more difficult. Access to financing has been negatively impacted by ongoing global economic risks. We will require substantial additional funds for further research and development, and the marketing and sale of our technology. We may attempt to raise additional funds for these purposes through public or private equity or debt financing, collaborations with other therapeutic companies, government grants or other sources. There can be no assurance that additional funding or partnerships will be available on terms acceptable to us, and which would foster the successful commercialization of our technologies. If additional funds are raised through further issuances of equity or convertible debt securities, existing shareholders could suffer significant dilution, and any new equity securities issued could have rights, preferences and privileges superior to those of the Common Shares. Any debt financing secured in the future could involve restrictive covenants relating to capital raising activities and other financial and operational matters, which may make it more difficult for us to obtain additional capital or to pursue business opportunities, including potential acquisitions. If adequate funds are not obtained, we may be required to reduce, curtail or discontinue operations.

We are substantially dependent on the success of our lead product candidates EP-104GI, which is currently being studied in an open label Phase 1b/2a clinical study, and EP-104IAR, for which we are evaluating funding alternatives for the continued development, including potential partnership

opportunities. If we are unable to complete development of, obtain approval for and commercialize EP-104GI or EP-104IAR, alone or through a potential partnership, in a timely manner, our business will be harmed.

Our future success is dependent on our ability to timely complete clinical trials, obtain marketing approval for and successfully commercialize our lead product candidates, EP-104GI, and EP-104IAR. We have invested significant efforts and financial resources in the research and development of EP-104GI and EP-104IAR. We are conducting a Phase 1b/2a clinical trial for the proposed indication of EoE and have conducted a Phase 2 clinical trial for the proposed indication of OA. Both indications will require additional clinical development, evaluation of clinical, preclinical and manufacturing activities, marketing approval from government regulators, substantial investment and significant marketing efforts before we can generate any revenues from sales of any approved products. In addition, we are evaluating funding alternatives for the continued development of EP-104IAR, including potential partnership opportunities. If we are unable to secure such funding, we may ultimately discontinue our efforts with respect to this candidate. We are not permitted to market or promote EP-104GI, EP-104IAR or any other product candidate before we receive marketing approval from the FDA and/or comparable foreign regulatory authorities, and we may never receive such marketing approval.

Our ability to generate revenue and achieve profitability depends significantly on several factors, including but not limited to the following:

- successful and timely completion of non-clinical and clinical development of our product candidates and any future product candidates, as well as the associated costs, including any unforeseen costs we may incur as a result of non-clinical study or clinical trial delays due to public health crises or other causes;
- the initiation and successful patient enrollment and completion of additional clinical trials on a timely basis;
- establishing and maintaining relationships with CROs and clinical sites for the clinical development, both in the United States and internationally, of our product candidates and any future product candidates;
- entering into strategic partnerships for the development and commercialization of our product candidates;
- the frequency and severity of adverse events in the clinical trials;
- the efficacy, safety and tolerability profiles that are satisfactory to the FDA, EMA, or any comparable foreign regulatory authority for obtaining marketing approval;
- timely receipt of marketing approvals from applicable regulatory authorities for any product candidates for which we successfully complete clinical development;
- making any required post-marketing approval commitments to applicable regulatory authorities;
- developing an efficient and scalable manufacturing process for our product candidates, including obtaining finished products that are appropriately packaged for sale;
- establishing and maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for product candidates that we develop, if approved;
- successful commercial launch following any marketing approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;
- a continued acceptable safety profile following any marketing approval of our product candidates;
- commercial acceptance of our product candidates by patients, the medical community and third-party payors;
- identifying, assessing and developing new product candidates;
- obtaining, maintaining and expanding patent protection, trade secret protection and/or regulatory exclusivity;
- protecting our rights in our intellectual property portfolio;
- defending against third-party interference or infringement claims, if any;
- negotiating favorable terms in any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- obtaining coverage and adequate reimbursement by hospitals, government and third-party payors for product candidates that we develop and receive regulatory approval;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring and retaining qualified personnel.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. To the extent we enter into strategic partnerships, we will be subject to the risks described under "*Collaboration arrangements we may enter into in the future may not be successful.*" We may never be successful in achieving our objectives and, even if we do, may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable may decrease the value of our company and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business and continue our operations.

We may also experience delays in developing a sustainable, reproducible and scalable manufacturing process or transferring that process to commercial partners, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all. Changes in the manufacturing process or facilities will require further comparability analysis and approval by the FDA before implementation, which could delay our clinical trials and product candidate development, and could require additional clinical trials, including bridging studies, to demonstrate consistent and continued safety and potency.

We have not previously submitted a NDA to the FDA or similar approval filings to a comparable foreign regulatory authority, for any product candidate. An NDA or other relevant regulatory filing must include extensive non-clinical and clinical data and supporting information to establish that the product candidate is safe and effective for each desired indication. The NDA or other relevant regulatory filing must also include significant information regarding the chemistry, manufacturing and controls for the product. We cannot be certain that our current or future product candidates will be successful in clinical trials or receive regulatory approval. Further, even if such product candidates are successful in clinical trials, our product candidates or any future product candidates may not receive regulatory approval. If we do not receive regulatory approvals for current or future product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approval to market a product candidate, our revenue will depend, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights, as well as the availability of competitive products, whether there is sufficient third-party reimbursement and adoption by physicians.

If we breach any of the agreements under which we license rights to our product candidates or technology from third parties, we could lose license rights that are important to our business. Our current license agreement may not provide an adequate remedy for its breach by the licensor.

We are developing the Products pursuant to the Amended and Restated License Agreement with Auritec. We are subject to a number of risks associated with our license from Auritec, including the risk that Auritec may terminate the Amended and Restated License Agreement upon the occurrence of certain specified events. The Amended and Restated License Agreement requires, among other things, that we make certain payments and use commercially reasonable efforts to meet certain clinical and regulatory milestones. If we fail to comply with any of these obligations or otherwise breach the agreements, Auritec may have the right to terminate the license in whole.

We could also suffer the consequences of non-compliance or breaches by Auritec in connection with the Amended and Restated License Agreement. Such non-compliance or breach could in turn result in our breach or default under our future agreements with collaboration partners, and we could be found liable for damages or lose certain rights, including rights to develop and/or commercialize a product or product candidate. Loss of our rights under the Amended and Restated License Agreement or any similar license granted to us in the future, including the exclusivity rights provided therein, could harm our financial condition and operating results.

Adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and our financial condition and results of operations.

Actual events involving limited liquidity, defaults, non-performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market-wide liquidity problems. For example, in March 2023 SVB was closed by the California Department of Financial Protection and Innovation, which appointed the FDIC as receiver. Also in March 2023, Signature Bank and Silvergate Capital Corp. were each swept into receivership. Although a statement by the U.S. Department of the Treasury, the Federal Reserve and the FDIC indicated that all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB, Signature Bank or any other financial institution that is placed into receivership by the FDIC were hampered in accessing undrawn amounts thereunder. If any of our suppliers or other parties with whom we conduct business are unable to access funds pursuant to such instruments or lending arrangements with such a financial institution or other distressed financial institutions, such parties' ability to pay their obligations to us or to enter into new commercial arrangements requiring additional payments to us could be adversely affected. We currently are a borrower under the Debt Agreement with SVB with the facility being fully drawn. We, and any suppliers or other parties that are counterparties to SVB credit agreements and arrangements, and third parties such as beneficiaries of letters of credit (among others), may experience direct impacts from the closure of SVB and uncertainty remains over liquidity concerns in the broader financial services industry. Similar impacts have occurred in the past, such as during the 2008-2010 financial crisis. In addition, due to the complexities surrounding SVB's receivership, we are not certain that SVB will be able to exercise its conversion rights under the Debt Agreement and receive Common Shares in satisfaction of amounts owed, even if the conversion feature under the Debt Agreement is in the money. If amounts outstanding under the Debt Agreement are not converted to Common Shares prior to the maturity date, we will either need to refinance amounts owing with a new debt facility or use our cash resources to pay amounts owing, which would divert such funds from our research and development efforts and potentially have a material and adverse impact on our business.

Inflation and rapid increases in interest rates have led to a decline in the trading value of previously issued government securities with interest rates below current market interest rates. Although the U.S. Department of Treasury, FDIC and Federal Reserve Board previously announced a program to provide loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. Additionally, there is no guarantee that the U.S. Department of Treasury, FDIC and Federal Reserve Board will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

Although we assess our banking and customer relationships as we believe necessary or appropriate, our access to funding sources and other credit arrangements in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect us, the financial institutions with which we have credit agreements or arrangements directly, or the financial services industry or economy in general. These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could involve financial institutions or financial services industry companies with which we have financial or business relationships, but could also include factors involving financial markets or the financial services industry generally.

The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, the following:

- Delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets;
- Delayed or lost access to, or reductions in borrowings available under credit facilities or other working capital sources and/or delays, inability or reductions in our ability to refund, roll over or extend the maturity of, or enter into new credit facilities or other working capital resources;
- Potential or actual breach of contractual obligations that require us to maintain letters of credit or other credit support arrangements;
- Potential or actual breach of financial covenants in our credit agreements or credit arrangements;

- Potential or actual cross-defaults in other credit agreements, credit arrangements or operating or financing agreements; or
- Termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, investor concerns regarding the U.S., Canadian, or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have a material adverse effect on our liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, any further deterioration in the macroeconomic economy or financial services industry could lead to losses or defaults by our counterparties, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. For example, counterparties may fail to make payments when due, default under their agreements with us, become insolvent or declare bankruptcy, or a supplier may determine that it will no longer deal with us as a customer. In addition, a counterparty could be adversely affected by any of the liquidity or other risks that are described above as factors that could result in a material adverse effect on us, including but not limited to delayed access or loss of access to uninsured deposits or loss of the ability to draw on existing credit facilities involving a troubled or failed financial institution. Any counterparty bankruptcy or insolvency, or the failure of any counterparty to make payments when due, or any breach or default by a counterparty, or the loss of any significant supplier relationships, could result in material losses to us and may have a material adverse effect on our business.

Clinical trials are expensive, time consuming and difficult to design and implement and may fail to demonstrate adequate safety and efficacy of our product candidates. Furthermore, the results of previous preclinical studies and clinical trials may not be predictive of future results, and the results of our current and planned clinical trials may not satisfy the requirements of the FDA or comparable foreign regulatory authorities or provide the basis for regulatory approval.

Before obtaining marketing approval from regulatory authorities for the sale of our product candidates, we must conduct preclinical development and then extensive clinical trials to demonstrate their safety and efficacy. Preclinical and clinical testing is expensive and difficult to design and implement. Preclinical and clinical testing can take many years to complete, and its ultimate outcome is uncertain.

A failure of one or more preclinical or clinical trials can occur at any stage of the process. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for use in a diverse patient population before we can seek regulatory approvals for their commercial sale. Our preclinical or clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional and expansive preclinical or clinical testing.

Because these lead product candidates utilize the same proprietary Diffusphere delivery technology, a failure of one of our clinical trials may also increase the actual or perceived likelihood that our other product candidates will experience similar failures. If our ongoing or future clinical trials are inconclusive with respect to the safety and efficacy of our product candidates, or if we encounter safety concerns associated with our product candidates, we may incur unplanned costs and be delayed in or prevented from obtaining marketing approval for our product candidates.

Positive or timely results from preclinical or early-stage trials do not ensure positive or timely results in future clinical trials or registrational clinical trials because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and comparable foreign regulatory authorities, despite having progressed through preclinical studies or initial clinical trials. Product candidates that have shown promising results in early clinical trials may still suffer significant setbacks in subsequent clinical trials or registration clinical trials. For example, a number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in earlier clinical trials.

Our lead product candidates may not be successful for their intended use.

EP-104GI is intended for the treatment of pain and inflammation in adult patients diagnosed with EoE, a chronic and incurable disease that leads to progressive fibrosis of the esophagus. EoE is characterized by inflammation and the accumulation of large numbers of eosinophils (a type of white blood cells) within the epithelial lining of the esophagus. The active pharmaceutical ingredient is an anti-inflammatory corticosteroid fluticasone propionate ("**FP**") that reduces the pain associated with inflammation.

EP-104IAR is intended as a long-acting pain relief for OA knee pain. EP-104IAR has the same active pharmaceutical ingredient as EP-104GI.

Inflammation is not the only contributor to pain in EoE and knee pain, and EP-104GI and EP-104IAR may not provide sufficient pain relief for other sources of pain in EoE, such as damage of the esophagus, esophageal strictures and proliferation of fibrotic tissue, or for other sources of knee pain, such as bone-on-bone interactions. EP-104GI and EP-104IAR are the first FP-based product candidates intended to have an extended release profile to be tested in the esophagus and knee, respectively, and the effective doses have not been determined. To achieve regulatory approval in North America, EP-104GI and EP-104IAR must each show significant benefit over placebo. This is complicated by the "placebo effect" in pain-related trials, whereby patients perceive pain relief despite having received no active pharmaceutical. We have not received FDA approval for either lead product candidate and cannot be certain that our approach will lead to the development of an approvable or marketable product. We may not succeed in demonstrating safety and efficacy of EP-104GI or EP-104IAR in our ongoing clinical trials or in larger-scale clinical trials.

Advancing EP-104 creates significant challenges for us, including:

- demonstrating adequate safety and efficacy to support NDA approval and a sustained safety profile following any marketing approval of our product candidates, including providing sufficient non-clinical and clinical data to support an extended-release claim in our proposed labeling and sufficient data on systemic exposure and local toxicity to support repeat dosing in humans;
- obtaining marketing approval, as the FDA, EMA or other regulatory authorities have never approved an FP-based product for EoE or OA knee pain;
- if EP-104 is approved in any indication, educating medical personnel regarding the potential benefits, as well as the challenges, of incorporating EP-104 into existing treatment regimens; and
- establishing the sales and marketing capabilities upon obtaining any marketing approvals to gain market acceptance.

Our current and future product candidates will require regulatory approval, which is costly, and we may not be able to obtain it and we may fail to obtain regulatory approvals or only obtain approvals for limited uses or indications.

Marketing authorization of EP-104 for any indication and other product candidates will fall under the regulatory purview of the FDA and other equivalent regulatory bodies worldwide. We are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval from the FDA. Foreign regulatory authorities impose similar requirements. The time required to obtain approval by the FDA, EMA and other comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions or change over time, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. Even if we eventually complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA, EMA and other comparable foreign regulatory authorities may approve our product candidates for a more limited indication, a narrower patient population than we originally requested or with a REMS. Further, regulatory authorities may not approve the price we intend to charge for products we may develop, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. We have not submitted for, or obtained, regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Further, development of our product candidates and/or regulatory approval may be delayed for reasons beyond our control. For example, a U.S. federal government shutdown or budget sequestration, may result in significant reductions to the FDA's budget, employees and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates or obtain regulatory approval for our product candidates. Applications for our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, EMA or other comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA, EMA or other comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- the FDA, EMA or other comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the United States or elsewhere;
- we may be unable to demonstrate to the FDA, EMA or other comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA, EMA or other comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

The clinical trials of our product candidates may not demonstrate safety and efficacy to the satisfaction of the FDA, EMA or other comparable foreign regulatory authorities or otherwise produce positive results.

Before obtaining marketing approval from the FDA, EMA or other comparable foreign regulatory authorities for the sale of our product candidates, we must complete preclinical development and extensive clinical trials to demonstrate the safety and efficacy of our product candidates. Clinical testing is expensive, difficult to design and implement, can take many years to complete and its ultimate outcome is uncertain. A failure of one or more clinical trials can occur at any stage of the process. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. For example, we completed an end of Phase 2 meeting with the FDA in January 2024 regarding EP-104IAR. Based on our interactions with the FDA at that meeting, we believe that we have an understanding of the remaining non-clinical and clinical studies that would be needed to support a 505(b)(2) application for EP-104IAR, including the need to conduct additional animal studies to evaluate the potential for dose dumping and immediate release of fluticasone propionate, sufficient safety and efficacy data to support repeat dosing, and adequate data to bridge the systemic safety of Flovent HFA to EP-104IAR, among other recommendations and comments received from the FDA. However, we cannot be certain that we and any potential partner will be successful in completing these anticipated studies, or if the FDA or any other regulatory authority will determine the data we and any potential partner obtain from such studies and any data obtained from any previously conducted clinical or non-clinical studies are sufficient to support an approval or that such regulatory authorities will not require additional trials. We can provide no assurance that FDA will approve the indication we and any potential partner seek in the NDA, if at all. If FDA grants approval, depending on FDA's interpretation of the data, FDA may impose labeling restrictions, reject the "extended release" claim in the labeling, restrict repeat dosing, or require additional safety monitoring or warnings. Ultimately, the FDA will need to conduct a full review of all studies submitted in support of approval and such studies may be unsatisfactory to the FDA. In addition, even if any of our product candidates receives FDA approval, any labeling restrictions that may be imposed by the FDA may materially and adversely impact our or any potential partner's ability to successfully commercialize our product candidates.

In addition, we may rely in part on preclinical, clinical and quality data generated by CROs and other third parties for regulatory submissions for our product candidates. While we have or will have agreements governing these third parties' services, we have limited influence over their actual performance. If these third parties do not make data available to us, or, if applicable, make regulatory submissions in a timely manner, in each case pursuant to our agreements with them, our development programs may be significantly delayed, and we may need to conduct additional studies or collect additional data independently. In either case, our development costs would increase.

We do not know whether our future clinical trials will begin on time or enroll patients on time, or whether our ongoing and/or future clinical trials will be completed on schedule or at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical studies;
- obtaining regulatory authorizations to commence a trial or reaching a consensus with regulatory authorities on trial design;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval from one or more institutional review boards ("**IRBs**");
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes to clinical trial protocol;
- clinical sites deviating from trial protocol or dropping out of a trial;
- manufacturing sufficient quantities of product candidate or obtaining sufficient quantities of combination therapies for use in clinical trials;
- subjects failing to enroll or remain in our trial at the rate we expect, or failing to return for post- treatment follow-up;
- subjects choosing an alternative treatment for the indication for which we are developing our product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected drug-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies;
- selection of clinical end points that require prolonged periods of clinical observation or analysis of the resulting data;
- a facility manufacturing our product candidates or any of their components being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of current good manufacturing practice ("**cGMP**"), regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices ("**GCPs**") or other regulatory requirements;
- third-party contractors not performing data collection or analysis in a timely or accurate manner; or
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for re-examination, which may impact the costs, timing or successful completion of a clinical trial.

Further, conducting clinical trials in foreign countries, as we may do for our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues.

In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

We completely rely on third parties to provide supplies and inputs required for our products.

We currently outsource all product manufacturing. The field of manufacturers capable of manufacturing the EP-104 API powder is narrow and not easily replaced. Although we depend heavily on these parties, we do not control them and, therefore, cannot be assured that these third parties will adequately perform all of their contractual obligations to us. If our third-party service providers cannot adequately fulfill their obligations to us in a timely and satisfactory basis, development plans may be delayed or terminated.

We expect to continue to rely on third-party manufacturers for the commercial supply of any of our product candidates for which we obtain marketing approval. We may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third party to manufacture our product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us due to any number of reasons including staffing issues, change in strategy, or concerns around manufacture of our drug substance due to perceived or actual safety concerns;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the failure of the third party to manufacture our product candidates according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements internationally. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or others, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, EMA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations. Our current and anticipated future dependence upon others for the manufacture of our product candidates or drugs may adversely affect our future profit margins and our ability to commercialize any product candidates that receive marketing approval on a timely and competitive basis.

We rely on CROs to provide clinical and non-clinical research services; if such CROs do not successfully carry out their contractual duties including to comply with applicable laws and regulations or meet expected deadlines, our business could be substantially harmed.

We engage with contractors, including CROs, for various aspects of our non-clinical studies and clinical trials, including trial conduct, data management, study management and managing, statistical analysis and electronic compilation of our regulatory submissions. We may enter into agreements with CROs to obtain resources and expertise in an attempt to accelerate our progress on new or ongoing clinical and non-clinical programs. Typically entering into relationships with CROs involves substantial cost and requires extensive management time and focus. In addition, typically there is a transition period between engagement of a CRO and the time the CRO commences work. As a result, delays may occur, which may materially impact our ability to meet desired non-clinical and clinical development timelines and ultimately have a material adverse effect on our operating results, financial condition or future prospects.

As CROs are not our employees, we cannot control whether or not they devote sufficient time and resources to our clinical trials for which they are engaged to perform, and whether they comply with the applicable GCPs and Good Laboratory Practices ("**GLPs**") for our product candidates, which include requirements related to the conduct of the study, subject informed consent, and research ethics board's approval among others. Regulatory authorities, including the FDA, monitor compliance with Good Manufacturing Practices, GLPs, and GCPs (collectively, "**GxPs**") through periodic inspections of trial sponsors, principal investigators and trial sites. Although we may rely on third parties for the execution of our clinical trials and non-clinical research, we are nevertheless responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on CROs does not relieve us of our regulatory responsibilities. If we or any of our CROs deviate from the approval protocols, make errors during the conduct of the studies, or fail to comply with applicable GCPs and GLPs, the data generated in the Company's studies may be deemed unreliable and the applicable regulatory authorities may take regulatory action against us and/or require us to perform additional studies before approving our marketing applications. We cannot assure you that, upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product candidate materials produced under GMP regulations. Our failure to comply with these regulations may require us to discontinue or repeat clinical trials, which would delay the regulatory approval process. If the CROs that we engage do not successfully carry out their contractual duties or obligations, conduct the studies in accordance with all regulatory requirements, or meet expected deadlines, or if they need to be replaced, or the quality or accuracy of the data they provide is compromised due to the failure to adhere to regulatory requirements or for other reasons, then our development programs may be extended, delayed or terminated, or we may not be able to obtain marketing approval for or successfully commercialize our product candidates. Failure to comply with clinical trial regulatory requirements may further subject us to significant penalties potentially including imprisonment or an injunction against manufacture or distribution and debarment.

The manufacture of drugs is complex, and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.

Manufacturing drugs, especially in large quantities, is complex and may require the use of innovative technologies. Each lot of an approved drug product must undergo thorough testing for identity, strength, quality, purity, potency, and stability. Manufacturing drugs requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our manufacturer, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business, including exposure to liabilities arising from any GxP non-compliance. If our manufacturers and suppliers are unable to produce sufficient quantities for clinical trials or for commercialization as a result of these challenges, or otherwise, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor or other third party will discover them or that our trade secrets will be misappropriated or disclosed.

Because we currently rely on third parties to manufacture our product candidates and to perform quality testing, we must, at times, share our proprietary technology and confidential information, including trade secrets, with them. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements, and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors or other third parties, are intentionally or inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets and despite our efforts to protect our trade secrets, a competitor's or other third party's discovery of our proprietary technology and confidential information or other unauthorized use or disclosure of such technology or information would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations and prospects.

The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, EMA or other comparable foreign regulatory authorities. Terminating the development of any of our product candidates could materially harm our business and the market price of our Common Shares.

Our clinical product candidates, along with product candidates we expect to enter clinical development, are in varying stages of development and will require substantial clinical development, testing and regulatory approval prior to commercialization. Before obtaining regulatory approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive pre-clinical testing and clinical trials that each product candidate is both safe and effective for use in each target indication. Failure can occur at any time during the clinical trial process. Clinical trials often fail to demonstrate safety and efficacy of the product candidate studied for the target indication. Most product candidates that commence clinical trials are never approved as products. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Patients treated with our product candidates may also be undergoing other treatments and may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to our product candidate. As a result, assessments of efficacy can vary widely for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes. While recent data obtained from our ongoing studies of EP-104GI and EP-104IAR is encouraging, we cannot be certain that future trials will not suffer setbacks, including for lack of efficacy and/or adverse safety profiles, or that previously conducted clinical and non-clinical studies will be deemed adequate for purposes of regulatory approval. For additional information regarding our recent study results, please see the section of this AIF titled "*Description of the Business – Product Candidates*".

In addition to the safety and efficacy trials of any product candidate, clinical trial failures may result from a multitude of factors including flaws in trial design, dose selection, statistical analysis plan, placebo effect, patient enrollment criteria, patient compliance and trial execution. Data obtained from trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent regulatory approval. Failure of a clinical trial due to any of these reasons could materially harm our business and the market price of our Common Shares. In the case of some of our product candidates, we may seek to develop treatments for certain diseases or disorders for which there is relatively limited clinical experience, and clinical trials may use novel endpoints and measurement methodologies or subjective patient feedback, which adds a layer of complexity to these clinical trials and may delay regulatory approval. Negative or inconclusive results from our clinical trials could lead to a decision or requirement to conduct additional pre-clinical testing or clinical trials or result in a decision to terminate the continued development of a product candidate. Any of the foregoing outcomes would materially and adversely impact our business, product candidate pipeline and future prospects.

If our product candidates are not shown to be both safe and effective in clinical trials, such product candidates will be unable to obtain regulatory approval or be successfully commercialized. In addition, our failure to demonstrate positive results in clinical trials in any indication for which we are developing clinical product candidates could adversely affect development efforts in other indications. In such case, we would need to develop other compounds and conduct associated pre-clinical testing and clinical trials, as well as potentially seek additional financing, all of which would have a material adverse effect on our business, growth prospects, operating results, financial condition and results of operations.

Interim, initial, "top-line", and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or top-line data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available.

Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our Common Shares.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could seriously harm our business.

Preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA, EMA or comparable foreign regulatory authority approval. We cannot guarantee that the FDA or foreign regulatory authorities will interpret trial results as we do, and more trials could be required before we are able to submit applications seeking approval of our product candidates. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the scope and use of our product candidate, which may also limit its commercial potential. Furthermore, the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval, which may lead to the FDA, EMA or comparable foreign regulatory authorities delaying, limiting or denying approval of our product candidates.

Our current or future product candidates may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other products that may result in a safety profile that could inhibit regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.

As is the case with pharmaceuticals generally, it is likely that there may be side effects and adverse events associated with our product candidates' use. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

If our product candidates are associated with undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial, or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may harm our business, financial condition and prospects significantly.

Patients in our ongoing and planned clinical trials may in the future suffer significant adverse events or other side effects not observed in our preclinical studies or previous clinical trials. Some of our product candidates, may be used as chronic therapies or be used in pediatric populations, for which safety concerns may be particularly scrutinized by regulatory agencies. In addition, if our product candidates are used in combination with other therapies, our product candidates may exacerbate adverse events associated with the therapy. Patients treated with our product candidates may also be undergoing other medical procedures or treatments, which can cause side effects or adverse events that are unrelated to our product candidate, but may still impact the success of our clinical trials.

If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, EMA, other comparable regulatory authorities or an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could

materially harm our business, financial condition and prospects.

Further, if any of our product candidates obtains marketing approval, toxicities associated with such product candidates and not seen during clinical testing may also develop after such approval and lead to a requirement to conduct additional clinical safety trials, additional contraindications, warnings and precautions being added to the drug label, significant restrictions on the use of the product or the withdrawal of the product from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or early-stage clinical trials.

Where appropriate and applicable, we may seek approval from the FDA or comparable foreign regulatory authorities through the use of expedited approval pathways, such as Fast Track designation or orphan drug designation. Even if we receive Fast Track designation or other designation, we can provide no assurance that we will be able to obtain FDA approval sooner or if at all.

Where possible, we may pursue accelerated development strategies in areas of high unmet need for one or more of our product candidates. In June 2023, we announced that the FDA has granted Fast Track designation for EP-104IAR in treatment of OA. Fast Track designation is designed to facilitate the development and expedite the review of therapies for serious conditions and fill an unmet medical need. Programs with Fast Track designation may benefit from early and frequent communications with the FDA, potential priority review and the ability to submit a rolling application for regulatory review. Fast Track designation applies to both the product candidate and the specific indication for which it is being studied. If any of our product candidates receive Fast Track designation but do not continue to meet the criteria for Fast Track designation, or if our clinical trials are delayed, suspended or terminated, or put on clinical hold due to unexpected adverse events or issues with clinical supply, we will not receive the benefits associated with the Fast Track program. Furthermore, Fast Track designation does not change the standards for approval. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. If a product that has orphan drug designation from the FDA subsequently receives the first FDA approval for an indication within the orphan disease, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication, for seven years, except in limited circumstances such as a showing of clinical superiority to the product with the orphan product exclusivity or if FDA finds that the holder of the orphan exclusivity has not shown that it can ensure the availability of sufficient quantities of the orphan product to meet the needs of patients with the disease or condition for which the product was designated. Even if we or our collaborators obtain orphan designation for a product candidate, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. The scope of exclusivity is limited to the scope of any approved indication, even if the scope of the orphan designation is broader than the approved indication. Additionally, exclusive marketing rights may be limited if we or our collaborators seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if a product obtains orphan drug exclusivity, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve a product with the same active moiety for the same condition if the FDA concludes that the later product is safer, more effective, or makes a major contribution to patient care. Furthermore, the FDA can waive orphan exclusivity if we or our collaborators are unable to manufacture sufficient supply of the product. If we or our collaborators do not receive or maintain orphan drug designation to product candidates for which we seek such designation, it could limit our ability to realize revenues from such product candidates. Further, in view of the court decision in *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), the FDA published a notice in the Federal Register in January 2023 to clarify that while the agency complies with the court's order in *Catalyst*, FDA intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the *Catalyst* order – that is, the agency will continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. It is unclear how future litigation, legislation, agency decisions, and administrative actions will impact the scope of the orphan drug exclusivity.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our drug candidates, if approved, we may be unable to generate any product revenue.

To successfully commercialize EP-104, in any indication, if approved, or any future product candidate that may result from our development programs, we will need to build out our sales and marketing capabilities, either on our own or with others. The establishment and development of our own commercial team or the establishment of a contract field force to market any product candidate we may develop will be expensive and time-consuming and could delay any drug launch. Moreover, we cannot be certain that we will be able to successfully develop this capability. We may seek to enter into collaborations with other entities to use their established marketing and distribution capabilities, but we may be unable to enter into such agreements on favorable terms, if at all. If any current or future collaborators do not commit sufficient resources to commercialize our product candidates, or we are unable to develop the necessary capabilities on our own, we may be unable to generate sufficient revenue to sustain our business. We may compete with many companies that currently have extensive, experienced and well-funded marketing and sales operations to recruit, hire, train and retain marketing and sales personnel. We will likely also face competition if we seek third parties to assist us with the sales and marketing efforts any future product candidates. Without an internal team or the support of a third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

We have a novel technology with uncertain market acceptance.

Even if any of our product candidates receive regulatory approval, the approved products may not achieve broad market acceptance among physicians, patients, the medical community and third-party payors, in which case revenue generated from their sales would be limited. Our delivery platform is at an early stage of development and uses novel technology, with uncertain market acceptance if our product candidates are approved. Product approval, should this be achieved, does not infer that the product will garner a good market price or be reimbursed by public or private insurers. Further, there are no guarantees that the product will be positively received by the target patient population. If any of our product candidates is approved but does not achieve an adequate level of acceptance by physicians, healthcare payors and patients, we may not generate or derive sufficient revenue from that product candidate and our financial results could be negatively impacted. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including, but not limited to:

- the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- restrictions on the use of our product candidates, such as boxed warnings or contraindications in labeling, or a REMS, if any, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of product candidates over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement, as well as pricing, by third-party payors, including government authorities;
- the availability of the approved product candidate for use as a combination therapy;
- relative convenience and ease of preparation and administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the effectiveness of sales and marketing efforts;
- unfavorable publicity relating to our products or product candidates or similar approved products or product candidates in development by third parties; and
- the approval of other new therapies for the same indications.

If we experience delays or difficulties in the enrollment and/or maintenance of patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Patient enrollment is a significant factor in the timing of clinical trials, and the timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to such trial's conclusion as required by the FDA, EMA or other comparable foreign regulatory authorities. Additionally, certain clinical trials for future product candidates may be focused on indications with relatively small patient populations, which may further limit enrollment of eligible patients or may result in slower enrollment than we anticipate. The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants.

Patient enrollment may also be affected if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' product candidates. Patient enrollment for any of our clinical trials may be affected by other factors, including:

- size and nature of the patient population;
- severity of the disease under investigation;
- availability and potency of approved drugs for the disease under investigation;
- patient eligibility criteria for the trial in question as defined in the protocol;
- perceived risks and benefits of the product candidate under study;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;

- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients;
- continued enrollment of prospective patients by clinical trial sites; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain marketing approval for the sale of our product candidates. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining enrollment of such patients in our clinical trials.

The FDA, EMA and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.

We may choose to conduct international clinical trials in the future. The acceptance of study data by the FDA, EMA or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (1) the data are applicable to the United States population and United States medical practice; (2) the trials are performed by clinical investigators of recognized competence and pursuant to current GCP requirements; and (3) the FDA is able to validate the data through an on-site inspection or other appropriate mean. Additionally, the FDA's clinical trial requirements, including the adequacy of the patient population studied and statistical powering, must be met. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, EMA or any applicable foreign regulatory authority will accept data from trials conducted outside of its applicable jurisdiction. If the FDA, EMA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval for commercialization in the applicable jurisdiction.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA or EMA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product candidate in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

If the market opportunity for any product candidate that we or our strategic partners develop is smaller than we believe, our revenue may be adversely affected, and our business may suffer.

We intend to initially focus our product candidate development on treatments for EoE and OA indications. Our projections of addressable patient populations that may benefit from treatment with our product candidates are based on our estimates. These estimates, which have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations and market research, may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of EoE or OA. Additionally, the potentially addressable patient population for our product candidates may not ultimately be amenable to treatment with our product candidates. FDA, EMA, or other regulatory agencies may also limit our proposed indication or target population. Our market opportunity may also be limited by future competitor treatments that enter the market. If any of our estimates prove to be inaccurate, the market opportunity for any product candidate that we or our strategic partners develop could be significantly diminished and have an adverse material impact on our business.

Even if our product candidates receive regulatory approval, we will be subject to significant post marketing regulatory requirements and oversight.

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or foreign regulatory authorities approve our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with cGMPs and GCP for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

In addition, failure to comply with FDA, EMA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- delays in or the rejection of product approvals;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning or untitled letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production; and
- imposition of restrictions on operations, including costly new manufacturing requirements.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates.

If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. If government regulation arises that puts constraints on FDA's or other regulatory authorities' ability to exercise their respective regulatory authority, including engaging in oversight and implementation activities in the normal course, our business may be negatively impacted.

It is difficult to predict how current and future legislation, executive actions, and litigation, including the executive orders, will be implemented, and the extent to which they will impact our business, our clinical development, and the FDA's and other agencies' ability to exercise their regulatory authority, including FDA's pre-approval inspections and timely review of any regulatory filings or applications we submit to the FDA. In addition, if the Supreme Court reverses or curtails the *Chevron* doctrine, which gives deference to regulatory agencies in litigation against FDA and other agencies, more companies may bring lawsuits against FDA to challenge longstanding decisions and policies of FDA, which could undermine FDA's authority, lead to uncertainties in the industry, and disrupt FDA's normal operations, which could delay FDA's review of our marketing applications.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA, had to furlough critical employees and stop critical activities. Separately, in response to the COVID-19 pandemic, the FDA temporarily postponed certain inspections before resuming normal operations.

If a prolonged government shutdown occurs, or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

We rely on key personnel.

Our success depends in large measure on certain key personnel, including our executive officers. The loss of the services of such key personnel could have a material adverse effect on us. The contributions of these individuals to our immediate operations are likely to be of central importance. In addition, the competition for qualified personnel in the biotech industry is intense and there can be no assurance that we will be able to continue to attract and retain all personnel necessary for the development and operation of our business. Investors must rely upon the ability, expertise, judgment, discretion, integrity and good faith of our management. Other biotechnology companies with which we compete for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high-quality candidates than those that we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate of and success with which we can develop and commercialize product candidates would be limited.

As a technology-driven company, intellectual input from key management and personnel is critical to achieve our business objectives. Consequently, our ability to retain these individuals and attract other qualified individuals is critical to our success. The loss of the services of key individuals might significantly delay or prevent achievement of our business objectives. In addition, because of a relative scarcity of individuals with the high degree of education and scientific achievement required for our business, competition among biotech companies for qualified employees is intense, and as a result we may not be able to attract and retain such individuals on acceptable terms, or at all.

We also have relationships with scientific collaborators at academic and other institutions, some of whom conduct research at our request or assist us in formulating our research and development strategies. These scientific collaborators are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, even though our collaborators are required to sign confidentiality agreements prior to working with us, they may have arrangements with other companies to assist such other companies in developing technologies that may prove competitive to us.

Incentive provisions for our key executives include the granting of stock options that vest over time, designed to encourage such individuals to stay with us. However, a low share price could render such agreements of little value to our key executives. In such event, our key executives could be susceptible to being hired away by our competitors who could offer a better compensation package. If we are unable to attract and retain key personnel our business, financial conditions and results of operations may be adversely affected.

We may not be able to successfully execute our business strategy.

The execution of our business strategy poses many challenges and is based on several assumptions. If we experience significant regulatory delays, supply chain disruptions, cost overruns on our programs, or if our business plan is more costly than we anticipate, certain research and development activities may be delayed or eliminated, resulting in changes or delays to our commercialization plans, or we may be compelled to secure additional funding (which may or may not be available) to execute our business strategy. We cannot predict with certainty our future revenues or results from our operations. If the assumptions on which our revenue or expenditure forecasts are based change, the benefits of our business strategy may change as well.

We are in a highly competitive industry which is continuously evolving with technological changes.

We are engaged in an industry that is highly competitive, evolving and characterized by technological change. As a result, it is difficult for it to predict whether, when and by whom new competing technologies or new competitors may enter the market. We face competition from companies with strong positions in certain markets we are currently targeting, and in new markets and regions we may enter. Some of these companies have significantly greater financial, technical, human, research and development, and marketing resources than us. We cannot assure you that we will be able to compete effectively against current and future competitors who may discover and develop products in advance of us that are more effective than those developed by us. As a consequence, our current and future technologies may become obsolete or uncompetitive, resulting in adverse effects on revenue, margins and profitability. In addition, competition or other competitive pressures may result in price reductions, reduced margins or loss of market share, any of which could have a material adverse effect on our business, financial condition or results of operations. To the extent that new or improved oral or other systemically administered pain medications are introduced that demonstrate better long-term efficacy and safety, patients and physicians may further delay the introduction of injectable therapies, such as EP-104, in the treatment for any indication we pursue. EP-104 could also face competition from other formulations or devices that deliver pain medication on an extended basis, such as transdermal delivery systems or implantable devices.

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staffs and experienced commercial and manufacturing organizations. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. As a result, these companies may obtain regulatory approval more rapidly than we are able and may be more effective in selling and marketing their products as well. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large, established companies. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Competitors may succeed in developing, acquiring or licensing on an exclusive basis drug products or drug delivery technologies that are more effective or less costly than EP-104 for any of our intended applications, or any other product candidate that we are currently developing or may develop.

We believe that our ability to compete effectively depends upon many factors both within and beyond our control, including:

- the usefulness, ease of use, performance and reliability of our technology compared to our competitors;
- the activity, tolerability, and potential benefits of EP-104 and our other product candidates, including relative to marketed products and product candidates in development by third parties;
- the ability to distinguish safety and efficacy from existing, alternative therapies;

- the timing for product candidates to complete clinical development and receive market approval;
- acceptance of EP-104 and any of our other product candidates that receive regulatory approval by patients, physicians and other health providers;
- our ability to monetize our technology;
- the selection of licensing partners for our technology with the necessary skills and resources to drive uptake;
- our marketing and selling efforts;
- our financial condition and results of operations;
- the ability to maintain a good relationship with regulatory authorities;
- the price of our future products, including in comparison to branded or generic competitors;
- whether coverage and adequate levels of reimbursement are available under private and governmental health insurance plans;
- acquisitions or consolidations within our industry, which may result in more formidable competitors;
- our ability to protect our intellectual property rights;
- our ability to attract, retain and motivate talented employees;
- our ability to cost-effectively manage and grow our operations; and
- our reputation and brand strength relative to that of our competitors.

Our future success will depend on our ability to continually enhance and develop our product candidates.

There is a broad pipeline of potential new therapies for pain. The market for pain management and treatment solutions is characterized by rapid technological change and the possibility of frequent new product introductions. Accordingly, our future success depends upon our ability to enhance our current product candidates and to develop, introduce and sell the most accurate products at competitive prices. The development of new technologies and products involves time, substantial costs and risks. Our ability to successfully develop new technologies depends in large measure on our ability to maintain a technically skilled research and development staff and to adapt to technological changes and advances in the industry.

The success of new product introductions depends on a number of factors including the efficacy and safety as demonstrated in clinical trials, the ability to demonstrate the impact of real world evidence, timely and successful product development, the timing and market introduction of competitive products, market acceptance, the effective management of purchase commitments and inventory levels in line with anticipated product demand, the availability of pharmaceutical components in appropriate quantities and costs to meet anticipated demand, the risk that new products may have quality or other defects in the early stages of introduction and our ability to manage distribution and production issues related to new product introductions, the clinical indications for which the product is approved, acceptance by physicians, the medical community and patients of the product as a safe and effective treatment, the ability to distinguish safety and efficacy from existing, less expensive alternative therapies, the convenience of prescribing, administrating and initiating patients on the product, the potential and perceived advantages and/or value of the product over alternative treatments, the cost of treatment in relation to alternative treatments, including any similar generic treatments, the availability of coverage and adequate reimbursement by third-party payors and government authorities to support the product's pricing, the prevalence and severity of adverse side effects and the effectiveness of sales and marketing efforts.

If we are unable, for any reason, to enhance, develop, introduce and sell new products in a timely manner, or at all, in response to changing market conditions or customer requirements or otherwise, our business would be harmed.

Even if we successfully advance any other product candidates into clinical development, their success will be subject to all of the clinical, regulatory and commercial risks described elsewhere in this "*Risk Factors*" section. Accordingly, we cannot assure you that we will ever be able to discover, develop, obtain regulatory approval of, commercialize or generate significant revenue from our product candidates.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus on research programs, therapeutic platforms and product candidates that we identify for specific indications. As a result, we may forgo or delay pursuit of opportunities with other therapeutic platforms or product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success. We are currently evaluating funding alternatives for the continued development of EP-104IAR, including potential partnership opportunities. As a result, we intend to use capital resources previously identified for EP-104IAR development to continue development of EP-104GI. We cannot be certain that our decision to prioritize development of EP-104GI over EP-104IAR will be beneficial to our shareholders. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs, therapeutic platforms and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates progress through preclinical and clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives.

Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates, if approved, and generate revenue.

If we are unable to differentiate EP-104 from existing therapies, or if the FDA or other applicable regulatory authorities approve additional, and potentially less costly, therapies that compete with EP-104, our ability to successfully commercialize EP-104GI or EP-104IAR would be adversely affected.

Our commercial opportunities could be reduced or eliminated if existing or future therapies for EoE, OA or any other indication we may pursue are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than EP-104. The key competitive factors affecting the success of our product candidates, if approved, are likely to be their efficacy, safety and/or tolerability, convenience and ease of administration, price, the potential advantages of alternative products, the level of generic competition, and the availability of coverage and adequate reimbursement from government and other third-party payers.

There are two approved treatments for EoE in the United States: Dupixent (dupilumab), a monoclonal antibody (mAb) marketed by Sanofi and Regeneron, and Takeda's recently-approved Eohilia, a twice-daily oral suspension of budesonide approved for up to 12 weeks of use. In addition, Jorveza is an effervescent orodispersible budesonide tablet available in the European Union and Canada. If these or any future treatment for EoE better meet the competitive factors described above, we may be unsuccessful in commercializing EP-104GI and our business, financial results and prospects could be adversely affected.

The current intra-articular standard of care for OA pain, immediate-release triamcinolone acetonide ("**TCA**") and other injectable immediate-release steroids, are available in generic form and are therefore relatively inexpensive compared to the potential pricing for EP-104IAR. Although we believe our Phase 2 study provides preliminary evidence of extended pain relief, it is possible that we and any potential partner will receive data from additional clinical trials or in a post marketing setting from physician and patient experiences with the commercial product that does not continue to support such interpretations. It is also possible that the FDA, physicians and healthcare payors will not agree with our and any potential partner's interpretation of existing and

future clinical trial data. If we and any potential partner are unable to demonstrate the value of EP-104IAR based on clinical data, patient experience, as well as real world evidence, the opportunity for EP-104IAR to obtain premium pricing and be commercialized successfully would be adversely affected.

In addition to existing treatments, the FDA or other applicable regulatory authorities may approve other generic products that could compete with EP-104 if we cannot adequately protect it with our patent portfolio. For example, in the United States, once an NDA, including a Section 505(b)(2) application, is approved, the product covered thereby becomes a "listed drug" which can, in turn, be cited by potential competitors in support of approval of an abbreviated new drug application ("**ANDA**"). The Federal Food, Drug, and Cosmetic Act, FDA regulations and other applicable regulations and policies provide incentives to manufacturers to create modified, non-infringing versions of a drug to facilitate the approval of an ANDA or other application for generic substitutes. These manufacturers might only be required to conduct a relatively inexpensive study to show that their product has the same active ingredient(s), dosage form, strength, route of administration, conditions of use, or labeling as our product candidate and that the generic product is bioequivalent to ours, meaning it is absorbed in the body at the same rate and to the same extent as EP-104. These generic equivalents, which must meet the same quality standards as branded pharmaceuticals, would be significantly less costly than ours to bring to market and companies that produce generic equivalents are generally able to offer their products at lower prices. Thus, after the introduction of a generic competitor, a significant percentage of the sales of any branded product is typically lost to the generic product. Accordingly, competition from generic equivalents to our products would materially adversely impact our ability to successfully commercialize EP-104.

A variety of risks associated with potential international business relationships could materially adversely affect our business.

We intend to evaluate from time to time entering into agreements with third parties for the development and commercialization of EP-104IAR and may in the future seek to enter into similar agreements for other product candidates in international markets. If we do so, we would be subject to additional risks related to entering into international business relationships, including:

- differing regulatory requirements in other countries including, among others, marketing approval, pricing, reimbursement and sales and marketing practices;
- potentially reduced protection for intellectual property rights;
- potential for so-called parallel importing, which is when a local seller, faced with higher local prices, opts to import goods from a foreign market with lower prices, rather than buying them locally;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees traveling and working abroad;
- foreign taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other risks incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in Canada or the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad or supply chain disruptions; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, tsunamis, hurricanes and fires.

These and other risks may materially adversely affect our ability to develop and commercialize products in international markets and may harm our business.

In particular, there is currently significant uncertainty about the future relationship between the United States and various other countries, most significantly China, with respect to trade policies, treaties, tariffs, taxes, and other limitations on cross-border operations. The U.S. government has made and continues to make significant additional changes in U.S. trade policy and may continue to take future actions that could negatively impact U.S. trade. For example, legislation has been introduced in Congress to limit certain U.S. biotechnology companies from using equipment or services produced or provided by select Chinese biotechnology companies, and others in Congress have advocated for the use of existing executive branch authorities to limit those Chinese service providers' ability to engage in business in the U.S. We cannot predict what actions may ultimately be taken with respect to trade relations between the United States and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation. If we are unable to obtain or use services from existing service providers or become unable to export or sell our products to any of our customers or service providers, our business, liquidity, financial condition, and/or results of operations would be materially and adversely affected.

Collaboration arrangements we may enter into in the future may not be successful.

In the ordinary course, we evaluate various partnerships, collaborations and other strategic transaction and may seek to enter into such transactions to help maximize the commercial potential of EP-104 and our other product candidates. In particular, we are evaluating funding alternatives for the continued development of EP-104IAR, including potential partnerships. We may enter into such arrangements on a selective basis depending on the merits of retaining commercialization rights as compared to entering into selective collaboration arrangements with leading pharmaceutical or biotechnology companies for EP-104 for any intended application and other product candidates, both in the United States and internationally. We face competition in seeking appropriate collaborators. Moreover, collaboration arrangements are complex and time consuming to negotiate, document and implement. We may not be successful in our efforts to establish and implement collaborations or other alternative arrangements should we choose to enter into such arrangements. The terms of any collaborations or other arrangements that we may establish may not be favorable to the us.

Even if we enter into partnerships, collaborations or other strategic transactions, such transactions that we enter into may not be successful. The success of any such arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations.

Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters could lead to delays in the development process or commercialization of our product candidates and in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority.

Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. If we do enter into partnerships, collaborations or other strategic transactions, any such termination or expiration could adversely affect us financially and could harm our business reputation.

Provisions of our existing and any future debt instruments may restrict our ability to pursue our business strategies.

From time to time, we have used debt financing to provide capital for our business. The Debt Agreement does, and debt instruments we may enter into in the future may, require us to comply with various covenants that limit our and our subsidiaries' ability to, among other things:

- dispose of assets;
- complete mergers or acquisitions;
- incur indebtedness;
- encumber assets;
- pay dividends or make other distributions to holders of our capital stock;
- make investments;
- change our organizational structure or jurisdiction of organization;
- engage in any new line of business; and
- engage in certain transactions with our affiliates.

Any future debt instruments could further inhibit our ability to pursue our business strategies and may also impose certain financial covenants that require us to achieve certain revenue targets and/or maintain certain minimum cash balances. If we default under any such debt instruments, the lenders could terminate commitments to lend and cause all amounts outstanding with respect to such debt to be due and payable immediately, which in turn could result in cross defaults under other debt instruments. Our assets and cash flow may not be sufficient to fully repay borrowings under all of our then outstanding debt instruments if some or all of these instruments are accelerated upon a default. If we are unable to repay, refinance or restructure indebtedness when payment is due, the lenders could also proceed against any collateral granted to them to secure such indebtedness or force us into bankruptcy or liquidation.

We may acquire businesses or products, or form strategic alliances in the future, and we may not realize the benefits of such acquisitions or alliances.

We may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction. In addition, we may require significant additional funds to either acquire such businesses or products or to commercialize them, which may result in significant dilution to shareholders or the incurrence of significant indebtedness by us.

We have traditionally relied on key collaborations and grants.

Our development programs may require substantial additional cash. Traditionally, we have received funds under grant reward programs to fund portions of such development. The grants we have received may become subject to repayment in full, under certain conditions. We cannot provide assurance that grants we have received will not become subject to repayment, that we will continue to receive all or any of the grant funding that we apply for, that such grants if received will provide sufficient funding or that we will be able to establish future collaborations on commercially reasonable terms or at all. Inability to obtain grant funding and establish collaboration agreements may result in product development delays or cancellation, particularly in regard to pipeline programs. In addition, the success of collaboration agreements will depend heavily on the efforts and activities of the third-party collaborators, which are outside our control.

We are subject to evolving global laws and regulations relating to privacy, data protection and information security, which may require us to incur substantial compliance costs, and any failure or perceived failure by us to comply with such laws and regulations may harm our business and operations.

In the ordinary course of business, we process personal data and other sensitive information, including our proprietary and confidential business data, trade secrets, intellectual property, data about trial participants collected in connection with clinical trials, and other sensitive data. Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contracts, and other obligations that govern the processing of personal data by us and on our behalf.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, and consumer protection laws. For example, the U.S. federal Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**"), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("**HITECH**"), imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. At the state level, the California Consumer Privacy Act of 2018 ("**CCPA**"), as amended and supplemented by the California Privacy Rights Act, imposes obligations on businesses to which it applies. The CCPA allows for statutory fines for noncompliance. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA, to the extent applicable to our business and operations, may increase compliance costs and potential liability with respect to other personal information we may maintain about California residents. Other states have also enacted data privacy laws, including sector-specific laws such as Washington's My Health, My Data Act, and numerous general privacy laws that share similarities with the CCPA. Additional data privacy and security laws have been proposed at the federal, state, and local levels in recent years, which could further complicate compliance efforts.

Outside the U.S., the European Union's general data protection regulation ("**EU GDPR**") and the United Kingdom's general data protection regulation impose strict requirements for processing the personal data of individuals. For example, under the EU GDPR, government regulators may impose temporary or definitive bans on data processing, as well as fines of up to 20 million euros or 4% of annual global revenue, whichever is greater. Further, individuals may initiate litigation related to our processing of their personal data. Certain other foreign jurisdictions have enacted laws and regulations relating to privacy, data protection, and information security, as well as certain data localization laws and cross-border personal data transfer laws, that could make it more difficult to transfer information across jurisdictions, such as transferring or receiving personal data that originates in the EU. For example, in Canada, where we are headquartered, federal and provincial legislation impose strict requirements for the processing of personal data of individuals, with substantial penalties for noncompliance.

Although we endeavor to comply with all applicable data privacy and security obligations, these obligations are quickly changing in an increasingly stringent fashion, creating some uncertainty as to how to comply, and potentially requiring us to modify our policies and practices, which may be costly and may divert the attention of management and technical personnel. Further, we may at times fail, or be perceived to have failed, to have complied with laws, regulations or other actual or asserted obligations relating to privacy, data protection or information security, and could face significant consequences. These consequences may include, but are not limited to, government enforcement actions, investigations and other proceedings; private claims, demands, and litigation; additional reporting requirements and/or oversight; bans on processing personal data; orders to destroy or not use personal data; imprisonment of company officials and fines, penalties, and other liabilities. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: interruptions or stoppages in our business operations, including our clinical trials; inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or revision or restructuring of our operations.

Our business and operations could suffer in the event of an actual or perceived information security incident such as a cybersecurity breach, system failure, or other compromise of our systems or those of a third-party or other contractor or vendor.

We rely on both internal information technology systems and networks, and those of third parties and their vendors and contractors, to transmit, store and otherwise process information in connection with our business activities. We are increasingly dependent upon our technology systems to operate our business and our ability to effectively manage our business depends on the security, reliability and adequacy of our and our third-party or other contractors' or vendors' technology systems and data. Any cyberattack, including phishing or other forms of social engineering, business email compromise, ransomware or other malware, or any security breach, security incident, or other destruction, loss, or unauthorized use, modification, or other processing of data maintained or otherwise processed by us or on our behalf could result in a loss of intellectual property or misappropriation of trade secrets, disruptions to our business and operations, subject us to increased costs and require us to expend time and resources to address the matter, may subject us to claims, demands, and proceedings by private parties, regulatory investigations and other proceedings, and fines, penalties, and other liability and have a material adverse effect on our business. In addition, the loss, alteration or other damage to or other unavailability of pre-clinical data or clinical trial data from completed or ongoing clinical trials for our product candidates could result in delays in our development and regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Any cyber-attack, security breach or incident, or other destruction, loss or unauthorized processing of data maintained or otherwise processed by us or on our behalf, or the perception any such matter has occurred, could result in actual or alleged violations of applicable U.S. and international privacy, data protection, information security and other laws and regulations, harm to our reputation, and subject us to claims, demands and litigation by private parties and governmental investigations and other proceedings by federal, state and local regulatory entities in the U.S. and by international regulatory entities, resulting in exposure to material civil and/or criminal proceedings and liability. In addition, we may incur significant additional expense to implement further measures and policies relating to privacy, data protection and information security, whether in response to an actual or perceived security breach or incident or otherwise.

To date, although we have faced cyberattacks and suffered information security incidents, we have not experienced any material impact to our business, financial position or operations resulting from cyberattacks or other information security incidents of which we are aware; however, because of frequently changing attack techniques, along with the increased volume and sophistication of such attacks, our business, financial position or operations could be adversely impacted in the future. Moreover, the prevalent use of mobile devices that access confidential information, widespread use of cloud-based applications with remote data centers, and ability to work remotely all increase the risk of security breaches and incidents. These risks may be heightened due to the increasing number of our and our vendors' and contractors' personnel working remotely. Further geopolitical events such as wars and conflicts may increase the cybersecurity threats we and the third parties we work with face. As cyber threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate information security

vulnerabilities. While we have implemented security measures, our computer systems and the external systems and services used by our third-party contract manufacturers and CROs and their vendors and contractors remain potentially vulnerable to these events and there can be no assurance that we will be successful in preventing cyber-attacks or successfully mitigating their effects. Our liability insurance may not be sufficient in type or amount to cover us against claims related to security breaches, cyberattacks and other related incidents, and we cannot be sure that such coverage will continue to be available on acceptable terms or at all. In addition, regulators are considering new cybersecurity laws and regulations. These proposed laws and regulations may impact the manner in which we operate and require us to incur increasing costs.

Any of the foregoing security risks could have a material adverse effect on our business, results of operations, or financial condition.

We may fail to manage our growth successfully which may adversely impact our operating results.

Our failure to manage our growth successfully may adversely impact our operating results. Managing our growth will require us to continue to build our operational, financial and management controls, contracting relationships, marketing and business development plans and controls and reporting systems and procedures. Our ability to manage our growth will also depend in large part upon a number of factors, including the ability for us to rapidly:

- expand our internal and operational and financial controls significantly so that we can maintain control over operations;
- attract and retain qualified technical personnel in order to continue to develop our product candidates; and
- build commercial infrastructure following any approval of product candidates.

An inability to achieve any of these objectives could harm our business, financial condition and results of operations.

Guidelines and recommendations published by various organizations can reduce the use of products that we may commercialize.

Government agencies promulgate regulations and guidelines directly applicable to us and to our product candidates and any future products. In addition, professional societies, such as the American Gastroenterological Association, the Joint Task Force for Allergy-Immunology Practice Parameters, the American College of Rheumatology, practice management groups, private health and science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to the healthcare and patient communities with respect to specific products. Recommendations of government agencies or these other groups or organizations may relate to such matters as usage, dosage, route of administration and use of concomitant therapies. Recommendations or guidelines that do not recognize our future products, suggest limitations or inadequacies of our future products, or suggest the use of competitive or alternative products as the standard of care to be followed by patients and healthcare providers, could result in decreased use or adoption of our future products.

We use hazardous chemicals and biological materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly.

Our product manufacturing, research and development, and testing activities involve the controlled use of hazardous materials, including chemicals and biological materials. We cannot eliminate the risks of accidental contamination or the accidental discharge of these materials, or any resulting injury from such an event. We may be subjected to litigation for any injury that results from our use or the use by third parties of these materials, and our liability may exceed our insurance coverage and our total assets. Our use, manufacture, storage, handling and disposal of these hazardous materials and specified waste products, as well as the discharge of pollutants into the environment and human health and safety matters, are governed by federal, state, provincial and local legislation. We are also subject to various laws and regulations relating to safe working conditions, laboratory and manufacturing practices. Our operations may require that environmental permits and approvals be issued by applicable government agencies, which can be costly and time-consuming to attain. These regulations and legislation can change, or new ones come into place, due to future legislative or administrative actions. These events could cause us to incur additional expense or restrict our operations. Compliance with environmental laws and regulations, current or future, may be expensive and prohibitive for our research, development,

or production efforts. Failure to comply could incur substantial costs and liabilities, including civil or criminal fines and penalties, clean-up costs or capital expenditures to achieve and maintain compliance.

If product liability lawsuits are brought against us, then we may incur substantial liabilities and may be required to limit commercialization of EP-104, if approved for any indication, and any other future products.

We face a potential risk of product liability as a result of distribution of our product candidates for testing and commercialization of EP-104 for any indication and other pipeline products, if approved. For example, we may face claims if use of EP-104 allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in product quality, a failure to warn of dangers inherent in the product candidate or product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of the product subject to such claims. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for any current and future approved product candidates;
- injury to our reputation;
- costs to defend any related litigation;
- diversion of management's time and our resources;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- inability to commercialize EP-104 for any indication and other products, if approved;
- decline in our stock price; and
- exposure to adverse publicity.

Although we currently have product liability insurance in place, we do not know whether the limits of the insurance will be sufficient to satisfy any claims should they arise. We may not have sufficient resources to pay for any liabilities resulting from a claim excluded from or beyond the limits of, our insurance coverage. If we cannot successfully defend ourselves against a product liability claim, we may incur substantial liabilities.

Our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading, which could significantly harm our business.

We are exposed to the risk that employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in fraudulent or other illegal activity, fraud or other misconduct. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violates: (i) the law and regulations of the FDA and non-US regulators, including those laws that require the reporting of true, complete and accurate information to the FDA and non-US regulators, (ii) healthcare fraud and abuse laws and regulations in the United States and elsewhere, and (iii) laws that require the true, complete and accurate reporting of financial information or data. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct in violation of these laws may also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by our executives, employees, consultants and other third parties, and any precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending itself or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in national healthcare programs, contractual damages, reputational

harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate the business and our results of operations.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of the Common Shares may be volatile, and in the past companies that have experienced volatility in the market price of their shares have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Litigation of this type could result in substantial costs and diversion of management's attention and resources, which could adversely impact our business. Any adverse determination in litigation could also subject us to significant liabilities.

Our directors and executive officers may be affiliated with other biotech companies and may have conflicts of interest.

Certain of our directors and executive officers may, from time to time, be employed by or affiliated with organizations which have entered into agreements or will enter into agreements with us. As disputes may arise between these organizations and us, or certain of these organizations may undertake or have undertaken research with our competitors, there exists the possibility for such persons to be in a position of conflict. We cannot assure you that any decision or recommendation made by these persons involving us will be made in accordance with his or her duties and obligations to deal fairly and in good faith with us and such other organizations.

Our business may be affected by macroeconomic conditions.

Various macroeconomic factors could adversely affect our business and our results of operations and financial condition, including changes in inflation, interest rates and foreign currency exchange rates, and overall economic conditions and uncertainties, including those resulting from political instability and the current and future conditions in the global financial markets. For instance, if inflation or other factors were to significantly increase our business costs, it may not be feasible to pass through price increases to patients. Interest rates, the liquidity of the credit markets and the volatility of the capital markets could also affect the value of our investments and our ability to liquidate our investments in order to fund our operations, if necessary.

Interest rates and the ability to access credit markets could also adversely affect the ability of payors and distributors to purchase, pay for and effectively distribute our products if and when approved. Similarly, these macroeconomic factors could affect the ability of our current or potential future contract manufacturers, sole-source or single-source suppliers, or licensees to remain in business or otherwise manufacture or supply our product candidates. Failure by any of them to remain in business could affect our ability to manufacture product candidates.

Our business may be affected by global geopolitical risks.

In addition to the risks specific to the countries in which we operate, global events such as war and occupation, terrorism and related geopolitical risks may lead to increased market volatility and may have adverse short-term and long-term effects on world economies and markets generally. For example, in late February 2022, Russian military forces launched significant military action against Ukraine, and conflict and disruption in the region is ongoing. This conflict has the potential to affect our clinical trial operations in Poland, Czech Republic and Denmark. The impact to Ukraine, as well as actions taken by other countries, including new and stricter sanctions by Canada, the United Kingdom, the European Union, the United States and other countries and organizations against officials, individuals, regions, and industries in Russia, Ukraine and Belarus, and each country's potential response to such sanctions, tensions, and military actions could have an adverse effect on our operations. These countries may impose further sanctions or other restrictive actions against governmental or other individuals or organizations in Russia or elsewhere. The effects of disruptive events could affect the global economy and financial and commodities markets in ways that cannot necessarily be foreseen at the present time. These events could also exacerbate other pre-existing political, social and economic risks, including those described elsewhere in this AIF.

We may be responsible for corruption and anti-bribery law violations.

Our business activities are subject to the to the United States *Foreign Corrupt Practices Act* (the "**FCPA**") and other anti-bribery and anti-corruption laws of the United States and other countries in which we operate, as well as U.S. and certain foreign export controls and trade sanctions which generally prohibit companies and company employees from engaging in bribery or other prohibited payments to foreign officials for the purpose of obtaining or retaining business. Our employees or other agents may, without our knowledge and despite our efforts, engage in prohibited conduct under our policies and procedures and the FCPA or other anti-bribery laws for which we may be held responsible. If our employees or other agents are found to have engaged in such practices, we could suffer severe penalties and other consequences that may have a material adverse effect on our business, financial condition and results of operations.

We are subject to foreign exchange risks.

As we grow and do business in foreign markets, including the United States and Europe, it is quite possible that transactions will take place in foreign currencies. At this point we do not participate in hedging activities. Although we cannot predict the effect of possible foreign exchange losses in the future, if such losses occurred, they could have a material adverse effect on our business, results of operation, and financial condition. In addition, fluctuations in exchange rates could affect the pricing of our products and negatively influence customer demand.

We are subject to taxation risks and changing rules by different tax authorities.

Tax examinations are often complex as tax authorities may disagree with the treatment of items reported by us, the result of which could have a material adverse effect on our financial condition and results of operations.

We are subject to a number of risks and hazards and may not be sufficiently insured for all of them.

Our business is subject to a number of general risks and hazards, including general liability. Such occurrences could result in damage to property, inventory or facilities, personal injury or death to end-customers or operators, damage to our properties or the properties of others, monetary losses and possible legal

liability. Although we maintain insurance to protect against certain risks in such amounts as we consider to be reasonable, our insurance may not cover all the potential risks associated with our operations. We may also be unable to maintain insurance to cover these risks at economically feasible premiums. Insurance coverage may not continue to be available or may not be adequate to cover any resulting liability. We might also become subject to liability which may not be insured against or which we may elect not to insure against because of premium costs or other reasons. Losses from these events may cause us to incur significant costs that could have a material adverse effect upon our financial performance and results of operations.

We will devote significant resources to regulatory compliance as a public entity.

As a public company, we incur significant legal, accounting and other expenses. Legal, accounting and other expenses associated with public company reporting requirements have increased significantly in recent years. We anticipate that costs may continue to increase with corporate governance related requirements, including, without limitation, requirements under National Instrument 52-109 - *Certification of Disclosure in Issuers' Annual and Interim Filings*, National Instrument 52-110 - *Audit Committees* and National Instrument 58-101 - *Disclosure of Corporate Governance Practices*.

Our management and other personnel will devote a substantial amount of time to regulatory compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance.

Our testing, or any subsequent testing by our independent auditor, has in the past and may in the future reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses. We will incur substantial accounting expense and expend significant management efforts to comply with internal control over financial reporting requirements. We currently do not have an internal audit group, and we anticipate hiring additional accounting and financial staff with appropriate public company experience and technical accounting knowledge. Moreover, if we are not able to comply with these requirements in a timely manner or if we or our independent auditor identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of the Common Shares could decline, and we could be subject to sanctions or investigations by applicable securities regulatory authorities, which would require additional financial and management resources.

Changes in accounting standards from IFRS to U.S. GAAP can be difficult to predict and could adversely impact how we record and report our financial condition and results of operations.

We have historically reported our financial condition and results of operation under IFRS. Beginning with our financial statements as of and for the years ended December 31, 2023, and 2022, we intend to begin reporting our financial condition and results of operations under United States generally accepted accounting principles ("**U.S. GAAP**"), which is periodically revised by the Financial Accounting Standards Board ("**FASB**"). Accordingly, from time to time we will be required to adopt new or revised accounting standards or interpretations issued by the FASB. The estimated impact of accounting pronouncements that have been issued but not yet implemented will be disclosed in our reports filed with the United States Securities and Exchange Commission (the "**SEC**") and SEDAR+.

Our consolidated financial statements have been prepared in accordance with IFRS as issued by the International Accounting Standards Board. There are, and may continue to be, certain significant differences between IFRS and U.S. GAAP, including but not limited to potentially significant differences related to the accounting and disclosure requirements relating to insurance contracts, investments, other nonfinancial assets and taxation. As a result, our financial information and reported earnings for historical or future periods could be significantly different if they are prepared in accordance with U.S. GAAP, and you may not be able to meaningfully compare our historical financial statements under IFRS with those that we prepare under U.S. GAAP in the future. The transition from IFRS to U.S. GAAP may also increase our company's legal, audit, accounting and financial compliance costs, make some activities more difficult, time consuming or costly and may also place undue strain on our company's personnel, systems and resources.

In the past, we have had to restate our previously issued consolidated financial statements and as part of that process identified a material weakness in our disclosure controls and procedures and internal control over financial reporting as of December 31, 2022. If we are unable to develop and maintain effective disclosure controls and procedures and internal control over financial reporting, we may not be able to accurately report our financial results in a timely manner, which may adversely affect investor confidence in us and may adversely affect our business, financial condition and results of operations.

Under the supervision and with the participation of management, including our chief executive officer and chief financial officer, and in conjunction with the reaudit of our consolidated financial statements by our new auditor, KPMG LLP, we determined that there were a number of areas where our historical consolidated financial statements for the periods ending September 30, 2022, December 31, 2022 and December 31, 2021 required adjustment largely related to the accounting treatment of select financial instruments (notably convertible debt instruments and warrant valuations) and their classification as liabilities versus shareholders equity. We expect that similar adjustments to our historical consolidated financial statements will need to be made for the periods ending March 31, 2023 and June 30, 2023 and potentially other periods in connection with the upcoming reviews of the periods ending March 31, 2024 and June 30, 2024. As a result of these restatements, our management re-evaluated the effectiveness of our disclosure controls and procedures and internal control over financial reporting as of December 31, 2022. Management concluded that our disclosure controls and procedures were not effective as of December 31, 2022, and that our internal control over financial reporting was not effective as of December 31, 2022, due to a material weakness.

A material weakness is a deficiency, or a combination of deficiencies, in disclosure controls and procedures and internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. Effective disclosure controls and procedures and internal control over financial reporting is necessary for us to provide reliable financial reporting and prevent fraud. Specifically, there was insufficient review of the classification of liabilities and equity under IAS 32 and the valuation of instruments in accordance with IFRS 13. We are working to remediate the material weakness, but we cannot be certain that we will be able to do so in a timely or efficient manner. Even if we are able to successfully remediate the material weakness, we may identify additional material weaknesses in the future.

As a reporting issuer in the United States, we are required to comply with the requirements of the Exchange Act, Sarbanes-Oxley Act of 2002 (the "**Sarbanes-Oxley Act**") and, if we are listed on Nasdaq, the listing standards of Nasdaq, including, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are continuing to develop and refine our disclosure controls and other procedures that are designed to ensure that information required to be disclosed by us in the reports that we will file with the SEC is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our management, including our principal executive and financial officers.

We are also continuing to improve our internal control over financial reporting. Pursuant to the SEC rules that implement Section 404 of the Sarbanes-Oxley Act, beginning with our second annual report on Form 40-F after we become subject to the reporting requirements of the Exchange Act, we will be required to make a formal assessment of the effectiveness of our internal control over financial reporting. To achieve compliance with this requirement within the prescribed time period, we will be engaging in a process to document and evaluate our internal control over financial reporting under such rules, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of our internal control over financial reporting, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed time period or at all, that our internal control over financial reporting is effective as required by Section 404 of the Sarbanes-Oxley Act. Moreover, our testing, or the subsequent testing by our independent registered public accounting firm, has in the past and may in the future reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses.

Any failure to implement and maintain effective disclosure controls and procedures and internal control over financial reporting, including the identification of one or more material weaknesses, could adversely impact our ability to report our financial condition and results of operations on a timely and accurate basis and could cause investors to lose confidence in the accuracy and completeness of our financial statements and reports, which would likely adversely affect the market price of our Common Shares. In addition, we could be subject to sanctions or investigations by Nasdaq, if our shares are approved for listing on such exchange, the SEC and other regulatory authorities. We also face potential for litigation or other disputes which may include, among others, claims invoking the securities laws, contractual claims or other claims arising from the restatement and the material weakness in our disclosure controls and procedures and internal control over financial reporting and the preparation of our financial statements. As of the date of this AIF, we have no knowledge of any such litigation or dispute. However, we can provide no assurance that such litigation or dispute will not arise in the future. Any such litigation or dispute, whether successful or not, could adversely affect our business, financial condition and results of operations.

Risks Relating to Our Intellectual Property

Our success depends on our ability to protect our intellectual property and our proprietary technologies.

Our commercial success depends in part on our ability to obtain and maintain patent and other intellectual property protection for our product candidates, proprietary technologies, and their uses as well as our ability to operate without infringing upon the proprietary rights of others.

We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates, proprietary technologies, and their uses that are important to our business. We also seek to protect our proprietary position by acquiring or in-licensing relevant issued patents or pending applications from third parties.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications or the patent applications of our future licensors will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties.

Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our and our future licensors' proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. These uncertainties and/or limitations in our ability to properly protect the intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operations.

We cannot be certain that the claims in our U.S. pending patent applications, corresponding international patent applications and patent applications in certain foreign territories, or those of our future licensors, will be considered patentable by the United States Patent and Trademark Office (the "**USPTO**"), courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our future issued patents will not be found invalid or unenforceable if challenged.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom may have substantially greater resources than we do and many of whom may have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell our potential product candidates;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

The patent prosecution process is also expensive and time-consuming, and we and any future licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. It is also possible that we or any future licensors will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications and those of our future licensors may not result in patents being issued which protect our product candidates or which effectively prevent others from commercializing competitive product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own or in-license in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we own or in-license may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether our product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents or the patents of our future licensors by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents or the patents of our current or future licensors may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, re-examination, post-grant review ("**PGR**") and inter partes review ("**IPR**"), or other similar proceedings challenging our owned or licensed patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, our patents or the patents of our current or future licensors may become subject to post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our patents and patent applications and those of our current or future licensors. Such challenges may result in loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technologies or product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or

strength of protection provided by our patents and patent applications or the patents and patent applications of our current or future licensors is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to develop products that are similar to our product candidates but that are not covered by the claims of the patents that we own or license;
- we or future licensors or collaborators might not have been the first to make the inventions covered by the issued patents or patent application that we own or license;
- we or our current or future licensors or collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that the pending patent applications we own or license will not lead to issued patents;
- issued patents that we own or license may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, it could significantly harm our business, results of operations and prospects.

Our patent rights may prove to be an inadequate barrier to competition.

The lifespan of any one patent is limited, and each of these patents will ultimately expire and we cannot be sure that pending applications will be granted, or that we will discover new inventions which we can successfully patent. Moreover, any of our granted patents may be held invalid by a court of competent jurisdiction, and any of these patents may also be construed narrowly by a court of competent jurisdiction in such a way that it is held to not directly cover our product candidates. Furthermore, even if our patents are held to be valid and broadly interpreted, third parties may find legitimate ways to compete with our product candidates by inventing around our patent. Finally, the process of obtaining new patents is lengthy and expensive, as is the process for enforcing patent rights against an alleged infringer. Any such litigation could take years, cost large sums of money, and pose a significant distraction to management. Indeed, certain jurisdictions outside of the U.S. and European Union, where we hope to commercialize our product candidates have a history of inconsistent, relatively lax or ineffective enforcement of patent rights. In such jurisdictions, even a valid patent may have limited value. Our failure to effectively enforce our patents would have a harmful impact on our ability to commercialize our product candidates in these jurisdictions.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.

Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidates and products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, oppositions, re-examinations, IPR proceedings and PGR proceedings before the USPTO and/or corresponding foreign patent offices. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third-party patents or patent applications with claims to materials, compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published, we may be unaware of third-party patents that may be infringed by commercialization of any of our product candidates, and we cannot be certain that we were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently-pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases, and the difficulty in assessing the meaning of patent claims. There is also no assurance that there is not prior art of which we are aware, but which we do not believe is relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our products that may be approved in the future, or impair our competitive position. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Any claims of patent infringement asserted by third parties would be time consuming and could:

- result in costly litigation that may cause negative publicity;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing any of our product candidates until the asserted patent expires or is held finally invalid or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- subject us to significant liability to third parties; or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in our competitors gaining access to the same technology.

Although no third party has asserted a claim of patent infringement against us as of the date of this AIF, others may hold proprietary rights that could prevent our product candidates from being marketed. It is possible that a third party may assert a claim of patent infringement directed at any of our product candidates. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to our product candidates, treatment indications, or processes could subject us to significant liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or market our product candidates. We could be forced, including by court order, to cease commercializing the infringing technology or product. A finding of infringement could prevent us from commercializing our planned products or force us to cease some of our business operations, which could materially harm our business. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or our future strategic partners were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign our product candidates, treatment indications, or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing our product candidates, which could harm our business, financial condition and operating results. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they may have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

Because our development programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that are commercially reasonable or would allow us to make an appropriate return on our investment, or at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology in order to establish or maintain our competitive position in the market. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may be involved in lawsuits to protect or enforce our patents or our future licensors' patents, which could be expensive, time consuming, and unsuccessful. Further, our issued patents or our current or future licensors' patents could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

Competitors may infringe our intellectual property rights. To prevent infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we own or in-license is not valid, is unenforceable and/or is not infringed. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of our product candidates, the defendant could counterclaim that our patent or the patent of our future licensors is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of sufficient written description, non-enablement, or obviousness-type double patenting. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution.

Our patent rights may be subject to priority, validity, inventorship, ownership and enforceability disputes. Third parties may also raise similar invalidity claims before the USPTO or patent offices abroad, even outside the context of litigation. Such mechanisms include re-examination, PGR, IPR, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). The outcome following legal assertions of invalidity and/or unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our future licensors, and the patent examiners are unaware during prosecution. There is also no assurance that there is not prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications or the patents and patent applications of our future licensors, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our technology or platform, or any product candidates that we may develop. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

In addition, if the breadth or strength of protection provided by our patents and patent applications or the patents and patent applications of our current or future licensors is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented product and practicing our own patented technology.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our Common Shares to decline.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings or developments in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing product candidates, approved products, programs or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

Derivation proceedings may be necessary to determine priority of inventions, and an unfavorable outcome may require us to cease using the related technology or to attempt to license rights from the prevailing party.

Derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our future licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with such proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our development programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our product candidates to market.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products and product candidates.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are or will be complete or thorough, nor can we be certain that we have identified or will identify each and every third-party patent and pending patent application in the United States and abroad that is relevant to or necessary for the commercialization of our current and future products and product candidates in any jurisdiction. Patent applications in the United States and elsewhere are not published until approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidates could have been filed by others without our knowledge. The scope of a patent claim is determined by the interpretation of the law, the words of a patent claim, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending patent application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products or product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and we may incorrectly conclude that a third-party patent is invalid and unenforceable or not infringed. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products and product candidates. If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. As the number of competitors in the market grows and the number of patents issued in this area increases, the possibility of patent infringement claims escalates. Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," have purchased patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or "invitations to license," or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates or services so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Changes in U.S. patent law, or laws in other countries, or their interpretation could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing pharmaceutical patents is costly, time consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us.

Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act (the "**America Invents Act**") enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application would be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This requires us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors are the first to either (i) file any patent application related to our product candidates and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our patents or patent applications.

The America Invents Act also included several significant changes that affect the way patent applications are prosecuted and also affect patent litigation. These include allowing third party protests and submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our owned and in-licensed patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

The U.S. law relating the patentability of certain inventions in the life sciences is uncertain and rapidly changing, which may adversely impact our existing patents or our ability to obtain patents in the future. The U.S. Supreme Court and federal courts have ruled on several patent cases in recent years that impact the scope of patentability of certain inventions or discoveries related to the life, including both narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. The trend of these decisions along with resulting changes in patentability requirements being implemented by the USPTO could make it increasingly difficult for us to obtain and maintain patents on our products, and could jeopardize or otherwise reduce patent term, reduce the scope of, or invalidate or render unenforceable our patent rights. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained.

Depending on future actions and/or decisions by the U.S. Congress, the U.S. federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patent and the patents we might obtain or license in the future.

Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. As an example, beginning June 1, 2023, European patent applications and patents may be subjected to the jurisdiction of the Unified Patent Court (the "**UPC**"). Also, European patent applications will have the option, upon grant of a patent, of becoming a Unitary Patent, which will be subject to the jurisdiction of the UPC. The UPC and Unitary Patent are significant changes in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation in the UPC.

In 2012, the European Union Patent Package (the "**EU Patent Package**") regulations were passed with the goal of providing a single pan-European Unitary Patent and a new European UPC for litigation involving European patents. The EU Patent Package was implemented on June 1, 2023. As a result, all European patents, including those issued prior to ratification of the EU Patent Package, now by default automatically fall under the jurisdiction of the UPC. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries. Our European patent applications, if issued, could be challenged in the UPC. During the first seven years of the UPC's existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We may decide to opt out our future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents, and allow for the possibility of a competitor to obtain pan-European injunction. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates due to increased competition and, resultantly, on our business, financial condition, prospects and results of operations.

We may be subject to claims challenging the inventorship or ownership of our patents, the patents we license, and other intellectual property.

We may also be subject to claims that former employees or other third parties have an ownership interest in our patents, the patents we license or other intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and distraction to management and other employees.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. If we do not have sufficient patent life to protect our products, our business, financial condition, results of operations, and prospects will be adversely affected.

We may not be able to protect or enforce our intellectual property rights throughout the world.

Although we have pending patent applications and patents in the United States, Canada and other countries, filing, prosecuting and defending patents and trademarks on all of our planned products in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents, the patents of our future licensors, or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our patents or our future licensors' patents or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents or the patents of our future licensors at risk of being invalidated or interpreted narrowly and our patent applications or the patent applications of our future licensors at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. In addition, geo-political actions in the United States and in foreign countries (such as the Russia and Ukraine conflict) could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any future licensors and the maintenance, enforcement or defense of our issued patents which could impair our competitive intellectual property position.

Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary submission, fee payment and other requirements imposed by regulations and governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or applications and those of our future licensors. We have systems in place to remind us to pay these fees, and we rely on our outside patent annuity service to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

We intend to use registered or unregistered trademarks or trade names to brand and market ourselves and our products. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected, harming our business and competitive position.

In addition, we rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in the market.

Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions assignment agreements with employees, consultants and advisors, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced, and our competitive position would be harmed. If we are unable to prevent disclosure of the intellectual property related to our technologies to third parties, we may not be able to establish or maintain a competitive advantage in our market, which would harm our ability to protect our rights and have a material adverse effect on our business. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

We may be subject to claims that we or our employees, independent contractors, or consultants have wrongfully used or disclosed alleged confidential information or trade secrets.

We have entered into and may enter in the future into non-disclosure and confidentiality agreements to protect the proprietary positions of third parties, such as outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors, potential partners, and other third parties. We may become subject to litigation where a third party asserts that we or our employees inadvertently or otherwise breached the agreements and used or disclosed trade secrets or other information proprietary to the third parties. Defense of such matters, regardless of their merit, could involve substantial litigation expense and be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions. Moreover, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology. Failure to defend against any such claim could subject us to significant liability for monetary damages or prevent or delay our developmental and commercialization efforts, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Parties making claims against us may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they may have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, operating results, financial condition and prospects.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees, independent contractors, or consultants have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industry, we employ individuals and engage the service of consultants, who were previously employed at, may have previously provided, or may be currently providing consulting services to, other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Many of our employees were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these individuals, including members of our senior management, executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. Although we use reasonable efforts to ensure that our employees, independent contractors, and consultants do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these individuals inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any such former employers, clients, or third parties. These and other claims that we have misappropriated the confidential information or trade secrets of third parties can have a similar negative impact on our business to the infringement claims discussed above.

Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We may be subject to claims that former employees, consultants, collaborators or other third parties have an interest in our patent rights, trade secrets, or other intellectual property as an inventor, co-inventor or owner of trade secrets. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing our product candidates and other proprietary technologies we may develop. Litigation may be necessary to defend against these and other claims challenging inventorship or our patent rights, trade secrets or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable personnel or intellectual property rights, such as exclusive ownership of, or the right to use intellectual property that is important to our product candidates and other proprietary technologies we may develop. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Our rights to develop and commercialize our technology and product candidates may be subject, in part, to the terms and conditions of any future licenses granted to us by others.

We may enter into license agreements in the future with others to advance our existing or future research or allow commercialization of our existing or future product candidates. These licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future.

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technology that we license from third parties. In such an event, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our future licensors fail to prosecute, maintain, enforce, and defend such patents or patent applications, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our future product candidates that are subject of such licensed rights could be adversely affected.

Our future licensors may rely on third-party consultants or collaborators or on funds from third parties such that our future licensors are not the sole and exclusive owners of the patents we in-license. If other third parties have ownership rights to our future in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

It is possible that we may be unable to obtain licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current technology, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our future licensors, we could lose license rights that are important to our business.

Disputes may arise between us and our future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our future licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we license in the future prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

In spite of our best efforts, our future licensors might conclude that we materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

The patent protection and patent prosecution for some of our product candidates may be dependent on third parties.

While we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our product candidates, there may be times when the filing and prosecution activities for patents and patent applications relating to our product candidates are controlled by our future licensors or collaboration partners. If any of our future licensors or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our future licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

Risks Relating to Marketing, Reimbursement, Healthcare Regulations and Ongoing Regulatory Compliance

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if approved, which could make it difficult for us to sell any product candidates or therapies profitably.

The success of our product candidates, if approved, depends on the availability of adequate coverage and reimbursement from third-party payors, including government agencies. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. Coverage may be more limited than the purposes for which a therapeutic is approved by the FDA or comparable regulatory authorities in other jurisdictions.

In the United States and some other jurisdictions, patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid in the United States, and commercial payors are critical to new product acceptance.

Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide which drugs and treatments they will cover and the amount of reimbursement. In the United States, the principal decisions about reimbursement for new medicines are typically made by the CMS an agency within the U.S. Department of Health and Human Services ("**HHS**"). CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare, and private payors often follow CMS' coverage decisions. Other jurisdictions have agencies, such as the National Institute for Health and Care Excellence in the UK, that evaluate the use and cost-effectiveness of therapies, which impact the utilization and price of the medicine in such jurisdiction.

In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. As a result, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to maintain pricing sufficient to achieve or sustain profitability or may require co-payments that patients find unacceptably high.

We intend to seek approval to market our product candidates in different jurisdictions, which could include the United States, Canada and other selected foreign jurisdictions. If we obtain approval in any of these jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. Market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from third-party payors for our product candidates and may be affected by existing and future health care reform measures. Thus, even if favorable coverage and reimbursement status is attained for a product for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Our relationships with healthcare providers and physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States, Canada, and elsewhere play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our current and future arrangements with healthcare providers, third-party payors, customers, and others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. In particular, the research of our product candidates, as well as the promotion, sales and marketing of healthcare items and services and certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business or financial arrangements.

The applicable U.S. federal, state and other healthcare laws and regulations laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual, or the purchase, lease, order, arrangement, or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. The term remuneration has been interpreted broadly to include anything of value. Further, courts have found that if "one purpose" of renumeration is to induce referrals, the federal Anti-Kickback Statute is violated. Violations are subject to significant civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, a claim submitted for payment to any federal healthcare program that includes items or services that were made as a result of a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act ("**FCA**"). The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers, among others, on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;
- the federal civil and criminal false claims laws, including the FCA, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs; knowingly making, using, or causing to be made or used, a false record or statement material to a false, fictitious or fraudulent claim or an obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding, decreasing or concealing an obligation to pay money to the federal government. A claim that includes items or services

resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim under the FCA. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring qui tam actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery or settlement. When an entity is determined to have violated the FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

- HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statement or representation, or making or using any false writing or document knowing the same to contain any materially false fictitious or fraudulent statement or entry in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA fraud provisions without actual knowledge of the statute or specific intent to violate it;

- HIPAA, as amended by HITECH, and their respective implementing regulations, which impose, among other things, certain requirements relating to the privacy, security and transmission of individually identifiable health information on certain covered healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their respective "business associates," those independent contractors or agents of covered entities that create, receive, maintain, transmit or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates and their covered subcontractors, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, there are additional federal, state and non-U.S. laws which govern the privacy and security of health and other personal information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts;

- the federal *Physician Payments Sunshine Act*, created under the ACA, as amended by the *Health Care and Education Reconciliation Act of 2010*, and its implementing regulations, which require manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to direct or indirect payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician providers such as physician assistants and nurse practitioners, and teaching hospitals, as well as ownership and investment interests held by the physicians and their immediate family members.

- federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- analogous U.S. state, local and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers and may be broader in scope than their federal equivalents; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and other relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources, including the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America's Code on Interactions with Healthcare Professionals; state and foreign laws that require drug manufacturers to report information related to

payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information, some of which may be more stringent than those in the United States (such as the European Union, which adopted the General Data Protection Regulation, which became effective in May 2018) in certain circumstances, and may differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The scope and enforcement of each of the aforementioned laws are uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming, costly, and can divert a company's attention from the business.

It is possible that governmental and enforcement authorities will conclude that our business practices, including our arrangements with physicians and other healthcare providers, may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to significant sanctions, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, reputational harm, exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to similar penalties. Any action for violation of these laws, even if successfully defended, could cause a pharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. In addition, the approval and commercialization of any product candidate in other countries will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. All of these could harm our ability to operate our business and our financial results.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities. Misconduct by these parties could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with federal and state health care fraud and abuse laws and regulations, accurately report financial information or data or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by these parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations.

Our research and development activities could be affected or delayed as a result of possible restrictions on animal testing.

Certain laws and regulations require us to test our product candidates on animals before initiating clinical trials involving humans. Animal testing activities have been the subject of controversy and adverse publicity. Animal rights groups and other organizations and individuals have attempted to stop animal testing activities by pressing for legislation and regulation in these areas and by disrupting these activities through protests and other means. To the extent the activities of these groups are successful, our research and development activities may be interrupted, delayed or become more expensive.

Ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations.

Changes in U.S., Canadian, and foreign regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

In the United States and in some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative initiatives and regulatory changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare. For example, in March 2010, the ACA was enacted, which substantially changed the way health care is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, expands the types of entities eligible for the 340B drug discount program; introduced a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations; established annual fees and taxes on manufacturers of

certain branded prescription drugs; created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered

under Medicare Part D; and provided incentives to programs that increase the federal government's comparative effectiveness research.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Other legislative changes include aggregate reductions to Medicare payments to providers of up to 2% per fiscal year pursuant to the Budget Control Act of 2011, which began in 2013 and, due to subsequent legislative amendments will remain in effect through 2032. Moreover, there has recently been heightened governmental scrutiny over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted, including:

- On January 2, 2013, the *American Taxpayer Relief Act of 2012* was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.
- On April 13, 2017, CMS published a final rule that gives states greater flexibility in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.
- On May 30, 2018, the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a pharmaceutical manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act.
- On May 23, 2019, CMS published a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020.
- On December 20, 2019, former President Trump signed into law the Further Consolidated Appropriations Act (H.R. 1865), which repealed the Cadillac tax, the health insurance provider tax, and the medical device excise tax. It is impossible to determine whether similar taxes could be instated in the future.

Under the American Rescue Plan Act of 2021, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs was eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than it receives on the sale of products, which could have a material impact on our business. In August 2022, Congress passed the Inflation Reduction Act of 2022 (the "**IRA**"), which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented, although the IRA may be subject to legal challenges. It is currently unclear how the IRA will be implemented but is likely to have a significant impact on the pharmaceutical industry. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025, and eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. Various industry stakeholders, including pharmaceutical companies and the Pharmaceutical Research and Manufacturers of America, have initiated lawsuits against the federal government asserting that the price negotiation provisions of the Inflation Reduction Act are unconstitutional. Further, in response to the Biden administration's October 2022 executive order, on February 14, 2023, HHS released a report outlining three new models for testing by the CMS Innovation Center which will be evaluated on their ability to lower the cost of drugs, promote accessibility, and improve quality of care. It is unclear whether the models will be utilized in any health reform measures in the future. The impact of these judicial challenges, legislative, executive, and administrative actions and any future healthcare measures and agency rules implemented by the government on us and the pharmaceutical industry as a whole is unclear. The implementation of cost containment measures, including the prescription drug provisions under the Inflation Reduction Act, as well as other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved. Complying with any new legislation and regulatory changes could be time-intensive and expensive, resulting in a material adverse effect on our business.

These laws and regulations may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biologic product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and in some cases, designed to encourage importation from other countries and bulk purchasing. For example, FDA recently authorized the state of Florida to import certain prescription drugs from Canada for a period of two years to help reduce drug costs, provided that Florida's Agency for Health Care Administration meets the requirements set forth by the FDA. Other states may follow Florida. Legally mandated price controls on payment amounts by third-party payors or other restrictions on coverage or access could harm our business, results of operations, financial condition and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be

included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates that we successfully commercialize or put pressure on our product pricing.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the extent to which state and federal governments cover particular healthcare products and services and could limit the amounts that the federal and state governments will pay for healthcare products and services. This could result in reduced demand for any product candidate we develop or could result in additional pricing pressures.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action in the United States. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

Risks Relating to our Securities

The market price of the Common Shares may be volatile.

The market price of the Common Shares may fluctuate due to a variety of factors relative to our business, including the following:

- announcements by us or our competitors of new products, product candidates or new uses for existing products, significant contracts, commercial relationships or capital commitments and the timing of these introductions or announcements;
- actions by any of our collaborators regarding our product candidates they are developing, including announcements regarding clinical or regulatory decisions or developments of our collaboration;
- unanticipated serious safety concerns related to the use of any of our products and product candidates;
- negative or inconclusive results from clinical trials of our product candidates, leading to a decision or requirement to conduct additional pre-clinical testing or clinical trials or resulting in a decision to terminate the continued development of a product candidate;
- delays of clinical trials of our product candidates;
- failure to obtain or delays in obtaining or maintaining product approvals or clearances from regulatory authorities;
- adverse regulatory or reimbursement announcements;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, licenses, joint ventures or capital commitments;
- the results of our efforts to discover or develop additional product candidates;
- our dependence on third parties, including our collaborators, CROs, clinical trial sponsors and clinical investigators;
- regulatory or legal developments in Canada, the U.S. or other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- actual or anticipated quarterly variations in our financial results or those of our competitors;
- sales of Common Shares by us, our insiders or our shareholders in the future, as well as the overall trading volume of the Common Shares;
- changes in the structure of healthcare payment systems;
- commencement of, or our involvement in, litigation;
- general economic, industry and market conditions;

- market conditions in the pharmaceutical and biotechnology sectors and other factors that may be unrelated to our operating performance or the operating performance of our competitors, including changes in market valuations of similar companies; and
- the other factors described in this "*Risk Factors*" section.

The effect of these and other factors on the market price of the Common Shares on the TSX, or any other exchange that we list securities on in the future, such as the Nasdaq if the Common Shares are listed on such exchange, cannot be predicted. There can be no assurance that the market price of the Common Shares will not experience significant fluctuations in the future, including fluctuations that are unrelated to our performance.

Investors may lose their entire investment.

An investment in the Common Shares is speculative and may result in the loss of an investor's entire investment in the Company. Only investors who are experienced in high-risk investments and who can afford to lose their entire investment should consider an investment in the Company.

We have no history of dividends.

To date, we have not paid any dividends on the outstanding Common Shares. We currently intend to retain future earnings to finance the operation, development and expansion of our business. We do not anticipate paying cash dividends on the Common Shares in the foreseeable future. Any decision to pay dividends on our shares will be made at the discretion of the board of directors of the Company (the "**Board**") and will depend on the Company's earnings, financial requirements and other conditions existing at such time, including potential restrictions on paying dividends pursuant to any effective credit agreements.

Our existing executive officers and directors own a significant percentage of Common Shares and may have a significant impact over matters submitted to our shareholders for approval.

Our executive officers and directors own approximately 9.68% of the issued Common Shares as of September 30, 2023. As a result, these shareholders, if they acted together, could significantly impact all matters requiring approval by our shareholders, including the election of directors and the approval of mergers or other business combination transactions. The interests of these shareholders may not always coincide with our interests or the interests of other shareholders. This may also prevent or discourage unsolicited acquisition proposals or offers for the Common Shares that other shareholders may feel are in their best interest.

Future sales of Common Shares by our existing shareholders could cause our share price to decline.

Subject to compliance with applicable securities laws, our officers, directors and significant shareholders may sell some or all of their Common Shares in the future. No prediction can be made as to the effect, if any, such future sales of Common Shares will have on the market price of the Common Shares prevailing from time to time. However, the future sale of a substantial number of Common Shares by our officers, directors and significant shareholders or the perception that such sales could occur, could adversely affect prevailing market prices for the Common Shares.

We will need to raise additional financing in the future which may dilute our share capital.

Our notice of articles and articles (the "**Articles**") permit the issuance of an unlimited number of Common Shares. Future issuance of Common Shares will result in dilution to the existing shareholders. Additionally, future sales of the Common Shares into the public market may lower the market price that may result in losses to our shareholders. We may, from time to time, issue stock options to purchase additional Common Shares in accordance with the policies of the TSX and, if applicable, the Nasdaq. Most of these Common Shares, including the Common Shares to be issued upon exercise of options, are freely tradable or will be freely tradeable after a four-month restriction period. Sales of substantial amounts of the Common Shares into the public market, or even the perception by the market that such sales may occur, may lower the market price of Common Shares.

If securities or industry analysts either do not publish research about us or publish inaccurate or unfavorable research about us, our business or our market, or if they adversely change their recommendations regarding our Common Shares, the trading price or trading volume of our Common Shares could decline.

The trading market for Common Shares will be influenced in part by the research and reports that securities or industry analysts may publish about us, our business, our market or our competitors. If one or more securities analysts initiate research with an unfavorable rating or downgrade our Common Shares, provide a more favorable recommendation about our competitors or publish inaccurate or unfavorable research about our business, our Common Shares price would likely decline. If few securities analysts commence coverage of us, or if one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets and demand for our securities could decrease, which in turn could cause the price and trading volume of our Common Shares to decline.

Any issuance of preferred shares could make it difficult for another company to acquire us or could otherwise adversely affect holders of our Common Shares, which could depress the price of our Common Shares.

The Board has the authority to issue preferred shares and to determine the preferences, limitations and relative rights of preferred shares and to fix the number of shares constituting any series and the designation of such series, without any further vote or action by our shareholders. Our preferred shares may be issued with liquidation, dividend and other rights superior to the rights of our Common Shares. The potential issuance of preferred shares may delay or prevent a change in control, discourage bids for our Common Shares at a premium over the market price and adversely affect the market price and other rights of the holders of our Common Shares.

Our constating documents permit us to issue an unlimited number of Common Shares without additional shareholder approval.

Our Articles permit us to issue an unlimited number of Common Shares. We anticipate that we will, from time to time, issue additional Common Shares in the future. Subject to the requirements of the TSX and, if applicable, Nasdaq, we will not be required to obtain the approval of shareholders for the issuance of additional Common Shares. Any further issuances of Common Shares will result in immediate dilution to existing shareholders and may have an adverse effect on the value of their shareholdings.

Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses and other similar arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. We are authorized to issue an unlimited number of Common Shares. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan.

If we raise additional funds through future collaborations, licenses and other similar arrangements, we may be required to relinquish valuable rights to our future revenue streams, product candidates, research programs, intellectual property or proprietary technology, or grant licenses on terms that may not be favorable to us and/or that may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed or on terms acceptable to us, we would be required to delay, limit, reduce or terminate our product development or future commercialization efforts, or grant rights to develop and market product candidates that we might otherwise prefer to develop and market ourselves, or on less favorable terms than we would otherwise choose.

In addition, we have outstanding stock options representing a right to receive Common Shares upon vesting and the exercise of the stock options as well as outstanding warrants that are exercisable for Common Shares. Pursuant to the terms of our Amended Plan, the number of Common Shares we may grant under such plan will automatically increase upon the closing of an offering of Common Shares such that the aggregate number of Common Shares that may be reserved for issuance under the Amended Plan equals 18.5% of our outstanding Common Shares. Furthermore, we have outstanding convertible debt that is convertible into Common Shares at the option of the holders, and Eupraxia Pharma, our subsidiary, has non-voting Class B Shares outstanding that are exchangeable into Common Shares at any time at the election of the holder. The exercise of stock options and warrants, conversion of such convertible debt and exchange of such Class B Shares and the subsequent resale of such Common Shares in the public market, could adversely affect the prevailing market price of the Common Shares and our ability to raise equity capital in the future at a time and price which we deem appropriate. We may also enter into commitments in the future which would require the issuance of additional Common Shares and we are expected to grant additional stock options. Any Common Shares issuances from our treasury will result in immediate dilution to existing shareholders' percentage interest in us.

We have warrants, convertible debt, and shares of a subsidiary exchangeable for Common Shares outstanding, which in each case, if exercised, converted or exchanged, respectively, could cause dilution to existing shareholders.

We have outstanding warrants that are exercisable for Common Shares. In addition, we have outstanding convertible debt that are convertible into Common Shares. Furthermore, Eupraxia Pharma our subsidiary, has non-voting Class B Shares outstanding that are exchangeable into Common Shares. The exercise of such warrants, conversion of such convertible debt and exchange of such Class B Shares and the subsequent resale of such Common Shares, issuable thereunder in each case, in the public market could adversely affect the prevailing market price and our ability to raise equity capital in the future at a time and price which it deems appropriate. We may also enter into commitments in the future which would require the issuance of additional Common Shares and we may grant additional share purchase warrants or stock options. Any share issuances from our treasury will result in immediate dilution to existing shareholders' percentage interest in us.

Our Common Shares may have limited liquidity.

Our shareholders may be unable to sell significant quantities of Common Shares into the public trading markets without a significant reduction in the price of their Common Shares, or at all. There can be no assurance that there will be sufficient liquidity of the Common Shares on the trading market, and that we will continue to meet the listing requirements of the TSX, achieve and maintain a listing on Nasdaq, if our Common Shares are listed on such exchange, or achieve or maintain a listing on any other securities exchange.

We cannot assure you that an active market will develop for Common Shares on Nasdaq if the Common Shares are listed.

Our Common Shares are currently listed on the TSX under the symbol "ERPX". We have applied to list our Common Shares on Nasdaq under the symbol "EPRX", which application is being reviewed by Nasdaq. However, there has been no prior public trading market for the Common Shares on Nasdaq. We cannot assure you that we will complete our listing of the Common Shares on Nasdaq, if we complete our listing of the Common Shares on Nasdaq that such listing is maintained, or that an active trading market for the Common Shares will develop on Nasdaq or elsewhere or, if developed, that any market will be sustained. Accordingly, we cannot assure you of the liquidity of any trading market, your ability to sell the Common Shares when desired or the prices that you may obtain for your shares.

United States investors may not be able to obtain enforcement of civil liabilities against us.

The enforcement by investors of civil liabilities under the United States federal or state securities laws may be affected adversely by the fact that we are governed by the *Business Corporations Act* (British Columbia), that the majority of our officers and directors are residents of Canada or otherwise reside outside the United States, and that all, or a substantial portion of their assets and a substantial portion of our assets, are located outside the United States. It may not be possible for investors to effect service of process within the United States on certain of our directors and officers or enforce judgments obtained in the United States courts against us or certain of our directors and officers based upon the civil liability provisions of United States federal securities laws or the securities laws of any state of the United States.

There is some doubt as to whether a judgment of a United States court based solely upon the civil liability provisions of United States federal or state securities laws would be enforceable in Canada against us or our directors and officers. There is also doubt as to whether an original action could be brought in Canada against us or our directors and officers to enforce liabilities based solely upon United States federal or state securities laws.

As a foreign private issuer, we are subject to different U.S. securities laws and rules than a domestic U.S. issuer, which may limit the information publicly available to our U.S. shareholders.

We are a foreign private issuer under applicable U.S. federal securities laws and, therefore, we will not be required to comply with all the periodic disclosure and current reporting requirements of the Exchange Act, as amended, and related rules and regulations, should we become subject to such requirements in the future. As a result, we will not file the same reports that a U.S. domestic issuer would file with the SEC, although we will be required to file with or furnish to the SEC the continuous disclosure documents that we are required to file in Canada under Canadian securities laws. In addition, our officers, directors and principal shareholders will be exempt from the reporting and "short swing" profit recovery provisions of Section 16 of the Exchange Act. Therefore, our shareholders may not know on as timely a basis when our officers, directors and principal shareholders purchase or sell Common Shares as the reporting periods under the corresponding Canadian insider reporting requirements are longer. In addition, as a foreign private issuer, we will be exempt from the proxy rules under the Exchange Act.

We may lose our foreign private issuer status in the future, which could result in significant additional costs and expenses to us.

In order to maintain our current status as a foreign private issuer, a majority of our Common Shares must be either directly or indirectly owned by non-residents of the United States unless we also satisfy one of the additional requirements necessary to preserve this status. We may in the future lose our foreign private issuer status if a majority of the Common Shares are held in the United States and we fail to meet the additional requirements necessary to avoid loss of foreign private issuer status. The regulatory and compliance costs to us under U.S. federal securities laws as a U.S. domestic issuer may be significantly more than the costs we incur as a Canadian foreign private issuer eligible to use the multijurisdictional disclosure system. If we are not a foreign private issuer, we would not be eligible to use the multijurisdictional disclosure system or other foreign issuer forms and would be required to file periodic and current reports and registration statements on U.S. domestic issuer forms with the SEC, which are more detailed and extensive than the forms available to a foreign private issuer. In addition, should we become listed on the Nasdaq, we may lose the ability to rely upon exemptions from Nasdaq corporate governance requirements that are available to foreign private issuers.

U.S. holders of our Common Shares may suffer adverse tax consequences if we are characterized as a passive foreign investment company.

We may be treated as a passive foreign investment company ("PFIC") for U.S. federal income tax purposes, in which case U.S. holders would be subject to a special, generally adverse tax regime. Generally, for any taxable year in which 75% or more of our gross income is passive income, or at least 50% of the value of our assets (as determined under applicable U.S. Treasury Regulations, which may be determined in part by the market value of our common shares, which is subject to change) are held for the production of, or produce, passive income, we would be characterized as a passive foreign investment company, or a PFIC, for U.S. federal income tax purposes. We will be treated as owning the proportionate share of the assets and earning the proportionate share of the income of any other corporation, the equity of which we own, directly or indirectly, 25% or more (by value). We have not yet completed a formal assessment of our status as a PFIC for 2023; however, based on our gross income and gross assets, we believe that we will be deemed a PFIC for the taxable year ending December 31, 2023, and may be a PFIC for subsequent taxable years. and may be a PFIC for subsequent taxable years. Our status as a PFIC is a fact-intensive determination, and we cannot provide any assurance regarding our PFIC status for the current taxable year or future taxable years. Our status as a PFIC is a fact-intensive determination, and no assurance can be provided regarding its PFIC status for the current taxable year or future taxable years.

If we are a PFIC for any year, U.S. holders of our common shares may suffer adverse tax consequences. If we are a PFIC in any year with respect to which a U.S. holder owns our common shares, we will continue to be treated as a PFIC with respect to such U.S. holder in all succeeding years during which the U.S. holder owns our common shares, whether or not we remain a PFIC unless such U.S. holder makes a qualified electing fund or mark-to-market election. Gains realized by non-corporate U.S. holders on the sale of our common shares would be taxed as ordinary income, rather than as capital gain, and the preferential tax rate applicable to dividends received on our common shares would be lost. Interest charges would also be added to taxes on gains and dividends realized by all U.S. holders. U.S. holders should consult their own tax advisors with respect to their particular circumstances.

The PFIC rules, including the rules governing any elections that may potentially be made by a U.S. Holder, are extremely complex. Each U.S. holder should consult its own tax advisor regarding our potential PFIC status and how the PFIC rules (including elections that may be available thereunder) would affect the U.S. federal income tax consequences of the acquisition, ownership and disposition of our common shares.

If a U.S. holder is treated as owning at least 10% of our common shares, such U.S. holder may be subject to adverse U.S. federal income tax consequences.

If a U.S. holder is treated as owning, directly, indirectly or constructively, at least 10% of the value or voting power of our common shares, such U.S. holder may be treated as a "United States shareholder" with respect to each "controlled foreign corporation" in our group, if any. Generally, a non-U.S. corporation is deemed as a controlled foreign corporation if more than 50% of its stock (by voting power or value) is owned (directly, indirectly or constructively) by United States shareholders. We will generally be classified as a controlled foreign corporation if more than 50% of our outstanding shares, measured by reference to voting power or value, are owned (directly, indirectly or by attribution) by United States shareholders. In addition, since our group includes one or more U.S. subsidiaries, certain of our non-U.S. subsidiaries could be treated as controlled foreign corporations, regardless of whether we are treated as a controlled foreign corporation.. If we or any of our non-U.S. subsidiaries are treated as controlled foreign corporations, a United States shareholder would be required to annually report and include in its U.S. taxable income its pro rata share of "Subpart F income," "global intangible low-taxed income" and investments in U.S. property by the controlled foreign corporation, regardless of whether we make any distributions, and generally would not be allowed certain tax deductions or foreign tax credits that would be allowed to a United States shareholder of a U.S. corporation. In addition, failure to comply with certain reporting obligations may

subject a United States shareholder to monetary penalties and may prevent the statute of limitations with respect to such shareholder's U.S. federal income tax return for the year for which reporting was due from starting. We cannot provide any assurances that we will assist our investors in determining whether any of our non-U.S. subsidiaries are treated as a controlled foreign corporation or whether such investor is treated as a United States shareholder with respect to any of such controlled foreign corporations. Further, we cannot provide any assurances that we will furnish to any United States shareholder information that may be necessary to comply with the reporting and tax paying obligations described in this risk factor. U.S. holders should consult their tax advisors regarding the potential application of these rules to their investment in our common shares.

DIVIDENDS

The Company has not, since its inception, declared or paid any dividends on its Common Shares. The declaration of dividends on our Common Shares is within the discretion of the Board and will depend on the assessment of, among other factors, capital requirements, earnings, and the operating and financial condition of the Company. At the present time, the Company's anticipated capital requirements are such that the Company follows a policy of retaining all available funds and any future earnings in order to finance the Company's technology advancement, business development and corporate growth. The Company does not intend to declare or pay cash dividends on its Common Shares within the foreseeable future.

CAPITAL STRUCTURE

The following description of our share capital summarizes certain provisions contained in our Articles and by-laws. These summaries do not purport to be complete and are subject to, and are qualified in their entirety by reference to, all of the provisions of our Articles and by-laws.

The authorized share capital of the Company consists of (i) an unlimited number of Common Shares without par value and (ii) an unlimited number of preferred shares in the capital of the Company (the "**Preferred Shares**") without par value, issuable in series. As of the date of this AIF, the Company had 35,622,553 Common Shares issued and outstanding. The maximum number of additional Common Shares issuable, should all convertible rights be exercised are as follows:

Common Shares Issuable:	**As of the date of this AIF**
Options[1]	3,482,490
2013 Warrants[2]	380,921
Founders Warrants[3]	315,500
Underlying Founders Warrants[4]	315,500
Class B Shares[5]	562,500
Warrants – Listed EPRX.WT[6]	2,826,024
Warrants – Listed EPRX.WT.A[7]	5,196,550
Compensation Warrants[8]	50,054
Nordic Warrants[9]	39,228
SVB Debt Facility[10]	2,143,445
Total Common Shares Issuable	**15,312,212**

Notes:

(1) Represents options outstanding under the Amended Plan, each having an exercise price between CDN$1.90 and CDN$8.00 and expiry dates ranging from March 31, 2025 to September 26, 2033.

(2) Represents common share purchase warrants to acquire up to 380,921 Common Shares at an exercise price of CDN$0.7572 per share, with each such common share purchase warrant expiring 120 days after the warrant holder or the holder's spouse ceases to be a director, officer or consultant of the Company.

(3) Represents common share purchase warrants to acquire 315,500 units, with each unit consisting of one Common Share and one underlying common share purchase warrant (an "**Underlying Founder Warrant**") at an exercise price of CDN$0.4984 per unit, expiring 120 days after the warrant holder ceases to be a director, officer or consultant of the Company.

(4) Represents Underlying Founder Warrants to acquire up to 315,500 Common Shares, at an exercise price of CDN$0.75 per share, expiring two years from the date of exercise of the Underlying Founder Warrant.

(5) Represents 562,500 Common Shares that are issuable upon conversion of the 225 Class B Shares of Eupraxia Pharma, the Company's subsidiary, held by Amanda Malone, the Chief Scientific Officer of the Company. Each Class B Share is exchangeable into Common Shares based on an exchange rate of 2,500 Common Shares for each Class B Share, subject to adjustments upon the occurrence of certain events, for a total of 562,500 Common Shares. The Class B Shares are exchangeable by Ms. Malone at her election, provided that the Company may force the exchange of the Class B Shares into Common Shares at any time on or after January 31, 2031, or on or after January 31, 2026 if the Company is listed on a stock exchange and is a reporting issuer in Canada at such time. The Company may also force the exchange of the Class B Shares into Common Shares if there is a change of control transaction involving the Company, a change in law which makes the exchange necessary or desirable or if there are a de minimis number of Class B Shares outstanding. If the Company is listed on a stock exchange at the time of the applicable exchange, the Company may elect to pay Ms. Malone cash in lieu of issuing Common Shares, with such cash amount to be determined based on the then current market price of the Common Shares.

(6) Each common share purchase warrant is exercisable into one common share of the Company (each, a "**Warrant Share**") at an exercise price of CDN$11.20 per Warrant Share at any time prior to 5:00 p.m. (Eastern time) on the date that is five years following the closing of the Company's initial public offering in Canada, subject to adjustment in certain events. The common share purchase warrants include an acceleration provision, exercisable at the Company's option, if the Company's daily volume weighted average share price is greater than CDN$22.40 for five consecutive trading days. Of the 2,826,274 warrants issued, 250 warrants have been exercised as of the date hereof.

(7) Each common share purchase warrant entitles the holder thereof to acquire one Common Share at an exercise price of CDN$3.00 per Common Share for a period of 48 months following the closing date of the 2022 Offering, being April 20, 2022. Of the 7,331,550 warrants issued, 2,135,000 warrants have been exercised as of the date hereof.

(8) 500,538 common share purchase warrants were issued to the agents of the 2022 Offering and represents 7% of the units issued in the 2022 Offering including the over-allotment option (the "**Compensation Warrants**"). Each Compensation Warrant shall entitle the agents to acquire a Common Share at the price of CDN$2.05 for a period of 48 months following completion of the 2022 Offering, being April 20, 2022. Of the 500,538 Compensation Warrants issued, 450,484 Compensation Warrants have been exercised as of the date hereof.

(9) Each Nordic Warrant is exercisable into one Common Share at an exercise price of CDN$11.20 per share at any time prior to 5:00 p.m. (Eastern time) on April 29, 2026, subject to adjustment in certain events. The Nordic Warrants include an acceleration provision, exercisable at the Company's option, if the Company's daily volume weighted average share price is greater than CDN$22.40 for five consecutive trading days.

(10) SVB may elect to convert the principal amount of the convertible debt into Common Shares at a conversion price equal to CDN$5.68 per Common Share. SVB may also elect to convert accrued and unpaid interest, the conversion price of the accrued and unpaid interest will be subject to the minimum pricing requirements of the TSX, to the extent applicable at the time of conversion.

Common Shares

Each Common Share entitles the holder thereof to one vote at any meeting of our shareholders. The holders of Common Shares are entitled to receive if, as and when declared by the Board, dividends in such amounts as shall be determined by the Board. After the holders of Preferred Shares have first received from the property and assets of the Company the amount they are entitled to, the holders of Common Shares have the right to receive the Company's remaining property and assets in the event of a liquidation, dissolution or winding-up, whether voluntary or involuntary. The Common Shares do not carry any pre-emptive, subscription, redemption or conversion rights, nor do they contain any sinking or purchase fund provisions.

Preferred Shares

We may issue Preferred Shares from time to time in one or more series. The terms of each series of Preferred Shares, including the number of shares, the designation, rights, preferences, privileges, priorities, restrictions, conditions and limitations, will be determined at the time of creation of each such series by our Board, without shareholder approval, provided that all Preferred Shares will rank equally within their class as to dividends and distributions in the event of our dissolution, liquidation or winding-up. The Preferred Shares are entitled to priority over the Common Shares with respect to the distribution of assets of the Company in the event of any liquidation, dissolution or winding up of the Company's affairs, whether voluntary or involuntary. The Preferred Shares are only entitled to voting rights and dividends as provided in the special rights and restrictions attached to any particular series.

MARKET FOR SECURITIES

Trading Price and Volume

The Common Shares are listed and posted for trading on the TSX under the symbol “EPRX” and the Warrants are listed and posted for trading on the TSX under the symbols “EPRX.WT” and “EPRX.WT.A”.

The following table sets forth the reported high and low prices and the aggregate monthly volume of trading of the Common Shares for the year ended December 31, 2023. All amounts in the table are expressed in Canadian dollars:

	High	Low	Volume
January 2023	$4.27	$3.65	802,936
February 2023	$5.23	$3.90	516,414
March 2023	$4.26	$3.27	375,854
April 2023	$6.36	$4.18	292,763
May 2023	$7.50	$5.76	503,686
June 2023	$8.86	$6.50	1,005,249
July 2023	$9.10	$7.17	626,339
August 2023	$8.46	$6.98	742,235
September 2023	$8.09	$6.87	642,991
October 2023	$7.20	$4.88	601,922
November 2023	$6.75	$5.03	243,854
December 2023	$6.46	$5.36	249,124

The following table sets forth the reported high and low prices and the aggregate monthly volume of trading of the listed “EPRX.WT” Warrants for the year ended December 31, 2023:

	High	Low	Volume
January 2023	$0.35	$0.12	132,500
February 2023	$0.35	$0.125	94,520
March 2023	$0.39	$0.30	108,000
April 2023	$0.39	$0.18	11,875
May 2023	$1.24	$0.405	241,561
June 2023	$1.88	$0.75	182,600
July 2023	$2.25	$1.55	39,650
August 2023	$2.00	$1.55	12,500
September 2023	$1.70	$1.22	9,850
October 2023	$1.22	$0.65	8,800
November 2023	$0.65	$0.65	2,000
December 2023	$0.65	$0.57	9,250

The following table sets forth the reported high and low prices and the aggregate monthly volume of trading of the listed “EPRX.WT.A” Warrants for the year ended December 31, 2023:

	High	Low	Volume
January 2023	$2.10	$1.45	33,900
February 2023	$2.50	$1.95	24,800
March 2023	$2.25	$1.95	4,600
April 2023	$3.00	$2.55	23,500
May 2023	$5.35	$3.50	146,200
June 2023	$6.00	$4.30	79,000
July 2023	$6.18	$4.95	4,000
August 2023	$5.20	$4.70	10,175
September 2023	$5.50	$4.95	10,500

October 2023	$4.00	$4.00	350
November 2023	$4.00	$4.00	100
December 2023	$4.00	$3.50	2,300

Prior Sales

The following table summarizes details of each class of securities of the Company that is outstanding but not listed or quoted on a marketplace, issued by the Company during the most recently completed financial year:

Date of Issuance/Grant	Type of Security	Number of Securities Issued	Issue/Exercise Price
May 18, 2023	Options	180,000	CDN$6.84
May 30, 2023	Options	17,200	CDN$6.75
September 26, 2023	Options	60,000	CDN$7.16

DIRECTORS AND OFFICERS

The names of the directors and executive officers of the Company as of the date hereof, their province or state and country of residence, their respective positions with the Company the date upon which the directors were first elected to the Board are set out in the table below. The term of each director expires on the date of our next annual meeting.

Name, Province of Residence and Position with Eupraxia	Principal Occupation or Business or Employment in the Past Five Years	Date Appointed as a Director of the Company
James A. Helliwell British Columbia, Canada *Chief Executive Officer and Director*	Chief Executive Officer, Eupraxia Pharmaceuticals Inc. (July 2012 – Present)	July 23, 2012
Amanda Malone British Columbia, Canada *Chief Scientific Officer*	Chief Scientific Officer, Eupraxia Pharmaceuticals Inc. (Sep 2012 – Present)	N/A
Bruce Cousins British Columbia, Canada *Chief Financial Officer and President*	Chief Financial Officer, Eupraxia Pharmaceuticals Inc. (May 2021 – Present)	N/A
Paul Brennan British Columbia, Canada *Chief Business Officer*	Chief Business Officer, Eupraxia Pharmaceuticals Inc. (December 2022 – Present)	N/A
Mark Kowalski Massachusetts, USA *Chief Medical Officer*	Chief Medical Officer, Eupraxia Pharmaceuticals Inc. (May 2023 – Present)	N/A

Simon Pimstone British Columbia, Canada *Chairman of the Board and Director*	Founder and Chief Executive Officer, XYON Health Inc. (Jan 2019 – Present) Chair of the Board, Alpha-9 Theranostics (May 2020 – Present) Non-Executive Chair of the Board, Xenon Pharmaceuticals, Inc. (June 2022 – Present) Executive Chair of the Board, Xenon Pharmaceuticals, Inc. (June 2021 – June 2022) Chief Executive Officer, Xenon Pharmaceuticals, Inc. (January 2003 - June 2021)	January 14, 2013 (as Director) and January 24, 2013 (as Chairman)
Richard M. Glickman British Columbia, Canada *Director*	Chairman of the Board, ESSA Pharma Inc. (October 2010 – Present) Co-founder and Executive Chairman (September 2013 - February 2014) and Chairman of the Board (February 2014 - April 2019) and Chief Executive Officer (February 2017 – April 2019), Aurinia Pharmaceuticals Inc. Venture Partner, Lumira Ventures (March 2016 - Present)	March 9, 2021
Paul Geyer[(3)] British Columbia, Canada *Director*	Chief Executive Officer, Discovery Parks and Nimbus Synergies (May 2017 – Present)	January 14, 2013
John Montalbano British Columbia, Canada *Director*	Director, AbCellera Biologics Inc. (November 2020 – Present) Director, XYON Health Inc. (June 2021 – Present) Director, Canada Pension Plan Investment Board (February 2017 – Present) Director, Aritzia Inc. (July 2019 – Present)	January 14, 2013
Michael Wilmink[(2)] Arizona, USA *Director*	Orthopaedic Surgeon, Partner in OrthoArizona practice (2002 - Present)	January 14, 2013

Notes:

(1) The information as to principal occupation, business or employment (for the preceding five years for any new director) and Common Shares beneficially owned, controlled or directed is not within the knowledge of the management of the Company and has been furnished by the respective nominees themselves. Beneficial ownership is determined in accordance with applicable Canadian securities laws.
(2) Members of the Compensation Committee, with Richard Glickman as chair.
(3) Members of the Audit Committee, with John Montalbano as chair.
(4) Members of the Nominating and Corporate Governance Committee, with Simon Pimstone as chair.

As of the date of this AIF, the directors and executive officers of the Company owned, directly or indirectly, or exercised control or direction over 2,649,834 (7.44%) of the issued and outstanding Common Shares of the Company.

Cease Trade Orders, Bankruptcies, Penalties and Sanctions

Cease Trade Orders

To the best of our knowledge, no director or executive officer of the Company, is, or within the ten years prior to the date hereof, has been, a director, chief executive officer or chief financial officer that: (i) while that person was acting in that capacity was the subject of a cease trade order or similar order or an order that denied the other issuer access to any exemptions under Canadian securities legislation, that was in effect for a period of more than thirty consecutive days or, (ii) after that person ceased to act in that capacity, was the subject of a cease trade order or similar order, or an order that denied the other issuer access to any exemptions under Canadian securities legislation, that was in effect for a period of more than thirty consecutive days and which resulted from an event that occurred while that person was acting in that capacity.

Penalties or Sanctions

To the best of our knowledge, no director or executive officer of the Company, or a shareholder holding a sufficient number of shares of the Company to affect materially the control of the Company, has been subject to any penalties or sanctions imposed by a court relating to Canadian securities legislation or by a Canadian securities regulatory authority or has entered into a settlement agreement with a Canadian securities authority, or any other penalties or sanctions imposed by a court or regulatory body that would likely be considered important to a reasonable investor in making an investment decision.

Personal Bankruptcies

To the best of our knowledge, no director or executive officer of the Company, or a shareholder holding a sufficient number of shares of the Company to affect materially the control of the Company, (i) has, during the ten years prior to the date hereof, been a director or executive officer of any company that, while that person was acting in that capacity, become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency, or been subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver manager or trustee appointed to hold his, her or its assets or (ii) has, during the ten years prior to the date hereof, become bankrupt, made a proposal under any legislation relating to bankruptcy or insolvency, or been subject to or instituted any proceedings, arrangement or compromise with creditors, or had a receiver, receiver manager or trustee appointed to hold his, her or its assets.

Conflicts of Interest

To the best of the Company's knowledge, there are no existing or potential material conflicts of interest between the Company and any of its directors or officers as of the date hereof. However, certain of the Company's directors and officers are, or may become, directors or officers of other companies with businesses which may conflict with its business. Accordingly, conflicts of interest may arise which could influence these individuals in evaluating possible acquisitions or in generally acting on the Company's behalf. See also "*Risk Factors – Our directors may serve as directors of other biotech companies and may have conflicts of interest*". Pursuant to the BCBCA, directors and officers of the Company are required to act honestly and in good faith with a view to the best interests of the Company. As required under the BCBCA and the Company's Articles:

- a director or senior officer who holds any office or possesses any property, right or interest that could result, directly or indirectly, in the creation of a duty or interest that materially conflicts with that individual's duty or interest as a director or senior officer of the Company, must promptly disclose the nature and extent of that conflict; and
- a director who holds a disclosable interest (as such term is defined under the BCBCA) in a contract or transaction into which the Company has entered or proposes to enter may generally not vote on any directors' resolution to approve such contract or transaction.

Generally, as a matter of practice, directors who have disclosed a material interest in any contract or transaction that the Board is considering will not take part in any board discussion respecting that contract or transaction. If on occasion such directors do participate in the discussions, they will refrain from voting on any matters relating to matters in which they have disclosed a material interest. In appropriate cases, the Company will establish a special committee of independent directors to review a matter in which directors or officers may have a conflict.

PROMOTERS

No person or company is, or has acted as, a promoter of the Company within the two most recently completed financial years or during the current financial year.

AUDIT COMMITTEE INFORMATION

Audit Committee

The Audit Committee is comprised of John Montalbano (Chair), Simon Pimstone and Paul Geyer, each of whom is "independent" and "financially literate" pursuant to NI 52-110.

The Audit Committee assists the Board in fulfilling its obligations relating to the integrity of the internal financial controls and financial reporting of the Company. The external auditors of the Company report directly to the Audit Committee. The Audit Committee's principal responsibilities include (i) recommending the external auditor to be nominated for the purpose of providing audit, review or attest services for the Company, (ii) recommending the compensation of the external auditor, (iii) overseeing the work of the external auditor in performing audit, review or attest services for the Company, (iv) reviewing the Company's financial statements, management's discussion and analysis and annual and interim earnings press releases before the Company publicly discloses this information, and (v) establishing procedures for addressing complaints or concerns regarding accounting, internal control or auditing matters.

A copy of the Audit Committee's charter is attached as Schedule "A" to this AIF.

Relevant Education and Experience

Each member of the Audit Committee has adequate education and experience that is relevant to their performance as an Audit Committee member and, in particular, the requisite education and experience that have provided the member with:

(a) an understanding of the accounting principles used by the Company to prepare its financial statements and the ability to assess the general application of those principles in connection with estimates, accruals and reserves;

(b) experience preparing, auditing, analyzing or evaluating financial statements that present a breadth and level of complexity of accounting issues that are generally comparable to the breadth and complexity of issues that can reasonably be expected to be raised by the Company's financial statements or experience actively supervising individuals engaged in such activities; and

(c) an understanding of internal controls and procedures for financial reporting.

John Montalbano, CFA, Director

John retired as CEO of RBC Global Asset Management in 2015, at which point the company managed $370 billion in assets, placing it among the 50 largest asset managers worldwide. John currently serves as Director and Audit Chair for the following organizations: Canada Pension Plan Investment Board, AbCellera Inc. (Nasdaq), and Eupraxia Pharmaceuticals (TSX). He also serves as Director for Aritzia Inc. and Chairs White Crane Capital, a Vancouver-based hedge fund.

John's past volunteer roles have included Chair of the UBC Board of Governors, Chair of St. Paul's Foundation, Chair of The Vancouver Police Foundation, Killam Trusts Trustee, co-Founder of Take a Hike Youth at Risk Foundation, Chair of the Vancouver Public Library Capital Campaign and Director/Chair Investments for the Asia Pacific

Foundation of Canada. He serves as a Director for the Gairdner Foundation, the Rideau Hall Foundation, and Windmill Microlending.

John holds a Chartered Financial Analyst designation, a Bachelor of Commerce degree with Honours from the University of British Columbia, and an Honorary Doctor of Letters degree from Emily Carr University of Art and Design

Simon Pimstone, MD, PhD, FRCPC (Chair), Chairman of the Board

Dr. Simon Pimstone is a founder and non-executive Board Chair at Xenon Pharmaceuticals Inc. ("Xenon"), a publicly traded Canadian biotechnology company (Nasdaq: XENE). Xenon is engaged in discovering and developing novel pharmaceuticals targeting neurological diseases with a key focus on ion channels.

Dr Pimstone is also a founder and CEO of XYON Health Inc., a privately held Canadian company delivering innovative healthcare solutions for men and women with hair loss.

Dr. Pimstone received his MD from the University of Cape Town (MBChB, 1991) and is an internal medicine specialist (FRCPC, UBC, 2001). Prior to his specialization, he trained as a clinical research fellow with the Department of Medical Genetics at the University of British Columbia and obtained his PhD in cardiovascular genetics through the University of Amsterdam (1998).

Dr. Pimstone also serves as a consultant physician at the UBC Medical and Cardiology Clinic at UBC Hospital in Vancouver.

Dr. Pimstone has served on numerous non-profit boards including BIOTECanada, LifeSciences BC, the Center for Molecular Medicine and Therapeutics, Providence Healthcare and numerous life sciences company boards including Eupraxia Pharmaceuticals and Alpha9 Oncology.

Dr. Pimstone has received a number of awards and is widely published.

Paul Geyer, P.Eng., Director

Mr. Geyer is a Medtech Entrepreneur, angel investor and venture capitalist, and has sat on the Boards of several companies. Over the past 30 years Mr. Geyer founded or led three companies through their growth phase, in one case to exit and in another to a public company. These companies have grown to employ more than 350 people.

Mr. Geyer is currently the CEO of Discovery Parks and Nimbus Synergies, a venture capital investment program focused on growing BC Digital Health companies that operate in the intersection between health, life sciences, and technology. He is an active mentor and angel investor in medical technology companies.

In 1991 he founded Mitroflow, a tissue heart valve company. Mr. Geyer grew the company from nine employees to more than 125 employees, selling in 1999 for more than $50 million. In 2001, Mr. Geyer founded Medical Ventures (Neovasc) where he is on the board and held the position of CEO until June 2008 and was responsible for raising over $40 million in equity financing and overseeing the acquisition of three other companies.

From 2009 to 2017, Mr. Geyer was the first CEO of LightIntegra Technology which developed the ThromboLux, a point of care device to determine platelet quality for blood transfusions.

Since 2008, Mr. Geyer has focused on assisting entrepreneurs to build successful businesses, as a mentor or board member, and as a Fellow of Creative Destruction Labs. He has also worked on building the local community through his involvement as a board member of BCTech, LifeSciences BC, and Science World, Vancouver General Hospital & UBC Hospital Foundation, and Junior Achievement BC along with a number of non-profit community-based organizations. He also participates in a range of philanthropic endeavours.

Pre-Approval Policies and Procedures

The Audit Committee has the authority and responsibility for pre-approval of all non-audit services to be provided to the Company or its subsidiary entities by the external auditors or the external auditors of the Company's subsidiary entities unless such pre-approval is otherwise appropriately delegated or if appropriate specific policies and procedures for the engagement of non-audit services have been adopted by the Audit Committee.

External Auditor Service Fees by Category

The aggregate fees billed by the Company's external auditors in the last two fiscal years for audit fees are set out in the table below. In the table, "Audit Fees" are fees billed by the Company's external auditor for services provided in auditing the Company's annual financial statements. "Audit-Related Fees" are fees not included in audit fees that are billed by the external auditor for assurance and related services that are reasonably related to the performance of the audit review of the Company's financial statements. "Tax Fees" are fees billed by the external auditor for professional services rendered for tax compliance, tax advice and tax planning. "All Other Fees" are fees billed by the external auditor for products and services not included in the foregoing categories. All fees are "as billed" on a cash basis by the Company. All amounts in the table are expressed in Canadian dollars.

Financial Year Ending	Audit Fees	Audit Related Fees[(1)]	Tax Fees[(2)]	All Other Fees
December 31, 2023	$335,000[(3)]	$73,200	$11,700	$-
December 31, 2022	$42,000	$42,500	$13,000	$-

Notes:

(1) Includes fees for services related to quarterly interim reviews and providing auditor consent letters with respect to financing related matters.

(2) Tax Fees related to the preparation of income tax returns for the Company and its subsidiaries, and fees related to the preparation of the Company's Scientific Research and Experimental Development claims.

(3) Includes fees related to the reaudit of the 2021/2022 financial statements as a result of appointment of KPMG LLP as auditor.

LEGAL PROCEEDINGS AND REGULATORY ACTIONS

To the Company's knowledge, there are no legal proceedings or regulatory actions to which the Company is a party, or has been a party to, or of which any of its property is the subject matter of, or was the subject matter of, since the beginning of the financial year ended December 31, 2023, and no such proceedings or actions are known by the Company to be contemplated.

As of December 31, 2023, and the date of this AIF, the Company is not subject to:

(a) any penalties or sanctions imposed against the Company by a court relating to securities legislation or by a securities regulatory authority during the financial year ended December 31, 2023;

(b) any other penalties or sanctions imposed by a court or regulatory body against the Company that would likely be considered important to a reasonable investor in making an investment decision; or

(c) settlement agreements the Company entered into before a court relating to securities legislation or with a securities regulatory authority during the financial year ended December 31, 2023.

The Company is unaware of any condition of default under any debt, regulatory, exchange related or other contractual obligation.

INTEREST OF MANAGEMENT AND OTHERS IN MATERIAL TRANSACTIONS

Other than as described elsewhere in this AIF, none of (i) the directors or executive officers of the Company, (ii) the shareholders who beneficially own or control or direct, directly or indirectly, more than 10% of the voting shares of the Company, or (iii) any associate or affiliate of the persons referred to in (i) and (ii), has or has had any material interest, direct or indirect, in any transaction within the three most recently completed financial years or during the

current financial year or in any proposed transaction that has materially affected or is reasonably expected to materially affect Eupraxia.

TRANSFER AGENT AND REGISTRAR

The registrar and transfer agent for the Common Shares in Canada and TSX Trust Company at its principal offices in Vancouver, British Columbia ("**TSX Trust**") and in the United States is Continental Stock Transfer and Trust Company at its principal offices in New York, New York. The Warrant Agent in respect of the listed Warrants is TSX Trust.

MATERIAL CONTRACTS

The following are "material contracts" of the Company, as defined in National Instrument 51-102 - *Continuous Disclosure Obligations*, that are outstanding as of the date of this AIF:

- The Amended and Restated License Agreement between Auritec and Eupraxia USA dated October 9, 2018, as amended, and the Security Agreement between Auritec and Eupraxia USA dated March 31, 2020.
- The warrant indenture between the Company and TSX Trust Company dated March 9, 2021.
- The 2021 contingent convertible debt agreement between the Company, Eupraxia Pharma, Inc., Eupraxia Holdings, Inc., Eupraxia Pharmaceuticals USA, LLC, SVB and SVB Innovation Credit Fund VIII, L.P dated June 21, 2021.
- The warrant indenture between the Company and TSX Trust Company dated April 20, 2022.

Copies of the foregoing documents are available on SEDAR+ at www.sedarplus.ca.

INTERESTS OF EXPERTS

Our auditors are KPMG LLP. KPMG LLP has confirmed with respect to the Company that they are independent within the meaning of the relevant rules and related interpretations prescribed by the relevant professional bodies in Canada and any applicable legislation or regulations, and are independent accountants with respect to us under all relevant U.S. professional and regulatory standards.

ADDITIONAL INFORMATION

Additional information relating to the Company, including directors' and officers' remuneration and indebtedness, principal holders of the Company's securities and securities authorized for issuance under equity compensation plans is contained in the Company's Management Information Circular dated May 8, 2023 and filed on SEDAR+ at www.sedarplus.ca. Additional financial information is provided in our audited consolidated financial statements and management's discussion and analysis for our most recently completed financial year, each of which and is available under the Company's profile at www.sedarplus.ca.

SCHEDULE "A"
Audit Committee Charter

PURPOSE

The primary function of the Audit Committee is to assist the board of directors (the "**Board**") of Eupraxia Pharmaceuticals Inc. (the "**Company**") in fulfilling its oversight responsibilities by reviewing the financial information to be provided to the shareholders and others, the systems of internal controls and management information systems established by the senior officers of the Company ("**Management**") and the Company's internal and external audit process and monitoring compliance with the Company's legal and regulatory requirements with respect to its financial statements.

The Audit Committee is accountable to the Board. In the course of fulfilling its specific responsibilities hereunder, the Audit Committee is expected to maintain an open communication between the Company's external auditors and the Board.

The Audit Committee does not plan or perform audits or warrant the accuracy or completeness of the Company's financial statements or financial disclosure or compliance with generally accepted accounting procedures as these are the responsibility of Management.

RESPONSIBILITIES

Subject to the powers and duties of the Board, the Board hereby delegates to the Audit Committee the following powers and duties to be performed by the Audit Committee on behalf of and for the Board. Nothing in this Charter is intended to or does confer on any member a higher standard of care or diligence than that which applies to the directors as a whole.

External Auditors

The Audit Committee has primary responsibility for the selection, appointment, dismissal, compensation and oversight of the external auditors, subject to the overall approval of the Board. For this purpose, the Audit Committee may consult with Management.

The external auditors shall report directly to the Audit Committee. In addition, the Audit Committee:

a. recommends to the Board:

   i. whether the current external auditors should be nominated for reappointment for the ensuing year and if applicable, select and recommend a suitable alternative for nomination; and

   ii. the amount of compensation payable to the external auditors;

b. resolves disagreements, if any, between Management and the external auditors regarding financial reporting;

c. provides the Board with such recommendations and reports with respect to the financial statements of the Company as it deems advisable;

d. takes reasonable steps to confirm the independence of the external auditors, including but not limited to pre-approving any non-audit related services provided by the external auditors to the Company or the Company's subsidiaries, if any;

e. confirms that the external auditors are a "participating audit" firm for the purpose of National Instrument 52-108 – *Auditor Oversight* and are in compliance with governing regulations;

f. reviews the plan and scope of the audit to be conducted by the external auditors of the Company;

g. reviews and evaluates the performance of the external auditors; and

h. reviews and approves the Company's hiring policy regarding partners, employees and former partners and employees of the Company's present and former external auditors.

Audit and Review Process and Results

The Audit Committee has a duty to receive, review and make any inquiry regarding the completeness, accuracy and presentation of the Company's financial statements to ensure that the financial statements fairly present the financial position and risks of the organization and that they are prepared in accordance with generally accepted accounting principles. To accomplish this, the Audit Committee:

a. considers the scope and general extent of the external auditors' review, including their engagement letter and major changes to the Company's auditing and accounting principles and practices;

b. consults with management regarding the sufficiency of the Company's internal system of audit and financial controls, internal audit procedures and results of such audits;

c. ensures the external auditors have full, unrestricted access to required information and have the cooperation of management;

d. reviews with the external auditors the audit process and standards, as well as regulatory or Company-initiated changes in accounting practices and policies and the financial impact thereof, and selection or application of appropriate accounting principles;

e. reviews with the external auditors and, if necessary, legal counsel, any litigation, claim or contingency, including tax assessments, that could have a material effect upon the financial position of the Company and the manner in which these matters are being disclosed in the financial statements;

f. reviews the appropriateness and disclosure of any off-balance sheet matters;

g. reviews disclosure of related party transactions;

h. receives and reviews with the external auditors, the external auditors' audit report and the audited financial statements;

i. makes recommendations to the Board respecting approval of the audited financial statements;

j. meets with the external auditors separately from management to review the integrity of the Company's financial reporting, including the clarity of financial disclosure and the degree of conservatism or aggressiveness of the accounting policies and estimates, any significant disagreements or difficulties in obtaining information, adequacy of internal controls over financial reporting, adequacy of disclosure controls and procedures, and the degree of compliance by the Company with prior recommendations of the external auditors;

k. directs management to implement such changes as the Audit Committee considers appropriate, subject to any required approvals of the Board arising out of the review; and

l. meets at least annually with the external auditors, independent of management, and reports to the Board on such meetings.

Interim Financial Statements

The Audit Committee:

a. reviews and determines the Company's practice with respect to review of interim financial statements by the external auditors;

b. conducts all such reviews and discussions with the external auditors and Management as it deems appropriate; and

c. makes recommendations to the Board respecting approval of the interim financial statements.

Involvement with Management

The Audit Committee has primary responsibility for overseeing the actions of management in all aspects of financial management and reporting. The Audit Committee:

a. reviews the Company's annual and interim financial statements, Management's Discussion and Analysis and earnings press releases, if any, before the Company publicly discloses this information;

b. reviews all of the Company's public disclosure of financial information extracted from the Company's financial statements, if such financial statements have not previously been reviewed by the Committee, prior to such information being made public by the Company and for such purpose,

the CFO assumes responsibility for providing the information to the Audit Committee for its review; reviews material financial risks with Management, the plan that Management has implemented to monitor and deal with such risks and the success of Management in following the plan;

c. consults annually and otherwise as required with the Company's CEO and CFO respecting the adequacy of the internal controls over financial reporting and disclosure controls and procedures and reviews any breaches or deficiencies;

d. obtains such certifications of annual and interim filings by the CEO and CFO attesting to internal controls over financial reporting and disclosure controls and procedures as deemed advisable;

e. reviews Management's response to significant written reports and recommendations issued by the external auditors and the extent to which such recommendations have been implemented by Management;

f. reviews with Management the Company's compliance with applicable laws and regulations respecting financial reporting matters, and any proposed regulatory changes and their impact on the Company; and

g. reviews as required with Management and approves disclosure of the Audit Committee Charter, and Audit Committee disclosure required in the Company's Annual Information Form, Information Circular and on the Company's website.

PROCEDURAL MATTERS

The Audit Committee:

a. invites the Company's external auditors, the CFO, and such other persons as deemed appropriate by the Audit Committee to attend meetings of the Audit Committee;

b. reports material decisions and actions of the Audit Committee to the Board, together with such recommendations as the Audit Committee may deem appropriate;

c. has the power to conduct or authorize investigations into any matter within the scope of its responsibilities;

d. has the right to engage independent counsel and other advisors as it determines necessary to carry out its duties and the right to set the compensation for any advisors employed by the Audit Committee;

e. has the right to communicate directly with the CFO and other members of Management who have responsibility for the internal and external audit process, as well as to communicate directly with the internal and external auditors; and

f. pre-approves non-audit services to be performed by the external auditors in accordance with the provisions of National Instrument 52-110 – *Audit Committees* ("**NI 52-110**").

COMPOSITION

The Audit Committee is composed of a minimum of three directors, all of whom are independent, subject to any exemptions or relief that may be granted from such requirements under NI 52-110, and have relevant skills and/or experience in the Audit Committee's areas of responsibility as may be required by the securities laws applicable to the Company, including those of any stock exchange on which the Company's securities are traded. No member shall have served as the CEO of the Company, or an affiliate, within the past five years, or as the CFO of the Company, or an affiliate, within the past three years.

The members of the Audit Committee shall not be members of more than three public company audit committees (including the Company), except for a member with demonstrable financial expertise such as a former CFO, who shall not be a member of more than four audit committees (including the Company).

Appointment of Committee Members and Vacancies

Members of the Audit Committee are appointed or confirmed by the Board annually and hold office at the pleasure of the Board. The Board fills any vacancy on, and may appoint any additional members to, the Audit Committee.

Committee Chair

The Board appoints a Chair for the Audit Committee.

STRUCTURE AND OPERATIONS

Meetings

The Chair of the Audit Committee or the Chair of the Board or any two of its members may call a meeting of the Audit Committee. The Audit Committee must meet at least four times each fiscal year, and at such other times during each year as it deems appropriate.

Quorum

A majority of the members appointed to the Audit Committee constitutes a quorum.

Notice of Meetings

The Chair of the Audit Committee arranges to provide notice of the time and place of every meeting in writing (including by electronic means) to each member of the Audit Committee at least two (2) business days prior to the time fixed for such meeting, provided, however, that a member may in any manner waive a notice of a meeting. Attendance of a member at a meeting constitutes a waiver of notice of the meeting, except where a member attends a meeting for the express purpose of objecting to the transaction of any business on the grounds that the meeting is not lawfully called. The Chair also ensures that an agenda for the meeting and all required materials for review by the members of the Audit Committee are delivered to the members with sufficient time for their review, or that such requirement is waived.

Absence of Committee Chair

If the Chair of the Audit Committee is not present at any meeting of the Audit Committee, the other members of the Audit Committee will choose a Chair to preside at the meeting.

Secretary of Committee

At each meeting the Audit Committee appoints a secretary who need not be a director of the Company.

Attendance of the Company's Officers at Meetings

The Chair of the Audit Committee or any two members of the Audit Committee may invite one or more officers of the Company to attend any meeting of the Audit Committee.

Delegation

The Audit Committee may, in its discretion and where permitted by NI 52-110, delegate all or a portion of its duties and responsibilities to a subcommittee, management or, to the extent otherwise permitted by applicable plans, laws or regulations, to any other body or individual.

Procedure and Records

Subject to any statute or constating documents of the Company, the Audit Committee determines its own procedures at meetings and may conduct meetings by telephone and keeps records of its proceedings.

REPORTING AND ASSESSMENT

The Audit Committee reports to the Board of Directors, and on an annual basis, presents to the Board a Committee Annual Report consisting of the Audit Committee's review of its charter, the Committee's and its Chair's performance over the past year, and any recommendations the Audit Committee makes in respect thereto.

EFFECTIVE DATE

This Charter was approved by the Board on March 2, 2021.

Exhibit 99.2

EUPRAXIA PHARMACEUTICALS INC.

CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2023 and 2022

(Expressed in U.S. Dollars)

EUPRAXIA PHARMACEUTICALS INC.
INDEX TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2023 and 2022
(Expressed in U.S. Dollars, except share amounts)

CONTENTS

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors

Eupraxia Pharmaceuticals Inc:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Eupraxia Pharmaceuticals Inc. (the Company) as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, changes in shareholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2023, and the related notes (collectively, the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2023, in conformity with U.S. generally accepted accounting principles.

Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has suffered recurring losses from operations and forecasted cash outflows from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ KPMG LLP

Chartered Professional Accountants

We have served as the Company's auditor since 2023.

Vancouver, Canada
April 1, 2024

EUPRAXIA PHARMACEUTICALS INC.
CONSOLIDATED BALANCE SHEETS
(Expressed in U.S. Dollars, except share amounts)

	December 31, 2023	December 31, 2022
ASSETS		
Current assets		
Cash and cash equivalents (Note 20)	$ 19,341,756	$ 18,263,389
Prepaid expenses and deposits	270,710	235,903
Amounts receivable (Note 4)	190,612	89,715
Total current assets	19,803,078	18,589,007
Non-current assets		
Prepaid expenses	6,904	2,492
Property and equipment, net (Note 5)	409,587	443,464
Right-of-use asset, net (Note 6)	46,660	87,286
Total assets	$ 20,266,229	$ 19,122,249
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable and accrued liabilities (Note 7)	$ 3,921,875	$ 2,928,566
Loans payable – current portion (Note 8)	62,709	79,418
Lease liability – current portion (Note 9)	53,316	50,403
Payable to Auritec (Note 10)	5,000,000	—
Convertible debt (Note 11)	10,336,003	—
Total current liabilities	19,373,903	3,058,387
Non-current liabilities		
Loans payable (Note 8)	—	62,709
Lease liability (Note 9)	—	51,303
Convertible debt (Note 11)	—	8,741,996
Total liabilities	19,373,903	11,914,395
Shareholders' equity (deficit)		
Share capital, without par value; unlimited shares authorized; issued and outstanding: 27,282,165 (December 31, 2022 - 21,593,145 (Note 12(b))	92,913,585	71,003,225
Additional paid-in capital (Notes 12(b), 12(c) and 12(d))	17,510,469	16,850,165
Deficit	(105,501,295)	(77,280,499)
Accumulated other comprehensive loss	(2,706,552)	(2,786,366)
Equity attributable to the owners of the Company	2,216,207	7,786,525
Non-controlling interest	(1,323,881)	(578,671)
Total shareholders' equity (deficit)	892,326	7,207,854
Total liabilities and shareholders' equity (deficit)	$ 20,266,229	$ 19,122,249

Nature of business and going concern (Note 1)
Commitments (Note 17)
Subsequent event (Note 21)

The accompanying notes are an integral part of these consolidated financial statements.

EUPRAXIA PHARMACEUTICALS INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Expressed in U.S. Dollars, except share amounts)

	Year ended December 31, 2023	Year ended December 31, 2022
Expenses		
General and administrative (Note 13)	$ 7,284,004	$ 3,987,598
Research and development (Note 14)	20,563,225	13,629,854
Total expenses	27,847,229	17,617,452
Other income/(expenses)		
Interest income	862,969	431,799
Interest expense (Note 19)	(1,170,173)	(982,856)
Loss on sale of equipment (Note 5)	(4,846)	(6,637)
Foreign exchange gain	66,291	240,547
Change in fair value of financial instruments (Note 11)	(836,595)	(1,056,165)
Total other income	(1,082,354)	(1,373,312)
Net loss before tax expense	(28,929,583)	(18,990,764)
Tax expense (Note 16)	(36,423)	—
Net loss for the year	$(28,966,006)	$(18,990,764)
Loss attributable to:		
Owners of the Company	$(28,220,796)	$(18,489,629)
Non-controlling interest	(745,210)	(501,135)
	(28,966,006)	(18,990,764)
Foreign currency translation adjustment	79,814	(1,276,388)
Comprehensive loss for the year	$(28,886,192)	$(20,267,152)
Loss per share – basic and diluted (Owners of the Company)	$ (1.17)	$ (0.96)
Weighted average shares outstanding – basic and diluted	24,146,623	19,285,447

The accompanying notes are an integral part of these consolidated financial statements.

EUPRAXIA PHARMACEUTICALS INC.
CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY
(Expressed in U.S. Dollars, except share amounts)

	Number of shares	Amount	Additional paid-in capital	Deficit	Accumulated other comprehensive income	Non-controlling interest	Total
Balance, December 31, 2021	14,242,595	$62,250,123	$ 13,226,108	$ (58,790,870)	$ (1,509,978)	$ (77,536)	$ 15,097,847
Overnight marketed public offering, net of transaction costs (Note 12(b)(i))	7,150,550	8,401,439	2,235,138	—	—	—	10,636,577
Redemption of warrants (Notes 12(b)(ii) and 12(d))	200,000	351,663	(44,893)	—	—	—	306,770
Share-based payments (Note 12(c))	—	—	1,433,812	—	—	—	1,433,812
Net loss for the year	—	—	—	(18,489,629)	—	(501,135)	(18,990,764)
Foreign Currency translation adjustment	—	—	—	—	(1,276,388)	—	(1,276,388)
Balance, December 31, 2022	21,593,145	71,003,225	16,850,165	(77,280,499)	(2,786,366)	(578,671)	7,207,854
Non-brokered private placement, net of transaction costs (Note 12(b)(v))	3,282,936	15,886,537	—	—	—	—	15,886,537
Share-based payments (Note 12(c))	—	—	1,412,257	—	—	—	1,412,257
Redemption of warrants (Notes 12(b)(iii) and 12(d))	2,385,484	5,974,988	(733,177)	—	—	—	5,241,811
Redemption of options (Notes 12(b)(iv) and 12(c))	20,600	48,835	(18,776)	—	—	—	30,059
Net loss for the year	—	—	—	(28,220,796)	—	(745,210)	(28,966,006)
Foreign currency translation adjustment	—	—	—	—	79,814	—	79,814
Balance, December 31, 2023	27,282,165	$92,913,585	$ 17,510,469	$(105,501,295)	$ (2,706,552)	$ (1,323,881)	$ 892,326

The accompanying notes are an integral part of these consolidated financial statements.

EUPRAXIA PHARMACEUTICALS INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Expressed in U.S. Dollars)

	Year ended December 31, 2023	Year ended December 31, 2022
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (28,966,006)	$ (18,990,764)
Items not affecting cash		
Accrued interest on convertible debt (Note 11)	571,603	643,233
Accrued interest on short term investments	—	(4,665)
Depreciation (Note 5 and 6)	155,527	147,894
Interest – lease liability	14,401	21,383
Loss on sale of equipment	4,846	6,879
Share-based payments (Note 12(c))	1,412,257	1,433,812
Change in fair value of financial instruments (Note 11)	836,595	1,056,165
Unrealized foreign exchange	(64,609)	(223,709)
Changes in operating assets and liabilities		
Accounts payable and accrued liabilities	577,908	1,324,049
Auritec payable (Note 10)	5,000,000	—
Prepaid expenses	(122,435)	(39,959)
Amounts receivable	(103,710)	230,481
Cash used in operating activities	(20,683,623)	(14,395,201)
CASH FLOWS FROM INVESTING ACTIVITIES		
Acquisition of equipment	(73,377)	(235,550)
Proceeds from sale of equipment (Note 5)	—	242
Purchase of short term investments	—	(3,272,379)
Proceeds from redemption of short-term investments	—	13,342,058
Cash provided by (used in) investing activities	(73,377)	9,834,371
CASH FLOWS FROM FINANCING ACTIVITIES		
Overnight marketed public offering (net of transaction costs) (Note 12(b)(i) and (v))	15,886,537	10,636,577
Redemption of warrants (Note 12(d))	5,241,811	306,770
Redemption of options (Note 12 (c))	30,059	—
Repayment of loans (Note 8)	(79,441)	(74,845)
Lease payments (Note 9)	(64,996)	(67,423)
Cash provided by financing activities	21,013,970	10,801,079
Increase in cash and cash equivalents	256,970	6,240,249
Foreign exchange effect on cash and cash equivalents	821,397	(507,395)
Cash and cash equivalents, beginning of year	18,263,389	12,530,535
Cash and cash equivalents, end of year	**$ 19,341,756**	**$ 18,263,389**

Supplemental disclosure with respect to cash flows (Note 20)

The accompanying notes are an integral part of these consolidated financial statements.

EUPRAXIA PHARMACEUTICALS INC.
NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2023 and 2022
(Expressed in U.S. Dollars, except share amounts)

1. NATURE OF BUSINESS AND GOING CONCERN

Eupraxia Pharmaceuticals Inc. (the "Company") was incorporated under the laws of the province of Alberta on May 12, 2011, under the name Plaza Capital Partners Inc. On May 11, 2012, the Company changed its name to Eupraxia Pharmaceuticals Inc. and continued from the province of Alberta to the province of British Columbia.

On October 10, 2012, Eupraxia Holdings, Inc. ("Holdings") was incorporated under the laws of the State of Delaware, USA. On November 16, 2012, Holdings was registered as an extra-provincial corporation under the laws of the province of British Columbia, Canada. On October 10, 2012, Eupraxia Pharmaceuticals USA, LLC ("Eupraxia USA") was incorporated under the laws of the State of Delaware. On November 16, 2012, Eupraxia USA was registered as an extra-provincial corporation under the laws of the province of British Columbia. On January 7, 2021, Eupraxia Pharma, Inc. ("Eupraxia Pharma") was incorporated under the laws of the State of Delaware. On July 4, 2022, Eupraxia Pharmaceuticals Australia Pty Ltd. ("Eupraxia Australia") was incorporated under the laws of the state of Victoria, Australia. On May 17, 2023, Eupraxia Pharma USA Inc. ("Eupraxia Pharma USA") was incorporated under the laws of the State of Delaware.

On March 9, 2021, the Company completed its initial public offering on the Toronto Stock Exchange ("TSX") and began trading under the symbol "EPRX".

The Company is a clinical stage biotechnology company leveraging its proprietary Diffusphere™ technology to optimize drug delivery for applications with significant unmet medical need. The address of the Company's corporate office and principal place of business is 201- 2067 Cadboro Bay Road, Victoria, British Columbia, Canada.

These consolidated financial statements have been prepared on a going concern basis with the assumption that the Company will be able to realize its assets and discharge its liabilities and commitments in the normal course of business. At December 31, 2023, the Company had cash and cash equivalents of $19,341,756. The Company has not yet generated revenue from operations. The Company incurred a net loss of $28,966,006 during the year ended December 31, 2023, and as of that date, the Company's accumulated deficit was $105,501,295. As the Company is in the research and development stage, the recoverability of the costs incurred to date is dependent upon the ability of the Company to obtain the necessary funding to complete the research and development of its projects and upon future commercialization or proceeds from the monetization of research activities. The Company will periodically have to raise funds to continue operations and raised $15,886,537 (CDN$20,836,005) through a non-brokered private placement of 3,183,875 common shares in 2023 (2022 - $11,768,459 through a marketed public offering) and raised $25,026,073 (CDN$33,867,784) through an overnight marketed public offering of 8,260,435 common shares in 2024. Although it has been successful in doing so in the past, there is no assurance it will be able to do so in the future, especially with the ongoing conflicts in the Ukraine and the Middle East affecting the global capital markets. Recent developments with Silicon Valley Bank ("SVB") have not impacted the Company's outlook for cash runway. The Company holds no amounts on deposit with SVB and the convertible debt (see Note 11 – Convertible Debt) which matures in June 2024 remains in good standing, is fully drawn and is not callable by SVB. The Company is active in its pursuit of additional funding through potential partnering and other strategic activities as well as grants to fund future research and development activities, and additional equity financing.

1. NATURE OF BUSINESS AND GOING CONCERN (continued)

The continued operations of the Company are dependent on its ability to generate future cash flows or obtain additional funding. There is a risk that in the future, additional financing will not be available on a timely basis or on terms acceptable to the Company. These events and conditions may cast substantial doubt about the Company's ability to continue as a going concern. These consolidated financial statements do not include any adjustments to the amounts and classification of assets and liabilities that might be necessary should the Company be unable to continue in business.

2. BASIS OF PRESENTATION

These consolidated financial statements are presented in U.S. dollars and have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP"). These consolidated financial statements include the accounts of the Company and the accounts of its subsidiaries. All significant intercompany transactions and balances have been eliminated upon consolidation.

Change in Reporting Currency to the US Dollar

Effective December 31, 2023, the Company changed its reporting currency to the US dollar ("USD") from the Canadian dollar ("CDN"). As such, all prior amounts originally reported in CDN are now reported in USD. The change in reporting currency was made to enhance comparability of the Company's results with other publicly traded companies in the life sciences industry. The Canadian dollar continues to be the functional currency of the Company.

In accordance with ASC 830, the consolidated financial statements of the Company are translated into U.S. dollars using the current rate method. Assets and liabilities are translated at the rate of exchange prevailing at the consolidated balance sheet date. Shareholders' equity is translated at the applicable historical rate. Revenue, expense and cash flow items are translated at the exchange rate in effect on the transaction dates. Translation gains and losses are reported as a separate component of shareholders' equity titled Accumulated Other Comprehensive Income.

The financial information for all prior periods is presented in U.S. dollars as if the U.S. dollar had been used as the reporting currency during those periods.

Transition to US GAAP

This is the first year that the Company's consolidated financial statements are prepared in accordance of generally accepted accounting principles in the United States of America **("GAAP")** as issued by the Financial Accounting Standards Board (**"FASB"**). Previously, the Company prepared its financial statements in accordance with IFRS Accounting Standards as issued by the International Accounting Standards Board ("IASB").

The policies set out in the Significant Accounting Policies section have been applied in preparing the financial statements for the years ended December 31, 2023 and 2022. In addition, comparative figures, which were previously prepared in accordance with IFRS, have been adjusted as required to be compliant with the Company's accounting policies under US GAAP.

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Measurement

The consolidated financial statements have been prepared on a historical cost basis, except for certain financial instruments which are measured at fair value. The consolidated financial statements are presented in U.S. dollars, which is the Company's reporting currency. The Company's functional currency is the Canadian dollar.

The preparation of consolidated financial statements in accordance with U.S. GAAP requires the Company to make estimates and judgments in certain circumstances that affect the reported amounts of assets, liabilities, expenses, and related disclosure. On an ongoing basis, the Company evaluates its estimates, most notably those related to accrual of expenses including clinical and preclinical study expense accruals, stock-based compensation, valuation allowance for deferred taxes, and fair value measurement of convertible debt. Management bases its estimates on historical experience and on various other assumptions that it believes to be reasonable under the circumstances. Actual results could differ from these estimates.

(Expressed in U.S. Dollars, except share amounts)

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Basis of Measurement (continued)

Consolidation

These consolidated financial statements include the accounts of the Company and the accounts of its subsidiaries. The financial statements of subsidiaries are included in the consolidated financial statements from the date that control commences until the date that control ceases. Control exists when an entity is exposed to or has rights to variable returns from its involvement with the entity and has the ability to affect these returns through its power over the entity. All significant intercompany transactions and balances have been eliminated.

Non-controlling interest in the net assets of consolidated subsidiaries are identified separately from the Company's equity. Non-controlling interest consists of the non-controlling interest as at the date of the original transaction plus the non-controlling interest's share of changes in equity since that date.

Company Entity	Date of Incorporation	Jurisdiction of Incorporation	Effective Interest (Note 13(e))
Eupraxia Holdings, Inc.	October 10, 2012	Delaware, USA	95%
Eupraxia Pharmaceuticals USA, LLC	October 10, 2012	Delaware, USA	95%
AMDM Holdings Inc.[2]	April 6, 2016	Washington, USA	95%
Eupraxia Pharma, Inc.	January 7, 2021	Delaware, USA	95%
Eupraxia Pharmaceuticals Australia Pty Ltd.	July 4, 2022	Victoria, Australia	100%[1]
Eupraxia Pharma USA Inc.	May 17, 2023	Delaware, USA	100%[1]

(1) Wholly-owned subsidiary of Eupraxia Pharmaceuticals Inc.
(2) Date of Control occurred on January 31, 2021 (see Note 13(e)).

Earnings (Loss) per Share

The Company applies the "Treasury Stock Method" to calculate loss per common share. Under this method, the basic earnings (loss) per share is calculated based on the weighted average aggregate number of common shares outstanding during each period. The diluted earnings (loss) per share assumes that the outstanding stock options and share purchase warrants had been exercised at the beginning of the period, or date of issuance if issued during the period, and proceeds from dilutive instruments are used to purchase common shares at the average market price during the period. Since the Company was in a loss position for the years ended December 31, 2023 and 2022, the assumed conversion of outstanding common share warrants, options, and convertible instruments has an anti-dilutive impact, therefore the diluted loss per share is equal to basic loss per share.

Equipment

Equipment is recorded at historical cost less accumulated depreciation and accumulated impairment losses. Depreciation is provided over the estimated useful lives of the assets as follows:

Computers	45% declining balance
Office furniture and equipment	20% declining balance
Leasehold improvements	straight-line over the shorter of the initial term of the lease or useful life
Lab equipment	20% declining balance

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Equipment (continued)

The useful lives and depreciation methods applied to each category of equipment are assessed on an annual basis by management and adjusted where necessary to reflect the recoverability of equipment.

Research and Development Expenditures

Research and development costs are expensed as they are incurred. These costs consist primarily of salaries and wages related to research and development activities, including share-based payments for employees engaged in research and development, clinical trial expenses and other research costs.

Investment Tax Credits

Investment tax credits ("ITCs") arising from research and development activities are deducted from the related costs and are included in profit or loss when there is reasonable assurance that the credits will be realized. ITCs arising from the acquisition or development of equipment and capitalized development costs are deducted from the cost of those assets with amortization calculated on the net amount.

Government Grants

Government grants related to research and development activities are recognized in profit or loss as a deduction from the related expenditure when there is reasonable assurance that the grant will be received. Grants that compensate the Company for the cost of an asset are recognized in profit or loss on a systematic basis over the useful life of the asset.

Government Assistance

Government contributions are recognized and deducted from the related costs when there is reasonable assurance that the contribution will be received and all attached conditions have been complied with by the Company. Government contributions arising from the acquisition or development of equipment and capitalized development costs are deducted from the cost of those assets with amortization calculated on the net amount.

Income Taxes

Current income tax is the expected tax payable or recoverable on the taxable profit or loss for the year using tax rates enacted at the reporting date and any adjustment to tax payable from previous years.

Deferred tax is recorded using the asset and liability method, providing for temporary differences, between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for taxation purposes. Temporary differences are not provided for if they relate to goodwill not deductible for tax purposes, or differences relating to investments in subsidiaries to the extent that they will probably not reverse in the foreseeable future. The amount of deferred tax provided is based on the expected manner of realization or settlement of the carrying amount of assets and liabilities, using tax rates and laws enacted at the reporting date and expected to apply when these differences reverse. A deferred tax asset is recognized only to the extent that it is more likely than not that future taxable profits will be available against which the asset can be utilized.

The Company uses a two-step process to recognize and measure the income tax benefit of uncertain tax positions taken or expected to be taken in a tax return. The tax benefit from an uncertain tax position is recognized if it more likely than not that the position will be sustained upon examination of the tax authority based solely on the technical merits of the position. A tax benefit that meets the more likely than not recognition threshold is measured as the largest amount that is greater than 50% likely to realized upon settlement with the tax authority. To the extent a full benefit is not expected to be realized, an income tax liability is established. Any change in judgement related to the expected resolution of an uncertain tax provision is recognized in the year of such a change. Interest an penalties related to income tax are included as a component of income tax expense.

Share-based Payments

The Company grants stock options to employees, directors and officers pursuant to stock option plans described in note 13c. Employee stock-based compensation expense is measured at the grant date, based on the estimated fair value of the award, and is recognized as an expense, net of actual forfeitures, over the requisite service period with a corresponding increase in additional paid-in capital. Stock-based compensation expense is amortized on a straight-line basis over the requisite service period for the entire award, which is generally the vesting period of the award.

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Share-based Payments (continued)

Any consideration received on exercise of stock options is credited to share capital.

Share Capital and Warrants

The Company records proceeds from share issuances net of issue costs and any related tax effects. Common shares issued for consideration other than cash are valued based on their market value at the date the agreement to issue shares was concluded. When units are issued during a private placement, which include both common shares and share purchase warrants, the warrants are classified as equity and as such, the proceeds should be allocated based on the relative fair values of the base instrument and the warrants on the day of the announcement of the private placement. Any value of the warrants is allocated to the warrants and credited to additional paid-in capital.

Foreign Currency Translation

The functional currency for each of the Company and the Company's subsidiaries is the currency of the primary economic environment in which each entity operates. Determination of functional currency may involve certain judgments to determine the primary economic environment. The Company reconsiders the functional currency of its entities if there is a change in events and conditions which determine the primary economic environment. The functional currency of Eupraxia Pharmaceuticals Inc., the parent entity, and each of the Company's subsidiaries is the Canadian dollar.

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Foreign Currency Translation (continued)

Transactions in foreign currencies are translated to the functional currency of the entity at the exchange rate at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies at the reporting date are retranslated at the period end date exchange rates.

Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rate at the date of the transaction. Non-monetary assets and liabilities denominated in foreign currencies that are measured at fair value are re-translated to the functional currency at the exchange rate at the date that the fair value was determined. Foreign currency differences arising on re-translation are recognized in profit or loss.

The reporting currency of the Company's consolidated financial statements is the U.S. dollar. All assets and liabilities are translated from the functional currency to the reporting currency using the spot rate at the period end date, equity components are translated at the historical rate, and income and expenses are translated using the average exchange rate for the period. All foreign currency differences arising on translation from functional to reporting currency are included in accumulated other comprehensive income.

Impairment of Long-Lived Assets

The Company assesses the recoverability of its long-lived assets whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of the long-lived asset is measured by a comparison of the carrying amount of the asset to future undiscounted net cash flows expected to be generated by the asset or group of assets. If carrying value exceeds the sum of undiscounted cash flows, the Company then determines the fair value of the underlying asset. Any impairment to be recognized is measured by the amount by which the carrying amount of the asset group exceeds the estimated fair value of the asset or asset group. As of December 31, 2023 and 2022, the Company determined that there were no indicators of impairment of long-lived assets.

Cash and Cash Equivalents

Cash and cash equivalents include cash on hand, bank deposits, and highly liquid investments with original maturities of three months or less from the date of purchase that are readily convertible to known amounts of cash and subject to insignificant risk of changes in value. Cash equivalents are recorded at cost plus accrued interest.

Short Term Investments

Short term investments include highly liquid investments with original maturity dates greater than three months and less than one year and cannot be redeemed prior to maturity without incurring a penalty.

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Financial Instruments and Fair Value

The Company measures certain financial instruments and other items at fair value into a three-level hierarchy established by US GAAP that prioritizes those inputs to valuation techniques used to measure fair value on the degree to which they are observable. This hierarchy includes:

i. Level 1 – Unadjusted quoted prices in active markets for identical instruments.

ii. Level 2 – Inputs other than quoted prices included within Level 1 that are observable for the financial instrument, either directly or indirectly. Level 2 inputs include quoted prices for similar assets or liabilities in active markets, quoted prices for identical or similar assets or liabilities in markets that are not active, inputs other than quoted prices that are observable for the asset or liability and inputs that are derived principally from or corroborated by observable market data by correlation or other means.

iii. Inputs are unobservable and reflect the Company's assumptions as to what market participants would use in pricing the asset or liability. The Company develops these inputs based on the best information available.

Assets and liabilities are classified on the lowest level of input that is significant to the fair value measurements. Reclassification of the level may be a result of changes in the observability of the valuation inputs for certain instruments within the fair value hierarchy. The carrying value of accounts receivable, accounts payable, and accrued expense approximate fair value due to the short-term nature of these instruments. On a recurring basis, the Company's cash and cash equivalents and marketable securities are measured at fair value.

3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (continued)

Financial Instruments and Fair Value (continued)

Leases

Leases classified as operating leases are recorded as lease liabilities based on the present value of minimum lease payments over the lease term, discounted using the lessor's rate implicit in the lease or the Company's incremental borrowing rate, if the lessor's implicit rate is not readily determinable. The lease term includes all periods covered by renewal and termination options where the Company is reasonably certain to exercise the renewal options or not to exercise the termination options. Corresponding right-of-use assets are recognized consisting of the lease liabilities, initial direct costs and any lease incentive payments. Lease liabilities are drawn down as lease payments are made and right-of-use assets are depreciated over the term of the lease. Operating lease expenses are recognized on a straight-line basis over the term of the lease, consisting of interest accrued on the lease liability and depreciation of the right-of-use asset, adjusted for changes in index-based variable lease payments in the period of change. Lease payments on short-term operating leases with lease terms twelve months or less are expensed on a straight-line basis over the lease term.

Upcoming Accounting Standards and Interpretations

The Company has not yet adopted certain new standards, amendments and interpretations to existing standards, which have been published but are only effective for accounting periods beginning on or after January 1, 2024 or later periods. The new and amended standards are not expected to have a material impact on the Company's consolidated financial statements.

(Expressed in U.S. Dollars, except share amounts)

4. AMOUNTS RECEIVABLE

	December 31, 2023	December 31, 2022
Government grants (Note 14)	$ —	$ 13,892
GST/HST recoverable	85,879	38,658
Other refundable tax credits [(1)]	104,733	37,165
Total	**$ 190,612**	**$ 89,715**

(1) Other refundable tax credits are due to tax incentives for R&D costs incurred by Eupraxia Australia (Note 14 – Research and Development Expenses).

(Expressed in U.S. Dollars, except share amounts)

5. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following:

	Computers	Office furniture and equipment	Leasehold Improvements	Lab Equipment	Total
Cost					
As at January 1, 2022	**$101,754**	**$ 73,267**	**$ 134,333**	**$289,569**	**$598,923**
Additions	20,279	5,551	—	209,720	235,550
Disposals	(47,603)	(8,158)	—	—	(55,761)
Foreign currency adjustments	(3,852)	(4,261)	(8,589)	(25,736)	(42,438)
As at December 31, 2022	**70,578**	**66,399**	**125,744**	**473,553**	**736,274**
Additions	18,534	—	—	54,843	73,377
Disposals	(5,488)	—	—	(16,124)	(21,612)
Foreign currency adjustments	2,001	1,597	3,023	12,992	19,613
As at December 31, 2023	**85,625**	**67,996**	**128,767**	**525,264**	**807,652**
Accumulated Depreciation					
As at January 1, 2022	**71,187**	**46,965**	**91,345**	**38,631**	**248,128**
Depreciation	17,153	5,256	14,366	73,328	110,103
Disposals	(43,540)	(5,342)	—	—	(48,882)
Foreign currency adjustments	(2,295)	(2,853)	(6,410)	(4,981)	(16,539)
As at December 31, 2022	**42,505**	**44,026**	**99,301**	**106,978**	**292,810**
Depreciation	17,612	4,492	13,849	76,930	112,883
Disposals	(5,162)	—	—	(11,604)	(16,766)
Foreign currency adjustments	1,226	1,149	2,666	4,097	9,138
As at December 31, 2023	**56,181**	**49,667**	**115,816**	**176,401**	**398,065**
Net Book Value					
As at December 31, 2022	**28,073**	**22,373**	**26,443**	**366,575**	**443,464**
As at December 31, 2023	**$ 29,444**	**$ 18,329**	**$ 12,951**	**$348,863**	**$409,587**

During the year ended December 31, 2023 and 2022, depreciation expense of $112,883 and $110,103, respectively, was recognized with $13,276 included in general and administrative and $99,606 included in research and development ($13,870 and $96,233 for general and administrative, and research and development in 2022, respectively).

6. RIGHT-OF-USE ASSET

The following table presents details of movement in the carrying value of the right-of-use asset:

	December 31, 2023	December 31, 2022
Balance, beginning	**$ 87,286**	**$ 132,020**
Depreciation	(42,644)	(37,791)
Foreign Exchange	2,018	(6,943)
Balance, ending	**$ 46,660**	**$ 87,286**

During the year ended December 31, 2023 and 2022, depreciation expense of $42,644 and $37,791, respectively, was recognized with $15,740 included in general and administrative and $26,904 included in research and development ($13,877 and $23,914 for general and administrative, and research and development in 2022, respectively).

(Expressed in U.S. Dollars, except share amounts)

7. ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

	December 31, 2023	December 31, 2022
Research and development	$ 1,968,263	$ 2,137,336
General and administrative	1,040,204	261,933
Wages and payroll remittances	18,357	15,996
Employee bonus payable[(1)]	858,628	513,301
Taxes payable	36,423	—
Total	**$ 3,921,875**	**$ 2,928,566**

(1) Bonus relates to corporate bonuses for the years ended December 31, 2023 and 2022.

8. LOANS PAYABLE

On September 10, 2021, the Company entered into a Master Loan and Security Agreement ("Loan Agreement") whereby the Company borrowed $235,000 to purchase production and test equipment (see Note 5 – Property and Equipment).

The Loan Agreement has a term of 36 months commencing September 13, 2021. The Loan Agreement accrues interest at 5.84% per annum with monthly payments (principal and interest) being made on the 1st of each month, beginning October 1, 2021. As part of the agreement, the Company granted the lender first priority interest on the equipment it purchased.

Below is a breakdown of loan balance as at December 31, 2023 and December 31, 2022:

	December 31, 2023	December 31, 2022
Balance, beginning	**$ 142,127**	**$ 216,994**
Loan repayment	(79,441)	(74,845)
Foreign exchange adjustment	23	(22)
Balance, ending	**$ 62,709**	**$ 142,127**
Current portion	**$ 62,709**	**$ 79,418**
Non-current portion	**$ —**	**$ 62,709**

(Expressed in U.S. Dollars, except share amounts)

9. LEASE LIABILITY

The Company entered into an operating lease agreement for its Victoria, BC facility (of approximately 4,900 square feet of office space) which expires on November 30, 2024.

The cost components of the operating lease were as follows for the years ended December 31, 2023 and 2022:

	December 31, 2023	December 31, 2022
Lease Cost		
Operating lease expense	$ 64,996	$ 67,423
Variable lease expense	68,584	66,455
Lease term and Discount Rate		
Weighted average remaining lease term (years)	0.92	1.92
Weighted average discount rate	14%	14%

Variable lease costs are payments that vary because of changes in facts or circumstances and include common area maintenance and property taxes related to the premises. Variable lease costs are excluded from the calculation of minimum lease payments.

The Company's future minimum lease payments as of December 31, 2023 are as follows:

Year ending December 31:	
2024	60,780
Total undiscounted future minimum lease payments	**$60,780**
Less: balance of unused tenant allowance	—
Less: imputed interest	(7,464)
Present value of lease liabilities at December 31, 2023	**$53,316**

The lease liability balance is comprised as follows:

	December 31, 2023	December 31, 2022
Current portion	$ 53,316	$ 50,403
Non-current portion	—	51,303
	$ 53,316	**$ 101,706**

During the year ended December 31, 2023, the Company subleased approximately 616 square feet office space with amounts totaling $24,387 for the year ended December 31, 2023 ($24,387 – year ended December 31, 2022) being recorded as a reduction to general and administrative expenses.

(Expressed in U.S. Dollars, except share amounts)

10. AURITEC LICENSE AGREEMENT

Eupraxia USA entered into an amended and restated license agreement with Auritec Pharmaceuticals Inc. ("Auritec") on October 9, 2018 (as further amended, the "Amended and Restated License Agreement"). Under the terms of the Amended and Restated License Agreement, Auritec has granted Eupraxia USA an exclusive license (including the right to sublicense to its affiliates and third parties) under the licensed patents owned or controlled by Auritec and for all the technical information and know-how relating to the technology claimed in such patents or possessed by Auritec with respect to the use of Auritec's "Plexis Platform" for the delivery of fluticasone in all medical fields (except for otolaryngology and the prevention, treatment and control of all diseases, disorders and conditions of the eye and its adnexa (collectively, the "Excluded Fields")), to develop, make, have made, manufacture, use, commercialize, sell, sub-license, offer for sale, import, and have imported products for the delivery of fluticasone drug products using the Plexis Platform in all medical fields except the Excluded Fields ("Licensed Products").

Pursuant to the terms of the Amended and Restated License Agreement, Eupraxia USA has paid $5,000,000 to Auritec (the "Upfront Fee"). In addition, Eupraxia USA has agreed to pay Auritec up to $30,000,000 upon achievement of certain regulatory and commercial milestones related to products licensed under the Amended and Restated License Agreement ("Licensed Products") as well as a royalty of 4% of net sales of Licensed Products by Eupraxia USA or its affiliates, subject to certain reductions.

The following table summarizes the milestone payment schedule. As of December 31, 2023, the only milestone that has been accrued and provided for in the financial statements is $5,000,000 related to the successful completion of the Phase 2b clinical study. It was recorded under research and development (see Note 14 – Research and Development Expenses).

Milestone Event	Milestone Payment
Successful Completion of a Phase 2b Study	5,000,000
First OA Regulatory Approval	5,000,000
Second OA Regulatory Approval	5,000,000
Non-OA Indication Regulatory Approval	10,000,000
First calendar year in which aggregate Net Sales by Eupraxia USA, its affiliates and sublicenses exceed $500,000,000	5,000,000
Maximum milestones payable	**$30,000,000**

(Expressed in U.S. Dollars, except share amounts)

10. AURITEC LICENSE AGREEMENT (continued)

Eupraxia USA also agreed to pay to Auritec 20% of sublicensing royalties or other consideration based on net sales of Licensed Products. Eupraxia USA further agreed to pay Auritec a percentage of Non-Royalty Monetization Revenue (as defined in the Amended and Restated License Agreement), which includes payments received for a sale of Eupraxia USA or its assets or sale or sublicense of a Licensed Product, which percentage ranges from 10% to 30% depending on the development stage of the most-advanced Licensed Product, up to a maximum of $100,000,000. The following table summarizes the Non-Royalty Monetization Revenue percentage schedule:

Date of Execution	Percentage of Non-Royalty Monetization Revenue
Prior to Successful Completion of a Phase 2b Study	30%
After Successful Completion of a Phase 2b Study but prior to Successful Completion of a Phase 3 Study	20%
After Successful Completion of a Phase 3 Study but prior to Regulatory Approval of a Product in the Eupraxia Field from FDA in the United States	15%
After Regulatory Approval of a Product in the Eupraxia Field from FDA in the United States	10%

Either party may terminate the Amended and Restated License Agreement in the event of the other party's bankruptcy, liquidation, or dissolution. Auritec may also terminate upon a material breach of the Amended and Restated License Agreement by Eupraxia USA that is not cured within 60 days (15 days in the case of a payment breach). Further, if Eupraxia USA directly or indirectly challenges any claim in any Auritec patent licensed under the Amended and Restated License Agreement, or assist a third party in doing so, Auritec may immediately terminate the Amended and Restated License Agreement. If Auritec directly or indirectly challenges any Eupraxia patent contemplated in the Amended and Restated License Agreement other than as reasonably required to defend Auritec patents as a basis for such challenge, or assists a third party in doing so, we may immediately terminate the Amended and Restated License Agreement.

11. CONVERTIBLE DEBT

On June 21, 2021, the Company entered into a contingent convertible debt agreement (the "Debt Agreement") with Silicon Valley Bank ("SVB") and concurrently drew down, in full, the CDN$10,000,000 principal amount under the Debt Agreement.

The Debt Agreement has a term of 36 months (or 48 months at SVB's election). The Debt Agreement accrues interest at the greater of 2.45% and the Canadian prime rate, requiring monthly interest payments. An additional payment in kind will accrue at a rate of 7% per annum, which will be settled at maturity or on conversion. During the year ended December 31, 2022, the Canadian prime rate ranged from 2.45% - 6.45%. During the year ended December 31, 2023, the Canadian prime rate ranged from 6.45% - 7.20%.

Subject to the terms and conditions of the Debt Agreement, SVB may elect to convert the principal amount of the convertible debt and the accrued and unpaid interest thereon into common shares at a conversion price equal to CDN$5.68 per common share. The conversion price of the accrued and unpaid interest will be subject to the minimum pricing requirements of the TSX, to the extent applicable, at the time of conversion.

The Company will have the right (the "Call Right") to call the convertible debt by paying to SVB an amount equal to:

i. 125% of the principal amount of the convertible debt (less principal amounts previously repaid), if the Call Right is exercised on or before the 18 month anniversary of the date of the Debt Agreement; and

ii. 150% of the principal amount of the convertible debt (less principal amounts previously repaid), if the Call Right is exercised after the 18 month anniversary of the date of the Debt Agreement,

(Expressed in U.S. Dollars, except share amounts)

11. CONVERTIBLE DEBT (continued)

in either case together with all accrued and unpaid interest on the principal balance of the convertible debt. If the Call Right is exercised by the Company, SVB will retain certain lookback rights in the event the Company subsequently announces its topline data from its Phase 2 clinical study or the Company enters into an agreement to be acquired in the 12 months following the exercise of the Call Right. The Company has agreed to grant SVB a security interest in all of its assets, excluding its patents and other intellectual property, and the testing and product equipment by way of the loan agreement it entered into on September 10, 2021 (Note 8 – Loans Payable) as security for its obligations under the Debt Agreement.

The Company was required, on or prior to June 30, 2022, to raise additional net new capital, as defined in the Debt Agreement, in the aggregate amount of CDN$10,000,000. During the year ended December 31, 2022, the Company completed a CDN$14.7 million financing which satisfied the net new capital requirement of the Debt Agreement (see Note 12 – Share Capital).

The loan balance is comprised of the following:

Balance – December 31, 2021	**$ 7,507,755**
Accrued interest	958,669
Interest paid	(315,436)
Change in fair value	1,056,165
Foreign exchange	(465,157)
Balance – December 31, 2022	**$ 8,741,996**
Accrued interest	1,162,773
Interest paid	(591,170)
Change in fair value	836,595
Foreign exchange	185,809
Balance – December 31, 2023	**$10,336,003**

12. SHARE CAPITAL AND OTHER COMPONENTS OF EQUITY

a) Authorized

- An unlimited number of Common shares, with no par value, with one vote per share.
- An unlimited number of Preferred shares, with no par value (none have been issued to date).

b) Issued

Capital transactions which took place during the year ended December 31, 2022 are as follows:

i) On April 20, 2022, the Company announced that it had closed an overnight marketed public offering (the "Offering"). Pursuant to the Offering, Eupraxia issued 7,150,550 units at a price of CDN$2.05 per unit and 181,000 warrants at a price of CDN$0.30 per warrant for aggregate gross proceeds of $11,768,459 ($9,309,707 related to the value of the shares and $2,458,752 related to the value of the warrants).

Each unit consists of one common share and one common share purchase warrant. Each warrant entitles the holder thereof to acquire one common share at an exercise price of CDN$3.00 per common share for a period of 48 months, expiring on April 20, 2026.

As consideration for the services rendered by the Underwriters in connection with the Offering, the Company paid the Underwriters a cash commission of $823,792 ($660,605 for the shares and $163,187 for the warrants) which is equal to 7% of the gross proceeds raised under the Offering and granted 500,538 warrants ("Compensation Warrant"), which is equal to 7% of the total units and warrants issued in the Offering. Each Compensation Warrant entitles the holder thereof to acquire one common share at an exercise price of CDN$2.05 per common share for a period of 48 months, expiring on April 20, 2026. An additional $68,470 in legal and agents' expenses were also paid to the Underwriters ($54,839 for the shares and $13,631 for the warrants). The Company incurred an additional $239,620 ($192,824 for the shares and $46,796 for the warrants) in share issuance costs associated with the Offering.

ii) During the year ended December 31, 2022, 200,000 common shares were issued on the exercise of warrants for gross proceeds of $306,770. The weighted average share price during the period in which these warrants were exercised was CDN$4.18. On exercise, $44,893 was transferred from additional paid-in capital to share capital.

Capital transactions which took place during the year ended December 31, 2023, are as follows:

iii) During the year ended December 31, 2023, 2,385,484 common shares were issued on the exercise of warrants for gross proceeds of $5,241,811. The weighted average share price during the period in which these warrants were exercised was CDN$7.15. On exercise, $733,177 was transferred from additional paid-in capital to share capital.

iv) During the year ended December 31, 2023, 20,600 common shares were issued on the exercise of options for gross proceeds of $30,059. The weighted average share price during the period in which these options were exercised was CDN$2.00. On exercise, $18,776 was transferred from additional paid-in capital to share capital.

v) On August 18, 2023, the Company closed a non-brokered private placement (the "Private Placement"). Pursuant to the Private Placement, the Company issued 3,183,875 common shares at a price of CDN$7.00 per Common share for aggregate gross proceeds of $16,445,635. The Company incurred cash costs of issuing shares of $559,098. In addition, the Company issued 99,061 common shares as finder's fees which were valued at $511,681.

(Expressed in U.S. Dollars, except share amounts)

12. SHARE CAPITAL AND OTHER COMPONENTS OF EQUITY (continued)

c) Options

Under the Amended Stock Option Plan (the "Amended Plan"), approved by the Board of Directors on October 27, 2021, and ratified by Shareholders on December 3, 2021, the Board of Directors may grant stock options to directors, officers, employees and consultants of the Company up to an aggregate of 18.5% of the Company's then issued and outstanding common shares.

Options granted under the Amended Plan have lives of up to ten years from the date of grant. The vesting schedule of all granted options is determined at the discretion of the Board. Unless otherwise determined by the Board, in its sole discretion, all grants of options will vest over a three-year period, with the first twenty-five percent (25%) of the Options vesting on the date of grant, and the remaining options vesting over the following thirty-six-month period in three equal instalments on an annual basis.

The following table summarizes the Company's option transactions:

	Number of options	Weighted average exercise price (CDN$)
Outstanding, December 31, 2021	2,134,250	$ 7.83
Granted	1,172,200	3.16
Outstanding, December 31, 2022	3,306,450	6.18
Exercised	(20,600)	2.00
Cancelled	(24,800)	3.73
Granted	257,200	6.91
Outstanding, December 31, 2023	**3,518,250**	**$ 6.27**

Grant Date	Options Outstanding	Options Exercisable	Exercise Price (CDN$)	Expiry Date	Remaining Contractual Life (years)
Sep 27, 2015	186,250	186,250	$ 8.00[3]	Mar 31, 2025	1.25
Nov 2, 2015	95,000	95,000	$ 8.00[3]	Nov 2, 2025	1.85
Mar 5, 2018	452,250	452,250	$ 8.00[3]	Mar 5, 2028	4.18
Mar 9, 2021	756,950	567,713	$ 8.00	Mar 9, 2031	7.20
Mar 9, 2021	326,800	326,800	$ 8.00	Mar 9, 2031	7.20
May 3, 2021	257,000	192,750	$ 8.00	May 3, 2031	7.35
Dec 9, 2021	60,000	57,500	$ 2.02	Dec 9, 2031	7.95
Mar 31, 2022	392,500	186,750	$ 1.90	Mar 31, 2032	8.26
Dec 9, 2022	734,300	407,983	$ 3.85	Dec 9, 2032	8.95
May 18, 2023	180,000	45,000	$ 6.84	May 18, 2033	9.39
May 30, 2023	17,200	4,300	$ 6.75	May 30, 2033	9.42
Sep 27, 2023	60,000	15,000	$ 7.16	Sep 27, 2033	9.75
	3,518,250	**2,537,296**	**$ 6.27**		**7.02**

(Expressed in U.S. Dollars, except share amounts)

12. SHARE CAPITAL AND OTHER COMPONENTS OF EQUITY (continued)

c) Options (continued)

The share-based compensation expense was determined based on the fair value of options at the date of measurement using the Black-Scholes option pricing model with the following weighted-average assumptions:

Options granted during the year ended	December 31, 2023	December 31, 2022
Expected dividend yield	0.00%	0.00%
Expected forfeiture rate	0.00%	0.00%
Weighted average annual volatility	79.60%	78.66%
Weighted average risk-free interest rate	3.54%	2.80%
Weighted average expected option life	5.75 years	5.70 years
Weighted average share price (CDN$)	$ 6.91	$ 3.16
Weighted average exercise price (CDN$)	$ 6.91	$ 3.16
Weighted average fair value of options granted (CDN$)	$ 4.78	$ 2.17

Share-based payments for the year ended December 31, 2023, was $1,412,257 (2022 - $1,433,812) (See Note 13 – General & Administrative Expenses and Note 14 – Research & Development Expenses for breakdown by function).

As of December 31, 2023, the unrecognized stock-based compensation expense related to the non-vested stock options was $961,535, which is expected to be recognized over a weighted-average period of 2.09 years.

d) Warrants

The following table summarizes the Company's warrant transactions:

	Number of warrants	Weighted average exercise price (CDN$)
Outstanding December 31, 2021	**4,161,898**	**$ 8.81**
Issued	7,832,088	2.94
Expired	(289,172)	8.00
Exercised	(200,000)	2.05
Outstanding December 31, 2022	**11,504,814**	**$ 4.95**
Exercised	(2,385,484)	2.90
Outstanding December 31, 2023	**9,119,330**	**$ 5.49**

(Expressed in U.S. Dollars, except share amounts)

12. SHARE CAPITAL AND OTHER COMPONENTS OF EQUITY (continued)

d) Warrants (continued)

As at December 31, 2023, the following warrants were outstanding:

Expiry date	Exercise price (CDN$)	Remaining contractual life (years)	Warrants outstanding and exercisable
120 days after holder to be a Director/ Officer or consultant	$ 0.7572	N/A	243,421
120 days after former spouse ceases to be a Director/ Officer or consultant	0.7572	N/A	137,500
120 days after holder ceases to be a Director/ Officer or consultant[1]	0.4984	N/A	315,500
January 4, 2024	5.5993	0.01	239,080
January 4, 2024	7.1991	0.01	39,846
January 8, 2024	5.5993	0.02	31,877
March 9, 2026	11.20	2.19	2,826,274
April 20, 2026	3.00	2.30	5,196,550
April 20, 2026	2.05	2.30	50,054
April 29, 2026	11.20	2.33	39,228
	$ 5.49		**9,119,330**

(1) Represents unit purchase to acquire 315,500 units consisting of one Common Share and one additional warrant at an exercise price of $0.75CDN. These underlying warrants expire two years from the date of exercise of the primary warrant.

e) Class B Non-Voting shares

On January 31, 2021, the Company entered into a contribution agreement with the Chief Scientific Officer of the Company, and certain of the Company's subsidiaries (the "Contribution Agreement"). Pursuant to the Contribution Agreement, the Company acquired AMDM Holdings Inc., a corporation wholly-owned by the Chief Scientific Officer, which held 5% of the equity interest in the Company's subsidiary, Eupraxia USA. In exchange, the Company issued to the Chief Scientific Officer 225 non-voting Class B shares (the "Class B Shares") in Eupraxia Pharma Inc. representing 5% of the outstanding securities of Eupraxia Pharma. The Company holds the remaining 95% of such securities, which consists of 4,275 voting Class A shares.

Each Class B Share is exchangeable into common shares of the Company based on an exchange rate of 2,500 common shares for each Class B Share, subject to adjustments upon the occurrence of certain events, for a total of 562,500 common shares. The Class B Shares are exchangeable by the Chief Scientific Officer at her election, provided that the Company may force the exchange of the Class B Shares into common shares of the Company at any time on or after January 31, 2031, or on or after January 31, 2026, if the Company is listed on a stock exchange and is a reporting issuer in Canada at such time. The Company may also force the exchange of the Class B Shares into common shares if there is a change of control transaction involving the Company, a change in law which makes the exchange necessary or desirable or if there are a *de minimis* number of Class B Shares outstanding. If the Company is listed on a stock exchange at the time of the applicable exchange, the Company may elect to pay the Chief Scientific Officer cash in lieu of issuing common shares, with such cash amount to be determined based on the then current market price of the common shares of the Company.

(Expressed in U.S. Dollars, except share amounts)

13. GENERAL AND ADMINISTRATIVE EXPENSES

General and administrative expenses are comprised of the following:

	December 31, 2023	December 31, 2022
Office expenses	$ 389,210	$ 332,951
Insurance	367,472	357,763
Travel	345,992	120,115
Professional fees	2,821,798	268,698
Public company costs	404,073	214,264
Salaries and benefits	2,241,079	1,641,049
Share based payments (Note 12(c))	714,380	1,052,758
Total expenses during the period	**$ 7,284,004**	**$ 3,987,598**

14. RESEARCH AND DEVELOPMENT EXPENSES

Research and development expenses are comprised of the following:

	December 31, 2023	December 31, 2022
Preclinical	$ 1,616,238	$ 1,073,668
Clinical	4,595,597	7,179,535
Manufacturing & analytical	4,986,502	2,177,070
Regulatory	341,589	588,652
Consulting	—	660
Direct research and development	11,539,926	11,019,585
Pipeline development	83,637	227,615
Other research and development	672,295	424,628
Salaries and benefits	2,794,891	1,901,257
Share based payments (Note 12(c))	697,877	381,054
License costs (Note 10)	5,000,000	—
Government grants (Note 15)	(122,542)	(288,515)
SR&ED and other R&D tax incentives	(102,859)	(35,770)
Total expenses during the period	**$20,563,225**	**$13,629,854**

(Expressed in U.S. Dollars, except share amounts)

15. GOVERNMENT GRANTS AND ASSISTANCE

National Research Council – Industrial Research Assistance Program ("NRC-IRAP")

On October 1, 2021, the Company entered into an agreement with NRC-IRAP for funding support of specified research and development activities during a project phase, commencing on September 1, 2021, and ending on December 15, 2023. Under the agreement, NRC-IRAP would reimburse up to 80% of supported salary costs, and 50% of supported contractor fees to a maximum of $553,185. During the year ended December 31, 2023, the Company claimed $122,542 pertaining to this agreement (2022 - $277,117).

At December 31, 2023 there was $nil (2022 - $13,892) of government grants recorded in amounts receivable (Note 4 – Amounts Receivable) and collected subsequent to year end.

The following table summarizes the government grants and assistance the Company received or accrued during the years ended December 31, 2023 and 2022:

	2023	2022
NRC-IRAP	$122,542	$277,117
BioTalent Canada	—	11,398
Total	**$122,542**	**$288,515**

Government assistance of $122,542 (2022 - $288,515) relating to research and development activities has been offset against research and development expense.

16. INCOME TAXES

For financial reporting purposes, loss before taxes includes the following components:

Year ended December 31,	2023	2022
Canadian	$(28,810,717)	$(18,925,281)
Foreign	(118,866)	(65,483)
Total	**$(28,929,583)**	**$(18,990,764)**

The income tax expense consists of the following:

Year ended December 31,	2023	2022
Canadian		
Current	$ —	$—
Deferred	$ —	$—
	$ —	$—
Foreign		
Current	$36,423	$—
Deferred	$ —	$—
	$36,423	$—
Total		
Current	$36,423	$—
Deferred	$ —	$—
	$36,423	$—

(Expressed in U.S. Dollars, except share amounts)

16. INCOME TAXES (continued)

Year ended December 31,	2023	2022
Loss before taxes	$(28,929,583)	$(18,990,764)
Statutory Canadian corporate tax rate	27%	27%
Expected tax recovery at statutory rates	(7,810,987)	(5,127,506)
Change in unrecognized deferred tax assets	9,523,404	5,127,732
Non-deductible share-based payments	381,285	414,724
Other items not deductible for tax purposes and other	242,460	11,570
Adjustments related to prior years	(624,973)	(257,636)
Share issue costs	(290,289)	(322,131)
Foreign exchange arising on translation to reporting currency	(1,384,477)	153,247
Income tax expense	**$ 36,423**	**$ —**

Income tax expense for the year ended December 31, 2023 arose from the operations of Eupraxia Pharma USA Inc., the Company's wholly-owned subsidiary in the United States.

Deferred income tax assets and liabilities result from the temporary differences between the amount of assets and liabilities recognized for financial statement and income tax purposes. The significant components of the Company's net deferred income tax assets are as follows:

	December 31, 2023	December 31, 2022
Convertible debt	$ 733,756	$ 360,307
Depreciable assets	3,092,163	1,655,346
Lease obligation	4,925	8,122
Non-capital losses	18,348,349	12,776,875
Share issue costs	728,046	694,773
Scientific research and experimental development pool	2,093,085	852,776
Tax credits	1,546,834	797,401
Other	121,846	—
Less: valuation allowance	(26,669,004)	(17,145,600)
Net deferred income tax assets	**$ —**	**$ —**

In assessing the realizability of the Company's deferred income tax assets, Management considers whether it is more likely than not that some portion or all of the deferred tax assets will not b realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during periods in which temporary differences become deductible and the loss carry-forwards or tax credits can be utilized. A full valuation allowance continues to be applied against deferred income tax assets as the Company has assessed that the realization of such assets does not meet the more likely than not criteria.

There are no unrecognized income tax benefits as of December 31, 2023, or 2022. Due to the net operating loss carryover position coupled with the lack of any unrecognized tax benefits, no provision has been made for any interest or penalties associated with any uncertain tax positions. It is not anticipated that there will be any significant changes to unrecognized tax benefits within the next 12 months.

16. INCOME TAXES (continued)

In assessing the realizability of the Company's deferred income tax assets, Management considers whether it is more likely than not that some portion or all of the deferred tax assets will not b realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during periods in which temporary differences become deductible and the loss carry-forwards or tax credits can be utilized. A full valuation allowance continues to be applied against deferred income tax assets as the Company has assessed that the realization of such assets does not meet the more likely than not criteria.

There are no unrecognized income tax benefits as of December 31, 2023, or 2022. Due to the net operating loss carryover position coupled with the lack of any unrecognized tax benefits, no provision has been made for any interest or penalties associated with any uncertain tax positions. It is not anticipated that there will be any significant changes to unrecognized tax benefits within the next 12 months.

The Company and its foreign subsidiaries have available non-capital losses for Canadian, Australian and US income tax purposes which may be carried forward to reduce taxable income in future years. If not utilized, the non-capital losses in each jurisdiction will expire as follows (all amounts expressed in USD):

Expiry date	Non-capital losses– Canada	Non-capital losses– US	Non-capital losses– Australia
2031	$ 281,235	$ —	$ —
2032	575,606	322,050	—
2033	2,481,600	1,111,122	—
2034	2,935,535	160,000	—
2035	2,466,288	160,000	—
2036	3,797,516	160,048	—
2037	7,294,414	160,000	—
2038	3,060,930	—	—
2039	1,666,415	—	—
2040	144,413	—	—
2041	6,404,809	—	—
2042	13,526,387	—	—
2043	17,642,270		—
Unlimited	—	1,479,139	69,093
	$ 62,277,418	**$ 3,552,359**	**$ 69,093**

The Company also has approximately $7,752,165 of SR&ED expenditures that may be carried forward indefinitely to be deducted against future Canadian taxable income. It also has federal investment tax credits of approximately $1,449,886 available to offset future Canadian federal income taxes payable as well as provincial investment tax credits of approximately $511,826. The federal tax credits are available to be carried forward 20 years (expiring in 2036 to 2043) to offset future Canadian federal income taxes payable and the provincial tax credits are available to be carried forward 10 years (expiring in 2026 to 2033) to offset future BC income taxes payable. The benefit of the investment tax credits has not been recognized as their realization is not reasonably assured.

The Company files income tax returns in Canada, United States and Australia, the jurisdictions in which the Company believes that it is subject to tax. In jurisdictions in which the Company does not believe it is subject to tax and therefore does not file income tax returns, the Company can provide no certainty that tax authorities in those jurisdictions will not subject one or more tax years (since the inception of the Company) to examination. Further, while the statute of limitations in each jurisdiction where an income tax return has been filed generally limits the examination period, as a result of loss carry-forwards, the limitation period for examination generally does not expire until several years after the loss carry-forwards are utilized. Other than routine audits by tax authorities for tax credits and tax refunds that the Company claims, the Company is not aware of any other material income tax examination currently in progress by any taxing jurisdiction. Tax years ranging from 2012 to 2023 remain subject to examinations in Canada and the United States 2022 to 2023 for Australia.

17. COMMITMENTS

The Company may be required to make milestone, royalty, and other research and development funding payments under research and development collaboration and other agreements with third parties (see Note 10 – Auritec License Agreement). These payments are contingent upon the achievement of specific development, regulatory and/or commercial milestones. The Company has not accrued these payments as at December 31, 2023 due to the uncertainty over whether these milestones will be achieved.

Eupraxia has entered into a number of service contracts with its vendors. Some of those contracts have cancellation clauses which state Eupraxia would pay a cancellation fee of between 15% and 100% of the next service milestone if it terminates the contract. As of December 31, 2023, there have been no cancellation of contracts that would trigger a cancellation fee.

18. FINANCIAL INSTRUMENTS

The Company's financial instruments consist of cash and cash equivalents, amounts receivable, accounts payable and accrued liabilities, payable to Auritec, loans payable and convertible debt.

There were no changes to the Company's risk exposures or management of risks during the year ended December 31, 2023. The Company's risk exposures and the impact on the Company's financial instruments are summarized below:

Credit risk

Credit risk is the risk that one party to a financial instrument will cause a financial loss for the other party by failing to discharge an obligation. The Company believes it has no significant credit risk, as its cash and cash equivalents and short-term investments, being its primary exposure to credit risk, is with a large Canadian bank. The Company's maximum exposure to credit risk is the carrying value of these financial assets.

Liquidity risk

Liquidity risk is the risk that an entity will encounter difficulty in meeting obligations associated with financial liabilities that are settled by delivering cash or another financial asset. The Company's approach to managing liquidity risk is to ensure that it will have sufficient liquidity to meet liabilities when due. As at December 31, 2023, the Company had cash and cash equivalents of $19,341,756 (2022 - $18,263,389) in addition to current liabilities of $19,373,903 (2022 - $3,058,387). Management is currently working on certain strategic alternatives including, but not limited to raising additional capital and strategic alternatives to its existing contingent convertible debt facility. There is no assurance, however, that any or all of these alternatives will materialize or that additional funding will be available, if and when needed.

18. FINANCIAL INSTRUMENTS (continued)

Market risk

Market risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market prices. Market risk comprises three types of risk: currency risk, interest rate risk and other price risk.

Interest rate risk

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates. The Company is exposed to interest rate cash flow risk; and to the extent that the prevailing market interest rates differ from the interest rate on the Company's monetary assets and liabilities, the Company is exposed to interest rate price risk. At December 31, 2023, the Company maintains a convertible debt facility totaling CDN$10,000,000 as well as having an equipment loan of $235,000 of which a principal balance of $62,709 remains as at December 31, 2023.

The convertible debt accrues interest at the greater of 2.45% and the Canadian prime rate, requiring monthly interest payments. An additional payment in kind accrues at a rate of 7% per annum, which will be settled at maturity or on conversion. The equipment loan accrues interest at a fixed rate of 5.84%.

As at December 31, 2023, management has determined the effect on the future results of operations due to a change in the current Canadian prime rate. An impact of a 1% change in the Canadian prime rate would impact the amount of interest to be paid over the remaining term of the convertible debt facility by approximately $43,807.

Currency risk

Currency risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in foreign exchange rates. The Company is exposed to currency risk due to its frequency of transactions in US dollars. The Company does not use derivatives to hedge against this risk, however, it has purchased US dollars to cover the majority of the costs of the Company's Phase 2 clinical trial.

18. FINANCIAL INSTRUMENTS (continued)

Currency risk (continued)

At December 31, 2023, the Company held cash of $933,816 (2022 – $1,159,926), had accounts payable of $1,292,128 (2022 – $1,814,067), a payable owing to Auritec of $5,000,000 (2022 – nil) and a loan payable of $62,709 (2022 – $142,127) denominated in US dollars which were translated to Canadian dollars at 1.3226 (2022 – 1.3544). The impact of a 10% change in the exchange rates would have an impact of approximately $542,102 (2022 – $79,627) on profit or loss. The Company also has cash in accounts payable in Australian dollars, Great British pounds and Euros. The impact of a 10% change in the exchanges of these currencies would have an immaterial effect on future cash flows.

Other price risk

Other price risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market prices (other than those arising from interest rate risk and foreign currency risk), whether those changes are caused by factors specific to the individual financial instrument or its issuer or by factors affecting all similar financial instruments traded in the market. The Company is not exposed to significant price risk with respect to commodity or equity prices.

Fair Value Measurement

The Company categorizes its financial instruments measured at fair value into one of three different levels depending on the observation of inputs used in the measurement.

Level 1: Fair value is based on unadjusted quoted prices for identical assets or liabilities in active markets

Level 2: Fair value is based on inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly

Level 3: Fair value is based on valuation techniques that require one or more significant unobservable inputs

The Company's financial instruments consist of cash and cash equivalents, short-term investments, accounts payable and accrued liabilities, loans payable and convertible debt. With the exception of convertible debt, the carrying value of the Company's financial instruments approximate their fair values due to their short-term maturities.

The following table summarizes information regarding the classification and carrying values of the Company's financial instruments measured at amortized cost:

Financial assets/liabilities	December 31, 2023	December 31, 2022
Cash and cash equivalents	$19,341,756	$18,263,389
Amounts receivable	$ 190,612	$ 89,715
Accounts payable and accrued liabilities	$ 3,921,875	$ 2,928,566
Payable to Auritec	$ 5,000,000	$ —
Loans payable	$ 62,709	$ 142,127

The following table summarizes information regarding the changes in fair value of liabilities measured at fair value, categorized as Level 3:

(Expressed in U.S. Dollars, except share amounts)

18. FINANCIAL INSTRUMENTS (continued)

	Convertible Debt
Balance – December 31, 2021	**$ 7,507,755**
Accrued interest	958,669
Interest paid	(315,436)
Change in fair value	1,056,165
Foreign exchange	(465,157)
Balance - December 31, 2022	**$ 8,741,996**
Accrued interest	1,162,773
Interest paid	(591,170)
Change in fair value	836,595
Foreign exchange	185,809
Balance - December 31, 2023	**$ 10,336,003**

For the convertible debt, the key inputs that affect the ongoing valuation are the discount price, the share price and the share price volatility.

(Expressed in U.S. Dollars, except share amounts)

19. INTEREST EXPENSE

Interest expense is comprised of the following:

	Year ended December 31, 2023	Year ended December 31, 2022
Interest on SVB debt facility (Note 11)	$ 1,162,773	$ 958,669
Other interest and accretion	7,400	24,187
Total	**$ 1,170,173**	**$ 982,856**

20. SUPPLEMENTAL DISCLOSURE WITH RESPECT TO CASH FLOWS

The Company paid interest of $598,046 during the year ended December 31, 2023 (2022 - $326,629).

The Company received interest of $912,033 during the year ended December 31, 2023 (2022 - $394,188).

The Company had the following significant non-cash transactions for the year ended December 31, 2023:

- 99,061 common shares (valued at $511,678) were issued as part of the financing on August 18, 2023, as a payment of finder's fees (see Note 12(b)(v)).

The Company had the following significant non-cash transactions for the year ended December 31, 2022:

- 500,538 warrants (valued at $160,147) were issued as part of the financing on April 20, 2022, to the Underwriters (see Note 12(b)(i)).

A detailed breakdown of cash and cash equivalents is as follows:

	December 31, 2023	December 31, 2022
Cash	$19,341,756	$10,830,891
Cash equivalents	—	7,432,498
Total	**$19,341,756**	**$18,263,389**

21. SUBSEQUENT EVENT

On March 15, 2024, the Company announced it had closed its previously announced overnight marketed public offering (the "Offering") of common shares of the Company (the "Shares"). Pursuant to the Offering, Eupraxia issued 8,260,435 Shares at a price of C$4.10 per Share for gross proceeds of $25,026,073 (CDN$33,867,784), which includes the issuance of 943,435 Shares upon exercise of the over-allotment option.

EUPRAXIA PHARMACEUTICALS INC.
MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

For the year ended December 31, 2023

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS FOR THE YEAR ENDED DECEMBER 31, 2023

This management's discussion and analysis ("**MD&A**") has been prepared as of April 1, 2024 and should be read in conjunction with the audited consolidated financial statements of Eupraxia Pharmaceuticals Inc. ("**Eupraxia**" or the "**Company**") as at and for the year ended December 31, 2023 and the related notes which are prepared in accordance with generally accepted accounting principles in the United States of America ("**U.S. GAAP**") as issued by the Financial Accounting Standards Board. All dollar amounts are expressed in U.S. dollars unless otherwise noted. In this MD&A, unless the context requires otherwise, references to "we" or "our" are references to Eupraxia. Additional information relating to the Company is available in our annual information form ("**AIF**"), filed on SEDAR+ and EDGAR on April 1, 2024.

All regulatory filings to-date and communication from the Company have been made referencing EP-104IAR. In the interest of greater clarity for investors, the Company will use EP-104IAR when referring to the product candidate that is intended for intra-articular ("**IAR**") injections for indications such as osteoarthritis ("**OA**"), EP-104GI when referring to the product candidate that is intended for submucosal injections in the GI tract for indications such as eosinophilic esophagitis ("**EoE**"), and simply refer to the product candidate as EP-104 in conjunction with topics that are related to both EP-104IAR and EP-104GI.

Change in Reporting Currency to the US Dollar

Effective December 31, 2023, the Company changed its reporting currency to the US dollar ("USD") from the Canadian dollar ("CDN"). As such, all prior amounts originally reported in CDN are now reported in USD. The change in reporting currency was made to enhance comparability of the Company's results with other publicly traded companies in the life sciences industry. The Canadian dollar continues to be the functional currency of the Company.

In accordance with ASC 830, the consolidated financial statements of the Company are translated into U.S. dollars using the current rate method. Assets and liabilities are translated at the rate of exchange prevailing at the consolidated balance sheet date. Shareholders' equity is translated at the applicable historical rate. Revenue, expense and cash flow items are translated at the exchange rate in effect on the transaction dates. Translation gains and losses are reported as a separate component of shareholders' equity titled Accumulated Other Comprehensive Income.

The financial information for all prior periods is presented in U.S. dollars as if the U.S. dollar had been used as the reporting currency during those periods.

Transition to U.S. GAAP

This is the first year that the Company's consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States of America as issued by the Financial Accounting Standards Board ("**FASB**"). Previously, the Company prepared its financial statements in accordance with IFRS Accounting Standards as issued by the International Accounting Standards Board ("IASB").

The policies set out in the Significant Accounting Policies section have been applied in preparing the financial statements for the years ended December 31, 2023 and 2022. In addition, comparative figures, which were previously prepared in accordance with IFRS, have been adjusted as required to be compliant with the Company's accounting policies under U.S. GAAP.

Forward-Looking Statements

Certain statements and information in this MD&A contain forward-looking statements or forward-looking information under applicable securities legislation that may not be based on historical fact, including, without limitation, statements containing the words "may," "might," "will," "likely," "could," "would," "should," "expect," "intend," "plan," "objective," "goal," "outlook," "anticipate," "believe," "estimate," "predict," "project," "forecast," "estimate," "potential," "target," "seek," "contemplate," "continue," "design," and "ongoing," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words and similar expressions. Forward-looking statements include estimates, plans, expectations, opinions, forecasts, projections, targets, guidance or other statements that are not statements of fact. Such forward-looking statements are made as of the date of this MD&A.

Forward-looking statements are necessarily based on estimates and assumptions made by us in light of our experience and perception of historical trends, current conditions and expected future developments, as well as factors that we believe are appropriate. Forward-looking statements in this MD&A include, but are not limited to, statements relating to:

- the Company's business strategies and objectives, including current and future plans, expectations and intentions;
- the Company's intent to use capital resources previously identified for EP-104IAR to continue the development of EP-104GI;
- the Company's intention to evaluate funding alternatives for the continued development of EP-104IAR, including potential partnership opportunities;
- the Company's ability to obtain sufficient funding for our operations, including funding for research, development and commercial activities;
- the Company's projected operating expenses and capital expenditures;
- the Company's ability to achieve profitability;
- projected revenues, future trends, opportunities and growth in the Company's industry and the drug development markets;
- the Company's ability to maintain and enhance its competitive advantages and technological advantages;

- the entry into commercial partnerships and commercialization of our technology;
- the Company's ability to enter into definitive agreements with its contract research organizations ("**CROs**");
- the Company's ability to enter into co-development and/or collaborative partnerships;
- the Company's clinical development programs and activities and the estimated timing thereof;
- the timing, status and results of clinical trials, including with respect to patient recruitment and data readout;
- the success of regulatory submissions;
- the obtaining of potential regulatory approval;
- the hiring of additional research and development team members;
- the potential for the Company's technology to impact the drug delivery process;

- the development of additional intellectual property, ability to patent or otherwise protect such developed intellectual property and licenses with third parties for intellectual property;
- the ability of patents and notices of allowance to provide protection over intellectual property in applicable jurisdictions;
- the Company's ability to protect, expand upon and exploit its existing intellectual property;
- the entry into sponsored research agreements and the benefits therefrom;
- the competitive advantages of the Company and its technology;
- the Company's product candidates and results gathered from studies thereof;
- the development of products from the Company's competitors;
- the application of regulations and standards to the Company's future products and services or research and development activities;
- the Company's retention of funds or payment of dividends;
- the translation of the Company's technologies and expansion of its offerings into clinical applications;
- the benefits to patients from Eupraxia's platforms;
- the value of the strategic relationship to Eupraxia's clients and investors;
- the Company's engagement with legal and regulatory authorities in various jurisdictions;
- the Company's anticipated use of proceeds from the Offering (as defined herein) and its existing cash and cash equivalents and the related estimated cash runway;
- the sufficiency of the Company's existing cash and cash equivalents to fund its future operating expenses and capital expenditure requirements;
- the Company's application for approval to list its common shares (the "Common Shares") on the Nasdaq Capital Market (the "Nasdaq");
- the Company's ability to successfully refinance the Debt Agreement (as defined herein) with Silicon Valley Bank ("SVB") and SVB Innovation Credit Fund VIII, L.P.;
- the demand and commercial viability of the Company's technology; and
- the demand and market acceptance for products developed by the Company.

Forward-looking statements and information involve significant risks, assumptions, uncertainties and other factors that may cause actual future results or anticipated events to differ materially from those expressed or implied in any forward-looking statements or information and, accordingly, should not be read as guarantees of future performance or results. These risks and factors include, but are not limited to:

- we have a limited operating history and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability;
- we will require substantial additional financing to achieve our goals and a failure to obtain this necessary capital when needed could force us to delay, limit, reduce or terminate our product development or commercialization efforts;
- we are substantially dependent on the success of our lead product candidates EP-104GI, which is currently being studied in an open label Phase 1b/2a clinical study, and EP-104IAR, for which we are evaluating funding alternatives for the continued development, including potential partnership opportunities. If we are unable to complete development of, obtain approval for and commercialize EP-104GI or EP-104IAR, alone or through a potential partnership, in a timely manner, our business will be harmed;
- if we breach any of the agreements under which we license rights to our product candidates or technology from third parties, we could lose license rights that are important to our business. Our current license agreement may not provide an adequate remedy for its breach by the licensor;
- adverse developments affecting the financial services industry, such as actual events or concerns involving liquidity, defaults, or non-performance by financial institutions or transactional counterparties, could adversely affect our current and projected business operations and our financial condition and results of operations;
- clinical trials are expensive, time consuming and difficult to design and implement and may fail to demonstrate adequate safety and efficacy of our product candidates. Furthermore, the results of previous preclinical studies and clinical trials may not be predictive of future results, and the results of our current and planned clinical trials may not satisfy the requirements of the U.S. Food and Drug Administration (the "**FDA**") or comparable non-U.S. regulatory authorities or provide the basis for regulatory approval;
- our lead product candidates may not be successful for their intended use;
- our current and future product candidates will require regulatory approval, which is costly, and we may not be able to obtain it and we may fail to obtain regulatory approvals or only obtain approvals for limited uses or indications;
- the clinical trials of our product candidates may not demonstrate safety and efficacy to the satisfaction of the FDA, European Medicine Agency ("**EMA**") or other comparable foreign regulatory authorities or otherwise produce positive results;
- we completely rely on third parties to provide supplies and inputs required for our products;
- we rely on CROs to provide clinical and non-clinical research services; if such CROs do not successfully carry out their contractual duties including to comply with applicable laws and regulations or meet expected deadlines, our business could be substantially harmed;

- the manufacture of drugs is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate

supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented;

- our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor or other third party will discover them or that our trade secrets will be misappropriated or disclosed;
- the outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, EMA or other comparable foreign regulatory authorities. Terminating the development of any of our product candidates could materially harm our business and the market price of our Common Shares;
- interim, initial, "top-line", and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data;
- any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could seriously harm our business;
- our current or future product candidates may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other products that may result in a safety profile that could inhibit regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences;
- where appropriate and applicable, we may seek approval from the FDA or comparable foreign regulatory authorities through the use of expedited approval pathways, such as Fast Track designation or orphan drug designation. Even if we receive Fast Track designation or other designation, we can provide no assurance that we will be able to obtain FDA approval sooner or if at all;
- if we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our drug candidates, if approved, we may be unable to generate any product revenue;
- we have a novel technology with uncertain market acceptance;
- if we experience delays or difficulties in the enrollment and/or maintenance of patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected;
- the FDA, EMA and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction;
- obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions;
- if the market opportunity for any product candidate that we or our strategic partners develop is smaller than we believe, our revenue may be adversely affected and our business may suffer;
- even if our product candidates receive regulatory approval, we will be subject to significant post marketing regulatory requirements and oversight;
- FDA's and other regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates;
- the FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses;
- disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business;
- we rely on key personnel;
- we may not be able to successfully execute our business strategy;
- we are in a highly competitive industry which is continuously evolving with technological changes;
- our future success will depend on our ability to continually enhance and develop our product candidates;
- we may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success;
- changes in methods of product candidate manufacturing or formulation may result in additional costs or delay;
- if we are unable to differentiate EP-104 from existing therapies or if the FDA or other applicable regulatory authorities approve additional, and potentially less costly, therapies that compete with EP-104, our ability to successfully commercialize EP-104GI or EP-104IAR would be adversely affected;
- a variety of risks associated with potential international business relationships could materially adversely affect our business;
- collaboration arrangements we may enter into in the future may not be successful;
- provisions of our existing and any future debt instruments may restrict our ability to pursue our business strategies;
- we may acquire businesses or products, or form strategic alliances in the future, and we may not realize the benefits of such acquisitions or alliances;
- we have traditionally relied on key collaborations and grants;

- we are subject to evolving global laws and regulations relating to privacy, data protection and information security, which may require us to incur substantial compliance costs, and any failure or perceived failure by us to comply with such laws and regulations may harm our business and operations;
- our business and operations could suffer in the event of an actual or perceived information security incident such as a cybersecurity breach, system failure, or other compromise of our systems or those of a third-party or other contractor or vendor;
- we may fail to manage our growth successfully, which may adversely impact our operating results;
- we use hazardous chemicals and biological materials in our business. Any claims relating to improper handling, storage or disposal of these materials could be time consuming and costly;
- if product liability lawsuits are brought against us, then we may incur substantial liabilities and may be required to limit commercialization of EP-104, if approved, for any indication, and any other future products;
- our employees, independent contractors, principal investigators, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading, which could significantly harm our business;
- we may be subject to securities litigation, which is expensive and could divert management attention;
- our directors and executive officers may be affiliated with other biotech companies and may have conflicts of interest;
- our business may be affected by macroeconomic conditions;
- our business may be affected by global geopolitical risks;
- we may be responsible for corruption and anti-bribery law violations;
- we are subject to foreign exchange risks;
- we are subject to taxation risks and changing rules by different tax authorities;
- we are subject to a number of risks and hazards and may not be sufficiently insured for all of them;
- we will devote significant resources to regulatory compliance as a public entity;
- changes in accounting standards from IFRS to U.S. GAAP can be difficult to predict and could adversely impact how we record and report our financial condition and results of operations;
- in the past, we have had to restate our previously issued consolidated financial statements and as part of that process identified a material weakness in our disclosure controls and procedures and internal control over financial reporting as of December 31, 2022. If we are unable to develop and maintain effective disclosure controls and procedures and internal control over financial reporting, we may not be able to accurately report our financial results in a timely manner, which may adversely affect investor confidence in us and may adversely affect our business, financial condition and results of operations;
- our success depends on our ability to protect our intellectual property and our proprietary technologies;
- if the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected;
- intellectual property rights do not necessarily address all potential threats to our competitive advantage;
- our patent rights may prove to be an inadequate barrier to competition;
- our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts;
- we may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses;
- we may be involved in lawsuits to protect or enforce our patents or our future licensors' patents, which could be expensive, time consuming, and unsuccessful. Further, our issued patents or our current or future licensors' patents could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad;
- intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our Common Shares to decline;
- derivation proceedings may be necessary to determine priority of inventions, and an unfavorable outcome may require us to cease using the related technology or to attempt to license rights from the prevailing party;
- we may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our products and product candidates;
- changes in U.S. patent law, or laws in other countries, or their interpretation could diminish the value of patents in general, thereby impairing our ability to protect our product candidates;
- we may be subject to claims challenging the inventorship or ownership of our patents, the patents we license, and other intellectual property;
- patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time;

- we may not be able to protect or enforce our intellectual property rights throughout the world;
- obtaining and maintaining our patent protection depends on compliance with various procedural, documentary submission, fee payment and other requirements imposed by regulations and governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements;
- if our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected;
- if we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected, harming our business and competitive position;
- we may be subject to claims that we or our employees, independent contractors, or consultants have wrongfully used or disclosed alleged confidential information or trade secrets;
- we may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees, independent contractors, or consultants have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers;
- we may be subject to claims challenging the inventorship of our patents and other intellectual property;
- our rights to develop and commercialize our technology and product candidates may be subject, in part, to the terms and conditions of any future licenses granted to us by others;
- if we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our future licensors, we could lose license rights that are important to our business;
- the patent protection and patent prosecution for some of our product candidates may be dependent on third parties;
- coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, if approved, which could make it difficult for us to sell any product candidates or therapies profitably;
- our relationships with healthcare providers and physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings;
- our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements;
- our research and development activities could be affected or delayed as a result of possible restrictions on animal testing;
- ongoing healthcare legislative and regulatory reform measures may have a material adverse effect on our business and results of operations;
- the market price of the Common Shares may be volatile;
- investors may lose their entire investment;
- we have no history of dividends;
- our existing executive officers and directors own a significant percentage of Common Shares and may have a significant impact over matters submitted to our shareholders for approval;
- future sales of Common Shares by our existing shareholders could cause our share price to decline;
- we will need to raise additional financing in the future which may dilute our share capital;
- if securities or industry analysts either do not publish research about us or publish inaccurate or unfavorable research about us, our business or our market, or if they adversely change their recommendations regarding our Common Shares, the trading price or trading volume of our Common Shares could decline;
- any issuance of preferred shares could make it difficult for another company to acquire us or could otherwise adversely affect holders of our Common Shares, which could depress the price of our Common Shares;
- our constating documents permit us to issue an unlimited number of Common Shares without additional shareholder approval;
- raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our technologies or product candidates;

- we have warrants, convertible debt, and shares of a subsidiary exchangeable for Common Shares outstanding, which in each case, if exercised, converted or exchanged, respectively, could cause dilution to existing shareholders;
- our Common Shares may have limited liquidity;
- [even if our Common Shares are approved for listing, we cannot assure you that an active market will develop for Common Shares on the Nasdaq;]
- United States investors may not be able to obtain enforcement of civil liabilities against us;
- as a foreign private issuer, we are subject to different U.S. securities laws and rules than a domestic U.S. issuer, which may limit the information publicly available to our U.S. shareholders;
- we may lose our foreign private issuer status in the future, which could result in significant additional costs and expenses to us;
- U.S. holders of our Common Shares may suffer adverse tax consequences if we are characterized as a passive foreign investment company; and
- if a U.S. holder is treated as owning at least 10% of our Common Shares, such U.S. holder may be subject to adverse U.S. federal income tax consequences.

Such statements reflect our current views with respect to future events, are subject to risks and uncertainties and are necessarily based upon a number of estimates and assumptions that, while considered reasonable by Eupraxia as of the date of such statements, are inherently subject to significant medical, scientific, business, economic, competitive, political and social uncertainties and contingencies. Many factors could cause our actual results, performance or achievements to be materially different from any future results, performance, or achievements that may be expressed or implied by such forward-looking statements. In making the forward-looking statements included in this MD&A, the Company has made various material assumptions, including but not limited to (i) the Company's ability to attract and retain skilled staff; (ii) future research and development plans for the Company proceeding substantially as currently envisioned; (iii) industry growth trends, including with respect to projected and actual industry sales; (iv) the Company's ability to obtain positive results from the Company's research and development activities, including clinical trials; (v) sufficient working capital and the Company's ability to control costs and raise additional financing going forward; (vi) obtaining regulatory approvals and the potential benefits of our products, if approved; (vii) general business and economic conditions; (viii) the Company's ability to achieve profitability; (ix) the Company's ability to successfully commercialize its current product candidates, enter into commercial partnerships and develop new products; (x) the availability of financing on reasonable terms; (xi) market competition; (xii) the products and technology offered by the Company's competitors; (xiii) the Company's ability to protect patents and proprietary rights; and (xiv) the availability and cost of personnel, materials and supplies.

In evaluating forward-looking statements, current and prospective shareholders should specifically consider various factors, including the risks outlined herein under the headings "*Credit risk*", "*Liquidity risk*", "*Market risk*", *"Other price risk", "Interest rate risk"* and "*Currency risk*" and under the heading "*Risk Factors*" in the short form base shelf prospectus dated February 5, 2024 (the "**Shelf Prospectus**") and the AIF. Should one or more of these risks or uncertainties, or a risk that is not currently known to us materialize, or should assumptions underlying those forward-looking statements prove incorrect, actual results may vary materially from those described herein. These forward-looking statements are made as of the date of this MD&A and we do not intend, and do not assume any obligation, to update these forward-looking statements, except as required by applicable securities laws. Investors are cautioned that

forward-looking statements are not guarantees of future performance and are inherently uncertain. Accordingly, investors are cautioned not to put undue reliance on forward-looking statements.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this report, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements.

Overview of the Company

We are a clinical-stage biotechnology company seeking to leverage our proprietary Diffusphere™ technology to optimize drug delivery for applications with significant unmet medical need. Each of our product candidates are designed to improve patient benefit by providing more prolonged activity than currently available treatments, combined with an improved pharmacokinetics ("**PK**") and related safety profile and precisely targeted local delivery. We believe a product with this profile could offer the dual potential of providing long-lasting treatment while minimizing tolerability complications in target and non-target tissues. Our strategy is to develop a portfolio of product candidates based on this delivery technology.

We currently have two distinct clinical development programs, one targeting eosinophilic esophagitis ("**EoE**") and the second targeting chronic osteoarthritis ("**OA**") pain in the knee. Currently, both programs are broadly based upon the same drug candidate (EP-104). The injectable drug is dispensed together with a "vehicle" diluent specifically designed for the target delivery modality and co-administered with the active pharmaceutical ingredient ("**API**"). For our ongoing clinical studies we are using the same underlying API and extended-release formulation. In the future, we anticipate that therapeutic targets will be differentiated by dosing levels, vehicle and delivery methods and will be distinct product candidates. The product candidate that is being developed specifically for submucosal injections in the GI tract with an initial indication of EoE is referred to as EP-104GI, and the product candidate that is being developed for intra-articular ("**IA**") injections with an initial indication of knee OA is referred to as EP-104IAR. EP-104 is intended to refer to the extended-release Diffusphere technology, which is used in the formulation of both EP-104GI and EP-104IAR.

We have successfully completed a Phase 2b trial with EP-104IAR in knee OA, and in January 2024 held a meeting with the FDA to determine the preclinical and clinical requirements for an NDA submission and approval in the United States. We believe that the future success of the product will be dependent on late phase development and commercialization expertise, and will require significant resources. We are currently evaluating funding alternatives for the continued development of EP-104IAR, including potential partnership opportunities and intend to modulate investment levels pending the outcomes. We intend to undertake certain preclinical and manufacturing activities as well as Phase 3 planning and preparation related to EP-104IAR to ensure continuity of the project, but we intend to wait until we have funding needs further sorted before committing to additional significant spend for this program.

We are currently conducting a Phase 1b/2a clinical trial with EP-104GI. We intend to continue development of EP-104GI through the ongoing clinical trial and any subsequent trials required by the FDA to obtain commercial approval. We intend to evaluate the possibility of identifying a corporate partner to help with the development of EP-104GI.

EP-104 (Long-Acting Fluticasone Propionate Injectable Suspension)

The primary active ingredient of the EP-104 product candidates consists of a solid core of fluticasone propionate ("**FP**") coated with an outer layer of polyvinyl alcohol ("**PVA**"). FP is a synthetic trifluorinated corticosteroid with potent anti-inflammatory activity and a well-established systemic safety record in the form of widely used inhaled, intranasal, and topical agents. It has been shown to be locally active, and FP that is systemically absorbed is rapidly metabolized. Relative to other corticosteroids (including triamcinolone acetonide or "**TCA**"), FP has a high affinity for the glucocorticoid receptor, low solubility, a low rate of dissociation, and a comparatively long half-life. It is currently approved by the FDA, Health Canada, European Medicines Agency and many other regulatory agencies around the world. PVA is a biocompatible polymer with numerous biomedical applications and a 30-year safety record in various human tissues. We believe these characteristics make EP-104 a promising candidate for prolonged anti-inflammatory use.

EP-104 technology is designed to work through the diffusion of the drug particles through a microns-thin polymer membrane. When the particles are injected at the disease site, extracellular fluid diffuses across the polymer membrane

and into the particles themselves, dissolving some of the solid drug core and creating a saturated drug solution inside the microsphere with relatively low drug concentrations in the outside microenvironment. Steady-state diffusion of FP across the polymer membrane and into the extracellular space then delivers the drug candidate to the intended area at a prolonged and steady release rate with close to constant drug levels. This rate can be controlled by changing the size of the drug core and the properties of the polymer membrane, creating a target drug release profile designed to maximize disease treatment and reduce systemic and local side effects often accompanying drugs having conventional release profiles.

Another key feature differentiating EP-104 from other extended-release IA corticosteroid formulations is that more than 90% by weight of EP-104 is the active FP component in the investigational drug product, compared to less than 20% in other polymer based extended-release products using degradation.

FP, although approved by the FDA, Health Canada, EMA and other regulatory agencies, is not currently approved for use in any formulation for the treatment of symptoms in either EoE or OA. To our knowledge, EP-104GI and EP-104IAR are the only extended-release formulations of FP in development for these conditions. We believe that the EP-104 drug delivery technology platform has the potential to have a beneficial application for EoE, given the already-established efficacy of oral immediate release of FP in this indication. The drug delivery technology platform also has the potential to be an effective treatment for OA based on the proven efficacy of other corticosteroids for this condition. The potential for an improved treatment of EoE and OA with our proprietary formulations of EP-104 is further supported by a continually expanding library of data supporting the value of extended-release steroids.

EP-104GI for Eosinophilic Esophagitis (EoE)

EP-104 is being developed for the treatment of EoE, a rare immune-mediated disease recognized by the U.S. National Organization for Rare Disorders. Adaptations to the original formulation of EP-104 will result in the creation of EP-104GI for this specific indication, including modifications to the carrier vehicle and dose.

EoE is characterized by inflammation and the accumulation of large numbers of eosinophils (a type of white blood cells) within the epithelial lining of the esophagus. In adults, EoE leads to dysphagia and food impaction. In children, it often presents with irritability, nausea and vomiting. Patients with EoE frequently develop esophageal strictures, a narrowing or tightening of the esophagus, accompanied by proliferations of fibrotic tissue.

Clinical Development of EP-104GI for EoE

Manufacturing

EP-104 consists of a vial of EP-104 powder and a separate vial of liquid (referred to as the "**Vehicle**"). Before injection, the Vehicle is mixed with the dry powder to suspend the EP-104 particles; this enables the EP-104 powder to be injected into the patient. In an ongoing stability study, the powder has proven stable for 48 months when stored at room temperature. Batches of EP-104 are currently manufactured at the projected initial batch scale required for launch. We expect to use the same coated and cured FP particles from our EP-104IAR program for EP-104GI. However, we anticipate refinements to both the dose and vehicle to optimize patient outcomes in EoE.

Clinical Studies

We commenced dosing patients in the second quarter of 2023 for an open label Phase 1b/2a clinical study (RESOLVE) using EP-104GI in EoE. The RESOLVE study will be conducted in up to 24 adult patients with a confirmed diagnosis and active EoE symptoms. Primary outcomes for safety, PK and efficacy will be collected at various points over a 12-week total period, with a subsequent follow up at six (6) months. Initial low-dose cohorts presented early signals of efficacy, and we anticipate ongoing safety, efficacy and PK readouts from subsequent dose-escalation cohorts throughout 2024. The RESOLVE protocol is active at sites in Canada, the Netherlands and Australia. Additional sites and jurisdictions will be added as necessary to complete target recruitment.

Subsequent steps in the research program will be determined following analysis of results as well as interaction with key opinion leaders and regulatory authorities. To seek marketing approval for EP-104GI, we expect to carry out at least one Phase 3 study assessing both efficacy (reduced eosinophils and improved symptoms) and safety of EP-104GI in this indication.

EP-104IAR for Osteoarthritis

OA is a chronic progressive disease characterized by deterioration of joint cartilage and inflammation, which results in pain and stiffness, usually in the morning or after a period of inactivity; and loss of joint function which limits daily activities. In normal joints, cartilage acts as a cushion between bones and provides a smooth gliding surface for movement. In OA, the inflammatory processes integral to disease progression damages the cartilage, and over time cartilage wears away, causing bone to rub directly against bone resulting in joint damage, severe pain and disability.

Globally, OA is a leading cause of disability in older adults. Estimates of prevalence and incidence vary according to the definition of OA used (i.e., radiographic (X-Ray) versus symptomatic) and the joints assessed. The global prevalence of knee OA is estimated at approximately 23% in adults over the age of 40. According to a report by the Centers for Disease Control and Prevention, OA is estimated to affect more than 32.5 million adults in the United States alone. A 2018 report estimated there were 14 million people with symptomatic knee OA. OA is also often associated with depression and loss of sleep which can greatly affect quality of life.

Current evidence-based OA treatment guidelines aim to manage signs and symptoms, with the goal of slowing progression if possible. Recommended pharmacological interventions include topical and oral non-steroidal anti-inflammatory drugs, and IA corticosteroids. IA corticosteroid injections have been used for decades to manage pain and stiffness associated with inflammation in knee OA and have been approved by regulatory authorities as safe and effective. However, IA corticosteroid injections often result in suboptimal patient outcomes because of their short duration of activity and systemic side effects such as flushing, glucose alterations and cortisol suppression due to the high peak exposures required to maintain efficacious concentrations for prolonged durations. Evidence is also emerging regarding the risk of adverse joint findings and/or OA progression following frequent/repeated immediate release IA corticosteroid injections.

Clinical Development of EP-104IAR

Manufacturing

EP-104 consists of a vial of EP-104 powder and the Vehicle. Before injection, the Vehicle is mixed with the dry powder to suspend the EP-104 particles; this enables the EP-104 powder to be injected into the patient's knee. In an ongoing stability study, the powder has proven stable for 48 months when stored at room temperature. Batches of EP-104 are currently manufactured at the projected initial batch scale required for launch.

Non-clinical Studies

We have completed multiple non-clinical investigations with EP-104, including a large IND-enabling non-clinical study in dogs. Non-clinical data have indicated that after a single high-dose IA injection of EP-104 to the knees of dogs, FP was released locally for greater than ten months with moderate exposure in the plasma. There was no evidence of cartilage damage in dogs over the ten-month follow-up period at any administered doses. In this study, a low dose of EP-104 released FP locally for longer than eight months with minimal systemic exposure. This dose was used to justify the dose selection in our Phase 2 clinical trial. Both U.S. and European competent authorities have reviewed our non-clinical safety data and deemed this information suitable to support clinical research studies.

Several non-clinical studies are underway to support the Phase 3 and registration program. These activities include safety and biocompatibility evaluations of EP-104 excipients as well as non-clinical studies to provide information needed to support the continued clinical investigation of EP-104 product candidates in humans.

Clinical Studies

EP-104IAR has been evaluated in two clinical studies in OA patients. The first clinical study was a Phase 1, double-blind, placebo-controlled clinical study (protocol EP-104-101) to assess safety, PK and preliminary efficacy in 32 knee OA patients at three sites in Canada. The single 15 mg dose was generally well tolerated and showed predictable PK. The study was not powered to detect efficacy; however, patient-reported outcome measures were collected and analyzed to evaluate pain and symptom relief. Despite the limitations of this study (small size, low dose, significant underdosing in nine subjects, and high placebo response), we believe it provides promising tolerability and PK data and preliminary clinical activity data that support future development of EP-104IAR. Results of the study have been published in *Osteoarthritis and Cartilage Open*.

The second clinical study was SPRINGBOARD – a Phase 2, double-blind, placebo-controlled clinical study (protocol EP-104IAR-201) that assessed the efficacy, safety and PK of a single 25 mg dose of EP-104IAR in 318 patients with moderate knee OA. The trial was conducted at 12 sites in Denmark, Poland and Czech Republic, with the last patient visit announced on May 25, 2023. Top-line data readout was announced on June 26, 2023.

EP-104IAR-201 met its primary endpoint with a clinically meaningful and statistically significant ($p=0.004$) improvement over vehicle-placebo in Western Ontario and McMaster Universities Osteoarthritis ("**WOMAC**") Pain at 12 weeks in the Intent to Treat population.

EP-104IAR-201 also showed statistically significant improvement over placebo at 12 weeks in three of four secondary endpoints: WOMAC Function ($p=0.014$), OMERACT-OARSI strict responders ($p=0.011$) and Area Under the Curve ("AUC") for WOMAC Pain ($p<0.001$). Importantly, statistical significance with OMERACT-OARSI strict responders to 15 weeks and AUC for WOMAC Pain to 24 weeks was also seen in the Phase 2b study, highlighting a strong and durable response. The secondary endpoint of the difference in change from baseline in the WOMAC Pain subscale at 24 weeks was not met, delivering statistical significance to 14 weeks.

We also performed pre-specified analyses in the moderate sub-population which comprised 68% of the study population ($n=214$). Statistically significant efficacy was seen for WOMAC Pain (17 weeks) and OMERACT-OARSI strict responders (22 weeks). Additionally, 40% of moderate patients achieved near complete pain relief (WOMAC Pain score of ≤ 2) which was statistically significant for 22 weeks.

EP-104IAR was well tolerated, with adverse events similar to placebo, and no withdrawals due to drug side effects. Changes in cortisol were minimal and transient and there were no differences in blood glucose levels between treatment groups, including diabetics. We believe these safety data and the observed pharmacokinetic profile support our goal of developing a product that can be used for repeat and bilateral dosing, and in certain at-risk populations.

In parallel to the main study, Magnetic Resonance Imaging ("**MRI**"), with macrocyclic gadolinium-based contrast agent, was obtained from participating patients who received EP-104IAR ($n=6$) or placebo ($n=6$). Scans were performed at baseline and weeks 12, 24 and 52 (or on early exit). The data obtained in the MRI sub-study demonstrated the following results:

- Treatment with EP-104IAR resulted in a decrease in inflammation at weeks 12 and 24 when compared to placebo. The two groups were similar at one year as the clinical effect of the single EP-104IAR injection had waned by one year.
- A correlation between reduction in inflammation and a reduction in WOMAC Pain scores was observed.
- A trend of equivalent or improved T2 relaxation times was observed in the EP-104IAR treated group compared to the placebo group at 12 weeks and that trend held steady, or improved, at 24 weeks and 52 weeks. These data suggest a trend of potential improvement in cartilage quality and morphology in the treated group.

Regulatory

We participated in a pre-IND meeting with the FDA regarding the OA program before submission and subsequent clearance of an IND, allowing evaluation of the product candidate under the SPRINGBOARD Phase 2 OA protocol.

In June 2023, EP-104IAR received Fast Track designation from the FDA. The Fast Track process is designed to facilitate and potentially expedite the development review of drugs to treat serious conditions and fill an unmet medical need. The designation recognizes both the seriousness of knee OA pain and the potential for EP-104IAR to fill the need for extended-release pain relief for this indication.

We believe our planned development pathway for EP-104IAR is supported by several key factors:

- following our recent End-of-Phase 2 meeting with the FDA in January 2024, we believe we have alignment on the required endpoints for our Phase 3 clinical trials in order to support an NDA submission;
- an open Investigational New Drug (IND) application with the FDA;
- an abbreviated New Drug Application (NDA) regulatory pathway under the FDCA, Section 505(b)(2);
- FDA Fast Track designation, recognizing the potential of EP-104IAR to meet an unmet medical need in a serious condition such as OA pain;
- a corticosteroid (FP) with a well-established record of clinical use that supports anti-inflammatory effects, and a well-characterized systemic tolerability profile;
- no evidence of cartilage damage at the therapeutic concentrations intended for humans in the IND-enabling preclinical study; and
- preliminary evidence of rapid and extended pain reduction versus placebo in both Phase 1 and Phase 2 clinical trials.

End-of-Phase-2 Meeting with FDA for EP-104IAR

In January 2024, we engaged with the FDA in an End-of-Phase-2 meeting to discuss results from the SPRINGBOARD study and to discuss planned clinical and non-clinical activities to support a New Drug Application ("**NDA**") for EP-104IAR. Based on these interactions, we believe that the following clinical trials will be required in support of a future NDA submission for EP-104IAR:

- PROMENADE 1 – A Phase 3 trial in approximately 740 knee OA patients to confirm the safety and efficacy of a single dose of EP-104IAR for six months post-dose. We anticipate that a subset of patients will be followed for one year.
- PROMENADE 2 – A Phase 3 trial in approximately 300 patients to evaluate the safety and durability of response after a second dose of EP-104IAR. We anticipate that the trial will be run in parallel with PROMENADE 1 and patients will be followed for a maximum of nine months after the second injection.
- A Phase 1 study carried out in approximately 30 patients comparing the pharmacokinetics of EP-104IAR and Flovent® HFA.

In addition to the anticipated clinical trials described above, we anticipate that we or a potential partner would need to conduct additional non-clinical work to support repeat dosing of EP-104IAR and the characterization of PVA in-line with the FDA's feedback.

We anticipate that we or a potential partner would submit the NDA for EP-104IAR under Section 505(b)(2) of the FDCA to obtain FDA approval, which is required before marketing a new drug in the United States. A 505(b)(2) NDA would rely in part on non-clinical studies and clinical trials conducted by us or a potential partner, and in part on the FDA's prior findings of safety and efficacy for the active ingredient for which we do not have a right of reference or which have been established in the scientific literature in the public domain. We intend to, either alone or with a

partner, pursue marketing approval and commercialization of EP-104 in the United States and additional ex-U.S. geographies along with the potential partner.

Lifecycle Opportunities for EP-104 Products

Corticosteroids are broadly used for various indications that may benefit from a targeted delivery and extended-release profile with minimal side effects. Natural lifecycle extensions for EP-104 products could include other joints affected by OA, other inflammatory arthropathies, or other inflammatory conditions.

Eupraxia Business Strategy

Our focus over the 24 months following the date of this MD&A will be the execution of the EP-104 development programs, including:

EP-104GI Program:

- Continued dose escalation and completed enrollment of the Phase 1b/2a RESOLVE clinical study to evaluate the safety and effectiveness of EP-104GI in EoE;
- Engage with the FDA in a Pre-IND meeting to discuss clinical and non-clinical topics related to the development program;
- Manufacture material to support EP-104GI clinical trials;
- Following feedback from the FDA, initiate Phase 1b/2a clinical study to evaluate the safety and effectiveness in EP-104GI preventing the recurrence of benign strictures; and
- Initiate a Phase 2 / 3 trial to demonstrate the effectiveness and safety of EP-104GI in EoE.

EP-104IAR Program:

- Complete non-clinical studies to support NDA filing that would enhance the EP-104IAR label and evaluate the safety and biocompatibility of all excipients; and
- Further development of the EP-104IAR program would be determined in conjunction with additional funding opportunities including a potential collaboration partner.
- Continue to strengthen the IP portfolio around the EP-104 technology;
- Continue to evaluate portfolio options for EP-104 and the Diffusphere technology platform; and
- Continued development of the manufacturing process to support both programs.

Where appropriate, we may use strategic collaborations or partnerships to accelerate development and maximize the commercial potential of our development programs. In parallel, we intend to seek out licencing, co-development or marketing partners for its technology, with the potential to expand and exploit its application fully. It is our intention to put in place conditions and resources, including the potential use of licensing partnerships, that support the success of the development program, marketing authorization(s) and commercialization across multiple jurisdictions, as well as exploitation of any opportunities for lifecycle and patent extension. Depending on market conditions, this may take

the form of co-development or commercialization partnerships, transactional opportunities and/or public financing options.

Pipeline programs are another area of potential growth in the next 24 months. Our technology is potentially compatible with various drugs and therapeutic indications. The pipeline strategy focuses on modulating the release of existing drugs to achieve better clinical outcomes in areas of high medical need. The technology has the potential to be particularly suitable for diseases requiring precisely targeted and controlled localized therapy where broader tissue or systemic exposure should be avoided (e.g., tumour oncology). We have previously investigated indications involving post-surgical pain (EP-105) and post-surgical site infections (EP-201). While both programs demonstrated preclinical evidence of supporting our technology, these programs are currently paused so we can remain focused on the other programs described previously in this MD&A.

We currently have several pipeline candidates in development with a goal to add a pipeline product candidate over the next 24 months to allow for sustained corporate growth. We expect this to involve a multidisciplinary review of candidate drugs, formulation development, *in vitro* screening to identify the most promising lead candidates and non-clinical proof-of-concept studies. Information generated from these inquiries will determine whether we should proceed with further development.

Significant Company Events

On May 18, 2023, the Company announced the appointment of Dr. Mark Kowalski to the role of Chief Medical Officer. This new position reports directly to the Chief Executive Officer ("**CEO**") and is responsible for advancing clinical trials and pipeline development.

On June 8, 2023, the Company announced the dosing of the first patient in an open label Phase 1b/2a clinical study (RESOLVE) using EP-104GI in EoE. The RESOLVE study will be conducted in up to 24 adult patients with a confirmed diagnosis and active EoE symptoms. Primary outcomes for safety, PK and efficacy will be collected at various points over a 12-week total period, with a subsequent follow up at six (6) months. Initial low-dose cohorts presented early signals of efficacy, and we anticipate ongoing safety, efficacy and PK readouts from subsequent dose-escalation cohorts throughout 2024. The RESOLVE protocol is active at sites in Canada, the Netherlands and Australia. Additional sites and jurisdictions will be added as necessary to complete target recruitment.

On June 13, 2023, the Company announced that it had received U.S. Fast Track designation for EP-104IAR in the treatment of OA. This process is designed to facilitate the development and expedite the review of drugs that treat serious conditions and fill an unmet medical need.

On June 22, 2023, the Company filed and obtained a receipt for a final short form base shelf prospectus (the "**2023 Shelf Prospectus**"). The 2023 Shelf Prospectus replaced the Company's existing shelf prospectus filed in January 2022.

On June 26, 2023, the Company announced positive results from its Phase 2b clinical trial of EP-104IAR for pain associated with knee OA. EP-104IAR met its primary endpoint with a clinically meaningful and statistically significant (p=0.004) improvement over vehicle-placebo in WOMAC Pain at 12 weeks.

On August 18, 2023, the Company announced the closing of a non-brokered private placement. The Company issued 3,183,875 Common Shares at a price of CDN$7.00 per share for gross proceeds of CDN$22,287,125.

On September 7, 2023, the Company announced the appointment of KPMG LLP as the auditor of the Company, effective August 30, 2023. Concurrently, Baker Tilly WM, LLP resigned as the Company's auditor. There were no reportable events involving Baker Tilly WM, LLP.

On October 11, 2023, the Company announced the initiation of a second cohort in its Phase 1b/2a clinical trial in EoE.

On December 12, 2023 the Company announced positive clinical data in its EP-104GI RESOLVE trial.

On January 30, 2024 the Company announced positive data from a MRI exploratory sub-study in its Phase 2 SPRINGBOARD trial evaluating the safety and efficacy of EP-104IAR for the treatment of osteoarthritis of the knee.

On February 1, 2024 the Company announced summary results from the End-of-Phase 2 meeting with the FDA and the initiation of the Phase 3 Development program for EP-104IAR.

On February 5, 2024 the Company announced updated positive clinical trial data in its EP-104GI RESOLVE trial for the treatment of Eosinophilic Esophagitis.

On February 5, 2024, the Company filed and obtained a receipt for a final short form base shelf prospectus (the "**Shelf Prospectus**"). The Shelf Prospectus replaced the Company's 2023 Shelf Prospectus filed in June 2023. The Shelf Prospectus will allow the Company and certain of its securityholders to qualify the distribution of up to US$200 million of Common Shares, preferred shares, debt securities, warrants, subscription receipts, and units, or any combination thereof during the 25-month period that the Shelf Prospectus is effective, in amounts, at prices and on terms based on market conditions at the time of any offering, and set forth in an accompanying shelf prospectus supplement.

On March 15, 2024 the Company announced the closing of an overnight marketed offering of Common Shares. The Company issued 8,260,435 Common Shares at a price of CDN$4.10 per Common Share for gross proceeds of CDN$33,867,784, which included the issuance of 943,435 Common Shares upon exercise of the over-allotment option.

Selected Financial Information

The financial information reported herein for the years ended December 31, 2023 and 2022 has been derived from the audited consolidated financial statements for the period ended December 31, 2023 prepared in accordance with U.S. GAAP. Effective December 31, 2023, the Company changed its reporting currency to the U.S. dollar from the Canadian dollar. As such, all prior amounts originally reported in CDN are now reported in USD. The change in reporting currency was made to enhance comparability of the Company's results with other publicly traded companies in the life sciences industry. The Company has retained the Canadian dollar as its functional currency.

The financial information reported herein for the year ended December 31, 2021 has been derived from the audited amended and restated consolidated financial statements for the period ended December 31, 2022, prepared in accordance with IFRS.

Selected Consolidated Statement of Financial Position Data

	December 31, 2023 **$**	**December 31, 2022** **$**	**December 31, 2021[(1)] (As Converted)** **$**	**December 31, 2021[(2)]** **CDN$**
Cash and cash equivalents	19,341,756	18,263,389	16,478,994	20,892,069
Total assets	20,266,229	19,122,249	24,626,966	31,222,067
Total non-current financial liabilities	-	8,856,008	7,758,536	9,836,272
Equity attributable to owners of the Company	2,216,207	7,786,525	15,737,374	19,951,843
Non-controlling interest	(1,323,881)	(578,671)	(657,703)	(833,836)
Total shareholders' equity	892,326	7,207,854	15,079,671	19,118,007

(1) Represents amounts previously reported in our Audited Amended and Restated Consolidated Financial Statements for the years ended December 31, 2022 and 2021. These financial statements were prepared under IFRS and presented in CDN dollars and have been converted to USD at the Bank of Canada spot rate as of 31 December 2021 (1USD = 1.2678). The converted figures are unaudited.

(2) Amounts previously reported in our Audited Amended and Restated Consolidated Financial Statements for the years ended December 31, 2022 and 2021. These financial statements were prepared under IFRS and presented in CDN dollars.

Cash and cash equivalents increased by $1,078,367 to $19,341,756 as at December 31, 2023. This increase was attributable primarily to the net Private Placement financing of $15,886,537 and redemption of warrants of $5,241,811 offset by the net loss of $28,966,006 less items not affecting cash of $3,006,936.

Total assets increased by $1,143,978 to $20,266,227 as at December 31, 2023. This increase was primarily due to the increase in cash and cash equivalents referenced above.

Total non-current financial liabilities decreased by $8,856,008 to $nil as at December 31, 2023. This decrease was primarily attributable to the reclassification of the SVB debt facility being reclassified as a current liability.

The Company did not pay any dividends or make any distributions to shareholders in any of the above periods.

Selected Consolidated Statements of Operations and Comprehensive Loss Data

	Year Ended December 31, 2023	Year Ended December 31, 2022	Year Ended December 31, 2021[1] (As Converted)	Year Ended December 31, 2021[2]
	$	$	$	CDN$
Revenue	-	-	-	-
Loss and comprehensive loss – Owners of the Company	(28,220,796)	(18,489,629)	(19,112,839)	(23,957,944)
Loss and comprehensive loss – Non-controlling interest	(745,210)	(501,135)	(303,107)	(379,945)
Net loss for the year	(28,966,006)	(18,990,764)	(19,415,947)	(24,337,889)
Comprehensive loss for the year	(28,886,192)	(20,267,152)	(19,415,947)	(24,337,889)
Loss per share, basic and diluted – Owners of the Company	(1.17)	(0.96)	(1.54)	(1.93)

(1) Represents amounts previously reported in our Audited Amended and Restated Consolidated Financial Statements for the years ended December 31, 2022 and 2021. These financial statements were prepared under IFRS and presented in CDN dollars and have been converted to USD at the Bank of Canada annual exchanges rate for 2021 (1USD = 1.2535). The converted figures are unaudited.

(2) Amounts previously reported in our Audited Amended and Restated Consolidated Financial Statements for the years ended December 31, 2022 and 2021. These financial statements were prepared under IFRS and presented in CDN dollars.

The net loss for the year ended December 31, 2023 increased by $9,975,242 when compared to the year ended December 31, 2022, primarily due to an increase in general and administrative costs of $3,296,406, research and development costs of $6,933,371 and offset by a decrease to other expenses of $290,958 and tax expense of $36,423.

The comprehensive loss for the year ended December 31, 2022 increased when compared to the year ended December 31, 2021, primarily due to higher research and development expenses resulting from the activities associated with the Phase 2 clinical trial for EP-104IAR offset by lower general administrative costs and share-based payments. Also, other expenses that were associated with the Company's initial public offering in 2021 were not incurred in 2022.

While several of the Company's vendors have inflationary clauses in their contracts, the impact of inflation is considered immaterial.

Comparison of the Year Ended December 31, 2023, and 2022

Results of Operations

	Year Ended December 31 2023	Year Ended December 31 2022	Change	Change
	$	$	$	%
General and administrative expenses	7,284,004	3,987,598	3,296,406	82.67
Research and development expenses	20,563,225	13,629,854	6,933,371	50.87
Other income (expenses)	(1,082,354)	(1,373,312)	(290,958)	(21.19)
Net loss before tax	28,929,583	18,990,764	9,938,819	52.34
Tax expense	36,423	-	36,423	100
Net loss	28,966,006	18,990,764	9,975,242	52.53
Foreign currency translation	79,814	(1,276,388)	1,356,202	106.25
Comprehensive loss	28,886,192	20,267,152	8,619,040	42.53

General and Administrative

General and administrative expenses consist of office and administrative costs, travel, professional fees, public company costs and salaries and benefits.

Comparing the year ended December 31, 2023, to the same period in 2022, general and administrative activities increased by $3,296,406. This increase is due to the following items:

- An increase of $2,553,100 related to professional fees. This increase is a result of increased business development consulting fees, legal fees associated with financing and compliance activities, and audit fees resulting from our change of auditor.
- An increase of $600,030 related to salaries, bonuses, and benefits as a result of increased headcount and salary increases.
- An increase of $189,809 related to public company costs associated with investor relation and compliance activities.
- An increase of $225,877 related to travel expenses associated with increased business development and financing activities.
- A reduction of $338,378 related to share based payments as a result of a number of the awards being fully or mostly vested thereby decreasing the vesting expense in addition to fewer options awarded in the current compared to the prior year.
- Increase in office costs of $56,259 due to increased headcount.

Research and Development

Comparing the year ended December 31, 2023, to the same period in 2022, research and development activities increased by $6,933,371. This increase is primarily due to the following items:

- an increase of $5,000,000 in licensing costs due to the successful completion of the Phase 2b study of the clinical trial related to EP-104IAR.
- An increase of $520,341 in costs related to direct research programs. Manufacturing and analytical costs increased as we commenced preparations for Phase 3 activities. Clinical expenses saw a reduction as we approached the conclusion of our Phase 2b clinical trial of EP-104IAR.
- An increase of $103,689 related to pipeline development and other research and development costs.
- An increase of $893,634 related to salaries and benefits due to increased head count and salary increases.
- An increase of $316,823 related to share-based payments as a result of increased number of options issued.
- A decrease of $98,884 related to government grants and tax incentives.

Other Income/(Expenses)

Comparing the year ended December 31, 2023, to the same period in 2022, other expenses decreased by $290,958. This decrease is due to the following items:

- A decrease of $431,170 related to interest income as a result of an increase in the Canadian prime rate for the purposes of interest on cash.
- An increase of $187,317 related to interest expense as a result of an increase in the Canadian prime rate for the purposes of interest on the convertible debt.
- An increase of $174,256 related to foreign exchange loss. The foreign exchange loss is a result of fluctuations in the U.S. and Australian exchange rate versus the Canadian dollar on our U.S. and Australian denominated assets and liabilities during the current period.
- A decrease of $219,570 related to negative changes in fair value of financial instruments on the SVB convertible debt facility.
- Decrease in loss on sale of equipment of $1,791 due to fewer items being sold.

Summary of Quarterly Results

The information in the tables below has been derived from the Company's consolidated financial statements. Effective December 31, 2023, the Company transitioned to U.S. GAAP as well as changing its reporting currency to USD from CDN. As such, all prior amounts originally reported in CDN are now reported in USD. The change in reporting currency was made to enhance comparability of the Company's results with other publicly traded companies in the life sciences industry. The Company has retained the Canadian dollar as its functional currency. In addition, all quarters have been retrospectively restated for the adoption of U.S. GAAP in the current period.

The Company's quarterly operating results have varied substantially in the past and may vary substantially in the future. Accordingly, the information below is not necessarily indicative of results for any future quarter.

	Dec 31, 2023 (Restated)	Sep 30, 2023 (Restated)	Jun 30, 2023 (Restated)	Mar 31, 2023 (Restated)	Dec 31, 2022 (Restated)	Sep 30, 2022 (Restated)	Jun 30, 2022 (Restated)	Mar 31, 2022 (Restated)
	$	$	$	$	$	$	$	$
Total Revenue	-	-	-	-	-	-	-	-
Total net loss	(10,607,396)	(4,896,080)	(9,506,442)	(3,956,088)	(7,771,019)	(4,115,343)	(4,206,221)	(2,898,181)
Loss per share, basic and diluted (Owners of the Company)	(0.38)	(0.18)	(0.43)	(0.18)	(0.36)	(0.19)	(0.21)	(0.20)

The Company has incurred net losses in each of its preceding eight quarters as a result of continued activities associated with the Phase 2 clinical trial for EP-104IAR and the Phase 1b/2a clinical trial of EP-104GI. This trend is expected to continue into the future as we make further investments in our EP-104 programs. Research and development expenses are expected to remain high as we undertake clinical trials and incur significant costs for CROs and consultants, and further investment in additional drug candidates in support of broader pipeline development. General and administrative expenses are likely to remain high in the future as a result of ongoing costs associated with public company compliance.

Use of Proceeds

The following tables show the estimated use of net proceeds for each financing, compared with the actual use of net proceeds:

March 2024 Financing

	Estimated Amount to be Expended CDN$	**Estimated Amount to be Expended[(1)] US$**	**Actual Amount Expended US$**
Research and development activities for EP-104GI and EP-104IAR	12,100,000	8,941,107	-
General and administrative expenses	7,700,000	5,689,795	-
Amended and restated license agreement payment	6,700,000	4,950,861	-
Total	**26,500,000**	**19,581,763**	**-**

(1) Converted as of March 15, 2024 using the daily rate of exchange published by the Bank of Canada of US$1.00 = CDN$1.3533.

We intend to use a portion of the capital resources previously identified for EP-104IAR development to continue development of EP-104GI.

April 2022 Financing

	Estimated Amount to be Expended CDN$	Actual Amount Expended CDN$
Research and development	8,500,000	9,837,000
General and administrative expenses	5,100,000	3,763,000
Total	**13,600,000**	**13,600,000**

There have been no material variances to the way the Company intended to use proceeds from the 2022 Offering (as defined herein).

Liquidity, Capital Resources and Outlook, Management of Cash Resources

As at December 31, 2023, the Company had cash and cash equivalents of $19,341,756 (December 31, 2022 - $18,263,389).

The Company's business does not currently generate revenue or positive cash flows from operations and is reliant on equity and debt financing to provide the necessary cash to continue its research and development activities and ongoing operations. There can be no assurance that equity financings will be available in the future with terms that are satisfactory to the Company.

The Company's cash flow forecasts are continually updated to reflect actual cash inflows and outflows so to monitor the requirements and timing for additional financial resources. Given the volatility of the Canadian dollar, U.S. dollar, and Australian dollar ("**AUD**") exchange rate, the Company estimates its USD and AUD expenses for the year and sets aside appropriate levels of USD and AUD cash. By holding USD and AUD, the Company remains subject to currency fluctuations which effect its loss during any given year.

Further, we continue to monitor additional opportunities to raise equity capital and/or secure additional funding through non-dilutive sources such as government grants and potential license agreements. However, it is possible that our cash and working capital position may not be enough to meet our business objectives in the event of unforeseen circumstances or a change in our strategic direction.

On March 15, 2024, the Company announced it had closed an overnight marketed public offering (the "**Offering**") of Common Shares of the Company. Pursuant to the Offering, Eupraxia issued 8,260,435 Common Shares at a price of CDN$4.10 per share for gross proceeds of $25,026,073 (CDN$33,867,784).

The following table sets out our pro-forma condensed balance sheet which has been prepared as if the proceeds from the Offering were received on December 31, 2023. These amounts are presented to provide additional information about the liquidity of the organization after taking into consideration these proceeds. These amounts have not been adjusted for any other matters or expenses incurred after the balance sheet date and are unaudited.

	December 31, 2023 Actual $	December 31, 2023 Pro Forma $
Cash and cash equivalents	19,341,756	44,367,829
Other assets	924,473	924,473
Total Assets	20,266,229	45,292,302
Current liabilities	19,373,903	19,373,903
Shareholders' equity (deficit)		
Common Shares (no par value — 27,282,165 common shares issued and outstanding, actual; 35,542,600 common shares issued and outstanding, as adjusted)	92,913,585	117,939,658
Additional Paid-In Capital	17,510,469	17,510,469
Deficit	(105,501,295)	(105,501,295)
Accumulated other comprehensive loss	(2,706,552)	(2,706,552)
Non-controlling interest	(1,323,881)	(1,323,881)
Total shareholders' equity	892,326	25,918,399
Total liabilities and shareholders' equity (deficit)	20,266,229	45,292,302

These funds are being used to fund our clinical trials in EP-104GI and EP-104IAR. The remainder of the proceeds will be used for general and administrative expenses, a milestone payment, working capital needs and other general corporate purposes. Assuming we are able to refinance our existing debt facility with Silicon Valley Bank, we anticipate our cash resources will be sufficient to fund the Company through to the third quarter of 2025.

Comparison of Cash Flow for the year ended December 31, 2023 and 2022.

	December 31, 2023 $	December 31, 2022 $
Net cash provided by (used in):		
Operating activities	(20,683,623)	(14,395,201)
Investing activities	(73,377)	9,834,371

Financing activities	21,013,970	10,801,079
Net decrease in cash and cash equivalents	**256,970**	**6,240,249**
Foreign Exchange effect on cash	821,397	(507,395)

Cash used in operating activities for the year ended December 31, 2023 increased by $6,288,180 compared to the same period in the prior year. The primary driver was the increase in expenditure on the EP-104IAR and EP-104GI

clinical trials, increased business development and financing related costs, payment of accounts payable and accrued liabilities, and increased salary costs.

Cash used in investing activities for the year ended December 31, 2023 2023 increased by $9,907,747 compared to the same period in the prior year. The primary driver of the decrease was due to no redemptions of short-term investments during the year ended December 31, 2023 as compared to the comparable period in 2022.

Cash provided by financing activities for the year ended December 31, 2023 increased by $10,212,891 compared to the same period in the prior year. The primary driver of the increase was the Private Placement offering which occurred during the year ended December 31, 2023 and the redemption of warrants and options during the same period, offset by the overnight marketed public offering which occurred during the year ended December 31, 2022.

Going Concern

These consolidated financial statements have been prepared on a going concern basis with the assumption that the Company will be able to realize its assets and discharge its liabilities and commitments in the normal course of business. At December 31, 2023, the Company had cash and cash equivalents of $19,341,756 and the Company has not yet generated revenue from operations. The Company incurred a net loss of $28,966,006 during the year ended December 31, 2023, and as of that date, the Company's accumulated deficit was $105,501,295. As the Company is in the research and development stage, the recoverability of the costs incurred to date is dependent upon the ability of the Company to obtain the necessary funding to complete the research and development of its projects and upon future commercialization or proceeds from the monetization of research activities to date. The Company will periodically have to raise funds to continue operations and raised $15,886,537 (CDN$20,836,005) through a non-brokered private placement of 3,183,875 common shares in 2023 (2022 - $11,768,459 through a marketed public offering) and raised and raised $25,026,073 (CDN$33,867,784) through an overnight marketed public offering of 8,260,435 common shares in March 2024. Although it has been successful in doing so in the past, there is no assurance it will be able to do so in the future, especially with the ongoing conflicts in the Ukraine and the Middle East affecting the global capital markets. Recent developments with SVB have not impacted the Company's outlook for cash runway. The Company holds no amounts on deposit with SVB and the convertible debt which matures in June 2024 remains in good standing, is fully drawn and is not callable by SVB. The Company is active in its pursuit of additional funding through potential partnering and other strategic activities as well as grants to fund future research and development activities, and additional equity financing.

The continued operations of the Company are dependent on its ability to generate future cash flows or obtain additional funding. There is a risk that in the future, additional financing will not be available on a timely basis or on terms acceptable to the Company. These events and conditions indicate a material uncertainty which may cast significant doubt about the Company's ability to continue as a going concern. These consolidated financial statements do not include any adjustments to the amounts and classification of assets and liabilities that might be necessary should the Company be unable to continue in business.

Long-Term Obligations and Other Contractual Commitments

The Company may be required to make milestone, royalty, and other research and development funding payments under research and development collaboration and other agreements with third parties. These payments are contingent upon the achievement of specific development, regulatory and/or commercial milestones. The Company has not accrued for these payments as at December 31, 2023 due to the uncertainty over whether these milestones will be achieved. The Company's significant contingent milestone, royalty and other research and development commitments are as follows:

Auritec License Agreement

Auritec Pharmaceuticals, Inc. ("Auritec") is a privately held clinical-stage drug delivery company that holds patents in the field of extended-release delivery of drug products utilizing its proprietary drug delivery platform, the "Plexis Platform". Eupraxia, through its subsidiary, Eupraxia USA, is a party to an amended and restated license agreement

dated effective October 9, 2018 (as further amended, the "**Amended and Restated License Agreement**") with Auritec.

Under the terms of the Amended and Restated License Agreement, Auritec has granted Eupraxia USA an exclusive license (including the right to sublicense to its affiliates and third parties) under the licensed patents owned or controlled by Auritec and for all the technical information and know-how relating to the technology claimed in such patents or possessed by Auritec with respect to the use of the Plexis Platform for the delivery of fluticasone in all medical fields (except for the Excluded Fields (as defined in the Amended and Restated License Agreement)), to develop, make, have made, manufacture, use, commercialize, sell, sub-license, offer for sale, import, and have imported the Licensed Products (as defined in the Amended and Restated License Agreement).

Pursuant to the terms of the Amended and Restated License Agreement, in consideration for the rights and exclusive license granted to Eupraxia USA, Eupraxia USA paid the Upfront Fee (as defined in the Amended and Restated License Agreement) of $5,000,000 by the end of December 31, 2021 with the agreement currently in good standing.

In addition to the Upfront Fee, pursuant to the Amended and Restated License Agreement, Eupraxia USA has agreed to pay Auritec up to USD30 million upon achievement of certain regulatory and commercial milestones related to Licensed Products under the Amended and Restated License Agreement as well as a royalty of 4% of net sales of Licensed Products by Eupraxia USA or its affiliates, subject to certain reductions.

The following table summarizes the milestone payment schedule. As of December 31, 2023, the only milestone that has been accrued and provided for in the financial statements is $5,000,000 related to the successful completion of the Phase 2b clinical study.

Milestone Event	**Milestone Payment**
Successful Completion of a Phase 2b Study	5,000,000
First OA Regulatory Approval	5,000,000
Second OA Regulatory Approval	5,000,000
Non-OA Indication Regulatory Approval	10,000,000
First calendar year in which aggregate Net Sales by Eupraxia USA, its affiliates and sublicenses exceed $500,000,000	5,000,000
Maximum milestones payable	**$30,000,000**

Eupraxia USA has also agreed to pay to Auritec 20% of sublicensing royalties or other consideration based on net sales of Licensed Products. Eupraxia USA has further agreed to pay Auritec a percentage of Non-Royalty Monetization Revenue (as defined in the Amended and Restated License Agreement), which includes payments received for a sale of Eupraxia USA or its assets or sale or sublicense of a Licensed Product, which percentage ranges from 10% to 30% depending on the development stage of the most-advanced Licensed Product, up to a maximum of $100 million. The following table summarizes the Non-Royalty Monetization Revenue percentage schedule:

Date of Execution	Percentage of Non-Royalty Monetization Revenue
Prior to Successful Completion of a Phase 2b Study	30%
After Successful Completion of a Phase 2b Study but prior to Successful Completion of a Phase 3 Study	20%
After Successful Completion of a Phase 3 Study but prior to Regulatory Approval of a Product in the Eupraxia Field from FDA in the United States	15%
After Regulatory Approval of a Product in the Eupraxia Field from FDA in the United States	10%

Either party may terminate the Amended and Restated License Agreement in the event of the other party's bankruptcy, liquidation, or dissolution. Auritec may also terminate upon a material breach of the Amended and Restated License Agreement by Eupraxia USA that is not cured within 60 days (15 days in the case of a payment breach). Further, if Eupraxia USA directly or indirectly challenges any claim in any Auritec patent licensed under the Amended and Restated License Agreement, or assist a third party in doing so, Auritec may immediately terminate the Amended and Restated License Agreement. If Auritec directly or indirectly challenges any Eupraxia patent contemplated in the Amended and Restated License Agreement other than as reasonably required to defend Auritec patents as a basis for such challenge, or assists a third party in doing so, we may immediately terminate the Amended and Restated License Agreement.

Lease Agreement

On October 21, 2019, the Company entered into a lease agreement for its head office located at Suite 201 – 2067 Cadboro Bay Road, Victoria BC. The lease is for a period of 5 years, expiring November 30, 2024. The annual base rent for the lease is CDN$87,696 with anticipated additional annual rent of CDN$92,568 to cover the Company's share of property taxes and operating costs. Additional rent is subject to adjustment at the end of each lease year based on actual costs incurred.

Convertible Debt Facility

On June 21, 2021, the Company entered into a debt agreement with SVB (the "**Debt Agreement**") and concurrently drew down, in full, the CDN$10 million principal amount under the Debt Agreement.

The Debt Agreement has a term of 36 months or 48 months at SVB's election. The Debt Agreement accrues interest at the greater of 2.45% and the Canadian prime rate, requiring monthly interest payments in cash. An additional payment in kind will accrue at a rate of 7% per annum, which will be settled at maturity or on conversion.

Subject to the terms and conditions of the Debt Agreement, SVB may elect to convert the principal amount of the convertible debt and the accrued and unpaid interest thereon into Common Shares at a conversion price equal to CDN$5.68 per Common Share. The conversion price of the accrued and unpaid interest will be subject to the minimum pricing requirements of the TSX, to the extent applicable, at the time of conversion.

The Company will have the right (the "**Call Right**") to call the convertible debt by paying to SVB an amount equal to:

i. 125% of the principal amount of the convertible debt (less principal amounts previously repaid), if the Call Right is exercised on or before the 18 month anniversary of the date of the Debt Agreement; and

ii. 150% of the principal amount of the convertible debt (less principal amounts previously repaid), if the Call Right is exercised after the 18 month anniversary of the date of the Debt Agreement,

in either case together with all accrued and unpaid interest on the principal balance of the convertible debt. If the Call Right is exercised by the Company, SVB will retain certain lookback rights in the event the Company subsequently announces its topline data from its Phase 2 clinical study or the Company enters into an agreement to be acquired in the 12 months following the exercise of the Call Right. The Company has agreed to grant SVB a security interest in all of its assets, excluding its patents and other intellectual property, and the testing and product equipment by way of the loan agreement it entered into on September 10, 2021 as security for its obligations under the Debt Agreement.

The Company was required, on or prior to June 30, 2022, to raise additional net new capital, as defined in the Debt Agreement, in the aggregate amount of CDN$10 million. This net new capital could originate from, but was not restricted to, a variety of sources as outlined in the Debt Agreement and could include up to CDN$5 million in reduced project expenses. On April 20, 2022, the Company closed an offering for gross proceeds of CDN$14.7 million that satisfied this requirement (the "**2022 Offering**"). The Company's Debt Agreement with SVB remains in good standing as at the date of approval of these consolidated financial statements and is fully drawn.

Transactions with Related Parties

There were no transactions with related parties during the year ended December 31, 2023 and 2022, reportable under U.S. GAAP.

Off-Balance Sheet Arrangements

The Company has no material undisclosed off-balance sheet arrangements that have or are reasonably likely to have, a current or future effect on our results of operations or financial condition.

Critical Accounting Estimates and Judgments

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities at the date of the consolidated financial statements and reported amounts of expenses during the reporting year, which, by their nature, are uncertain. Actual outcomes could differ from these estimates. The impacts of such estimates are pervasive throughout the consolidated financial statements, and may require accounting adjustments based on future events. Revisions to accounting estimates are recognized in the year in which the estimate is revised and future periods if the revision affects both current and future years. These estimates are based on historical experience, current and future economic conditions and other factors, including expectations of future events that are believed to be reasonable under the circumstances that affect the reported amounts of assets, liabilities, income and expenses.

Critical accounting estimates

Significant assumptions about the future and other sources of estimation uncertainty that management has made at the end of the reporting period, that could result in a material adjustment to the carrying amounts of assets and liabilities in the event that actual results differ from assumptions made, relate to, but are not limited to, the following:

i) Share-based payments are measured at fair value, using the Black-Scholes option pricing model, at the grant date and expensed over the vesting period. In determining the fair value, the Company makes estimates of the expected volatility of the shares, the expected life of the share-based instrument, and an estimated risk-free interest rate; and

ii) The determination of the amount allocated to the liability and equity components (for those financial instruments that are comprised of both). This requires management to estimate various components and characteristics of present value calculations used in determining the fair value of the instrument, including the market interest rates of non-convertible debentures.

Critical accounting judgments

Critical accounting judgments are accounting policies that have been identified as being complex or involving subjective judgments or assessments. The Company's management made the following critical accounting judgments:

i) The determination of the functional currency of the Company and its subsidiaries; and

ii) Assessment of the appropriateness of the going concern assertion and events and conditions that indicate a material uncertainty that may cast substantial doubt thereon.

Accounting Standards and Amendments Issued but Not Yet Adopted

The Company has not yet adopted certain new standards, amendments and interpretations to existing standards, which have been published but are only effective for accounting periods beginning on or after January 1, 2024 or later periods. The new and amended standards are not expected to have a material impact on the Company's consolidated financial statements.

Financial Instruments

The Company's financial instruments consist of cash and cash equivalents, amounts receivable, accounts payable and accrued liabilities, loans payable and convertible debt.

There were no changes to the Company's risk exposures or management of risks during the year ended December 31, 2023. The Company's risk exposures and the impact on the Company's financial instruments are summarized below:

Credit risk

Credit risk is the risk that one party to a financial instrument will cause a financial loss for the other party by failing to discharge an obligation. The Company believes it has no significant credit risk, as its cash and cash equivalents and short-term investments, being its primary exposure to credit risk, is with a large Canadian bank. The Company's maximum exposure to credit risk is the carrying value of these financial assets.

Liquidity risk

Liquidity risk is the risk that an entity will encounter difficulty in meeting obligations associated with financial liabilities that are settled by delivering cash or another financial asset. The Company's approach to managing liquidity risk is to ensure that it will have sufficient liquidity to meet liabilities when due. As at December 31, 2023,

the Company had cash and cash equivalents of $19,341,756 (2022 -$18,263,389) in addition to current liabilities of $19,373,903 (2022 -$3,058,387). Management is currently working on certain strategic alternatives including, but not limited to raising additional capital and strategic alternatives to its existing contingent convertible debt facility. There is no assurance, however, that any or all of these alternatives will materialize or that additional funding will be available, if and when needed.

Contractual Obligations	**Total**	**Less than 1 year**	**1 - 3 years**
Convertible Debt [(1)]	$ 9,101,749	$ 9,101,749	$ -
Accounts Payable and Accrued Interest [(2)]	3,903,602	3,903,602	-
Loans Payable	62,709	62,709	-
Leases	60,780	60,780	-
Total Contractual Obligations	**$ 13,128,840**	**$ 13,128,840**	**$ -**

(1) Included principal of CDN$10,000,000 ($7,560,865) and paid in kind interest of CDN$1,961,859.05 ($1,540,884). The counterparty to this instrument has the option to extend the maturity to June 2025 or convert this instrument at a price of CDN$5.68 / share.
(2) Included amounts owing to vendors as well as accrued interest.

Market risk

Market risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market prices. Market risk comprises three types of risk: currency risk, interest rate risk and other price risk.

Interest rate risk

Interest rate risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market interest rates. The Company is exposed to interest rate cash flow risk; and to the extent that the prevailing market interest rates differ from the interest rate on the Company's monetary assets and liabilities, the Company is exposed to interest rate price risk. At December 31, 2023, the Company maintains a convertible debt facility totaling CDN$10,000,000 as well as having an equipment loan of $235,000 of which a principal balance of $62,709 remains as at December 31, 2023.

The convertible debt accrues interest at the greater of 2.45% and the Canadian prime rate, requiring monthly interest payments. An additional payment in kind accrues at a rate of 7% per annum, which will be settled at maturity or on conversion. The equipment loan accrues interest at a fixed rate of 5.84%.

As at December 31, 2023, management has determined the effect on the future results of operations due to a change in the current Canadian prime rate. An impact of a 1% change in the Canadian prime rate would impact the amount of interest to be paid over the remaining term of the convertible debt facility by approximately $43,807.

Currency risk

Currency risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in foreign exchange rates. The Company is exposed to currency risk due to its frequency of transactions in U.S. dollars. The Company does not use derivatives to hedge against this risk, however, it has purchased U.S. dollars to cover the majority of the costs of the Company's Phase 2 clinical trial. At December 31, 2023, the Company held cash of $933,816 (2022 – $1,159,926) had accounts payable of $1,292,128 (2022 – $1,814,067), a payable to Auritec of $5,000,000 (2022 – $nil) and a loan payable of $62,709 (2022 – $142,127) denominated in USD which were translated to CDN at 1.3226 (2022 – 1.3544). The impact of a 10% change in the exchange rates would have an impact of

approximately $542,102 (2022 – $79,627) on profit or loss. The Company also has cash in accounts payable in Australian dollars, Great British pounds and Euros. The impact of a 10% change in the exchanges of these currencies would have an immaterial effect on future cash flows.

Other price risk

Other price risk is the risk that the fair value or future cash flows of a financial instrument will fluctuate because of changes in market prices (other than those arising from interest rate risk and foreign currency risk), whether those changes are caused by factors specific to the individual financial instrument or its issuer or by factors affecting all similar financial instruments traded in the market. The Company is not exposed to significant price risk with respect to commodity or equity prices.

Fair Value Measurement

The Company categorizes its financial instruments measured at fair value into one of three different levels depending on the observation of inputs used in the measurement.

Level 1: Fair value is based on unadjusted quoted prices for identical assets or liabilities in active markets.

Level 2: Fair value is based on inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.

Level 3: Fair value is based on valuation techniques that require one or more significant unobservable inputs.

The Company's financial instruments consist of cash and cash equivalents, accounts payable and accrued liabilities, loans payable and convertible debt. With the exception of convertible debt, the carrying value of the Company's financial instruments approximate their fair values due to their short-term maturities.

The following table summarizes information regarding the classification and carrying values of the Company's financial instruments measured at amortized cost:

Financial assets/liabilities	**December 31, 2023**	**December 31, 2022**
Cash and cash equivalents	$ 19,341,756	$ 18,263,389
Amounts receivable	$ 190,612	$ 89,715
Accounts payable and accrued liabilities	$ 3,921,875	$ 2,928,566
Payable to Auritec	$ 5,000,000	$ -
Loans payable	$ 62,709	$ 142,127

The following table summarizes information regarding the changes in fair value of liabilities measured at fair value, categorized as Level 3:

	Convertible Debt
Balance as at December 31, 2021	**$ 7,507,755**
Interest expense	971,873
Interest paid	(315,436)
Change in fair value	1,056,165
Foreign exchange	(478,361)
Balance as at December 31, 2022	**$ 8,741,996**
Interest expense	1,162,773
Interest paid	(591,170)
Change in fair value	836,595
Foreign exchange	(185,806)
Balance as at December 31, 2023	**$ 10,336,003**

Risks and Uncertainties

The primary risk factors affecting the Company are set forth under the heading "*Risk Factors*" in the Shelf Prospectus and the AIF.

Outstanding Share Capital

As of the date of this MD&A, the Company had 35,622,553 Common Shares issued and outstanding. The maximum number of additional Common Shares issuable, should all convertible rights be exercised are as follows:

Common Shares Issuable:	As of the date of MD&A
Options [1]	3,482,490
2013 Warrants [2]	380,921
Founders Warrants [3]	315,500
Underlying Founders Warrants [4]	315,500
Class B Shares [5]	562,500
Warrants – Listed EPRX.WT[6]	2,826,024
Warrants – Listed EPRX.WT.A[7]	5,196,550
Compensation Warrants[8]	50,054
Nordic Warrants [9]	39,228
SVB Debt Facility [10]	2,143,445
Total Common Shares Issuable	**15,312,212**

Notes:

(1) Represents options outstanding under the Company's stock option plan, each having an exercise price between $1.90 and $8.00 and expiry dates ranging from March 31, 2025 to September 26, 2033.

(2) Represents common share purchase warrants to acquire up to 380,921 Common Shares at an exercise price of $0.7572 per share, with each such common share purchase warrant expiring 120 days after the warrant holder or the holder's spouse ceases to be a director, officer or consultant of the Company.

(3) Represents common share purchase warrants to acquire 315,500 units, with each unit consisting of one Common Share and one underlying common share purchase warrant (an "**Underlying Founder Warrant**") at an exercise price of $0.4984 per unit, expiring 120 days after the warrant holder ceases to be a director, officer or consultant of the Company.

(4) Represents Underlying Founder Warrants to acquire up to 315,500 Common Shares, at an exercise price of $0.75 per share, expiring two years from the date of exercise of the Underlying Founder Warrant.

(5) Represents 562,500 Common Shares that are issuable upon conversion of the 225 Class B Shares of Eupraxia Pharma Inc., the Company's subsidiary, held by Amanda Malone, the Chief Scientific Officer of the Company. Each Class B Share is exchangeable into Common Shares based on an exchange rate of 2,500 Common Shares for each Class B Share, subject to adjustments upon the occurrence of certain events, for a total of 562,500 Common Shares. The Class B Shares are exchangeable by Ms. Malone at her election, provided that the Company may force the exchange of the Class B Shares into Common Shares at any time on or after January 31, 2031, or on or after January 31, 2026 if the Company is listed on a stock exchange and is a reporting issuer in Canada at such time. The Company may also force the exchange of the Class B Shares into Common Shares if there is a change of control transaction involving the Company, a change in law which makes the exchange necessary or desirable or if there are a de minimis number of Class B Shares outstanding. If the Company is listed on a stock exchange at the time of the applicable exchange, the Company may elect to pay Ms. Malone cash in lieu of issuing Common Shares, with such cash amount to be determined based on the then current market price of the Common Shares.

(6) Each common share purchase warrant is exercisable into one common share of the Company (each, a "**Warrant Share**") at an exercise price of $11.20 per Warrant Share at any time prior to 5:00 p.m. (Eastern time) on the date that is five years following the closing of the Company's initial public offering in Canada, subject to adjustment in certain events. The common share purchase warrants include an acceleration provision, exercisable at the Company's option, if the Company's daily volume weighted average share price is greater than $22.40 for five consecutive trading days. Of the 2,826,274 warrants issued, 250 warrants have been exercised as of the date hereof.

(7) Each common share purchase warrant entitles the holder thereof to acquire one Common Share at an exercise price of $3.00 per Common Share for a period of 48 months following the closing date of the 2022 Offering, being April 20, 2022. Of the 7,331,550 warrants issued, 2,135,000 warrants have been exercised as of the date hereof.

(8) 500,538 common share purchase warrants were issued to the agents of the 2022 Offering and represents 7% of the units issued in the 2022 Offering including the over-allotment option (the "**Compensation Warrants**"). Each Compensation Warrant shall entitle the agents to acquire a Common Share at the price of $2.05 for a period of 48 months following completion of the 2022 Offering, being April 20, 2022. Of the 500,538 Compensation Warrants issued, 450,484 Compensation Warrants have been exercised as of the date hereof.

(9) Each Nordic Warrant is exercisable into one Common Share at an exercise price of $11.20 per share at any time prior to 5:00 p.m. (Eastern time) on April 29, 2026, subject to adjustment in certain events. The Nordic Warrants include an acceleration provision,

exercisable at the Company's option, if the Company's daily volume weighted average share price is greater than $22.40 for five consecutive trading days.

(10) SVB may elect to convert the principal amount of the convertible debt into Common Shares at a conversion price equal to $5.68 per Common Share. SVB may also elect to convert accrued and unpaid interest, the conversion price of the accrued and unpaid interest will be subject to the minimum pricing requirements of the TSX, to the extent applicable at the time of conversion.

Disclosure Controls and Procedures and Internal Controls Over Financial Reporting

The Chief Executive Officer ("**CEO**") and Chief Financial Officer ("**CFO**") have designed or caused to be designed under their supervision, disclosure controls and procedures which provide reasonable assurance that material information regarding the Company is accumulated and communicated to the Company's management, including its CEO and CFO, in a timely manner.

In addition, the CEO and CFO have designed or caused to be designed under their supervision internal controls over financial reporting ("**ICFR**") to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements. The control framework used to design the Company's ICFR uses the framework and criteria established in the *Internal Control-Integrated Framework* (2013), issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that its objectives are met. Due to inherent limitations in all such systems, no evaluations of controls can provide absolute assurance that all control issues, if any, within a company have been detected. Accordingly, our disclosure controls and procedures and our ICFR are designed to be effective in providing reasonable, not absolute, assurance that the objectives of our control systems have been met.

The Company had previously identified the following material weakness:

- Insufficient management review of the classification of liabilities and equity under IAS 32 and the valuation of instruments in accordance with IFRS 13.

The Company has since remediated the deficiency by engaging an external party to assist in the valuation of certain instruments.

The CEO and the CFO have evaluated, or caused to be evaluated under their supervision, whether or not there were changes to its ICFR during the year ended December 31, 2023 that have materially affected or are reasonably likely to materially affect the Company's ICFR. Other than the remediation of the material weakness identified above, no such changes were identified through their evaluation and concluded that as at December 31, 2023, the Company's disclosure controls and procedures were effective to provide reasonable assurance that material information regarding required disclosures was made known to them on a timely basis. The Company's CEO and CFO will certify Eupraxia's annual filings with the Canadian securities regulatory authorities.

Additional Information

Additional information about the Company is available on SEDAR+ at www.sedarplus.ca. and EDGAR at www.sec.gov/edgar.

Exhibit 99.4

Consent of Independent Registered Public Accounting Firm

The Board of Directors
Eupraxia Pharmaceuticals Inc.

We consent to the use of our report dated April 1, 2024 on the consolidated financial statements of Eupraxia Pharmaceuticals Inc. (the "Entity") which comprise the consolidated balance sheets as of December 31, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, changes in shareholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2023, and the related notes (collectively the "consolidated financial statements"), which is included in the Annual Report on Form 40-F of the Entity for the fiscal year ended December 31, 2023.

We also consent to the incorporation by reference of such report in the Registration Statement No. 333-276586 on Form F-10 of the Entity.

/s/ KPMG LLP

Chartered Professional Accountants

April 1, 2024
Vancouver, Canada

Exhibit 99.5

CERTIFICATIONS

I, James A. Helliwell, certify that:

1. I have reviewed this annual report on Form 40-F of Eupraxia Pharmaceuticals Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the issuer as of, and for, the periods presented in this report;

4. The issuer's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the issuer and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(c) Evaluated the effectiveness of the issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the issuer's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the issuer's internal control over financial reporting; and

5. The issuer's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the issuer's auditors and the audit committee of the issuer's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the issuer's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the issuer's internal control over financial reporting.

Date: April 1, 2024

/s/ James A. Helliwell
Chief Executive Officer

Exhibit 99.6

CERTIFICATIONS

I, Bruce Cousins, certify that:

1. I have reviewed this annual report on Form 40-F of Eupraxia Pharmaceuticals Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the issuer as of, and for, the periods presented in this report;

4. The issuer's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the issuer and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the issuer, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(c) Evaluated the effectiveness of the issuer's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) Disclosed in this report any change in the issuer's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the issuer's internal control over financial reporting; and

5. The issuer's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the issuer's auditors and the audit committee of the issuer's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the issuer's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the issuer's internal control over financial reporting.

Date: April 1, 2024

/s/ Bruce Cousins

President and Chief Financial Officer

Exhibit 99.7

EUPRAXIA PHARMACEUTICALS INC.
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Eupraxia Pharmaceuticals Inc. (the "Company") on Form 40-F for the year ended December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, James A. Helliwell, Chief Executive Officer *(Principal Executive Officer)* of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 1, 2024

/s/ James Helliwell
Name: James Helliwell
Title: Chief Executive Officer

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Eupraxia Pharmaceuticals Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.

Exhibit 99.8

EUPRAXIA PHARMACEUTICALS INC.
CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Eupraxia Pharmaceuticals Inc. (the "Company") on Form 40-F for the year ended December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Bruce Cousins, President and Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)* of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 1, 2024

/s/ Bruce Cousins
Name: Bruce Cousins
Title: President and Chief Financial Officer

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

This certification accompanies the Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Eupraxia Pharmaceuticals Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.