UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 8-K

Current Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 18, 2024

FENNEC PHARMACEUTICALS INC.

(Exact name of registrant as specified in its charter)

001-32295

(Commission File Number)

British Columbia, Canada (State or other jurisdiction of incorporation)

20-0442384 (I.R.S. Employer Identification No.)

PO Box 13628, 68 TW Alexander Drive, **Research Triangle Park, NC**

(Address of principal executive offices)

27709 (Zip Code)

Registrant's telephone number, including area code: (919) 636-4530

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

□ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

□ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12 of the Act:

		Name of each exchange on which
Title of each class	Trading symbol(s)	registered
Common shares, no par value	FENC	Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company \Box

If an emerging growth company, 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.

Item 1.01. Entry into a Material Definitive Agreement.

As previously disclosed, on August 1, 2022, Fennec Pharmaceuticals Inc. (the "Company") entered into a Securities Purchase Agreement with Petrichor Opportunities Fund I LP (the "Petrichor") in connection with the issuance of up to \$45 million of senior secured floating rate convertible notes (the "Notes"), issuable in multiple tranches, pursuant to which the Company issued \$5 million in Notes on August 1, 2022 (the "First Closing Notes"), \$20 million in Notes on September 23, 2022 (the "Second Closing Notes"), and \$5 million in Notes on December 4, 2023 (the "Third Closing Notes").

On December 18, 2024, the Company entered into a Waiver and Redemption Agreement (the "Redemption Agreement") with Petrichor, pursuant to which the Company repurchased and redeemed Notes in an aggregate principal amount of \$13,000,000 (consisting of approximately \$11.8 million of original principal balance and approximately \$1.2 million in PIK interest) (collectively, the "Note Redemptions").

As a result of the Note Redemptions, the First and Third Closing Notes were repurchased and redeemed in full, and, as of December 19, 2024, there remains outstanding Second Closing Notes in the aggregate principal amount (inclusive of PIK interest) of approximately \$19.2 million.

The foregoing description of the Redemption Agreement is not complete and is qualified in its entirety by reference to the full text of the Redemption Agreement, which is filed as Exhibit 10.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 8.01. Other Events.

On December 19, 2024, the Company issued a news release announcing the Note repayments resulting from the Note Redemptions described under Item 1.01 of this Current Report on Form 8-K. A copy of the news release is attached as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in this Item 8.01, as well as Exhibit 99.1 attached hereto, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No. Description

Exhibit 10.1Waiver and Redemption Agreement, dated December 18, 2024, between Fennec Pharmaceuticals Inc. and Petrichor Opportunities Fund I LPExhibit 99.1News Release dated December 19, 2024Exhibit 104Cover Page Interactive Data File (the cover page XBRL tags are embedded within the inline XBRL document)

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: December 20, 2024

FENNEC PHARMACEUTICALS INC.

By: /s/ Robert Andrade Robert Andrade

Chief Financial Officer

WAIVER AND REDEMPTION AGREEMENT

This Waiver and Redemption Agreement, dated as of December 18, 2024 (this "*Agreement*"), is entered into by and among Fennec Pharmaceuticals, Inc., a British Columbia corporation (the "*Company*"), the investors party hereto (the "*Investors*"), and Petrichor Opportunities Fund I LP, as collateral agent (in such capacity, the "*Collateral Agent*"; and together with the Company and the Investors, collectively, the "*Parties*"). Capitalized terms used but not otherwise defined herein shall have the respective meanings ascribed thereto in the Securities Purchase Agreement.

RECITALS

WHEREAS, the Parties have heretofore entered into that certain Securities Purchase Agreement, dated as of August 1, 2022 (the "Securities Purchase Agreement"), pursuant to which, among other things, the Company has issued and sold certain Notes to the Investors;

WHEREAS, the Company has informed the Investors and the Collateral Agent that the Company desires to repurchase and redeem from the Investors Notes in an aggregate outstanding principal amount of \$13,000,000;

WHEREAS, pursuant to the terms of the Securities Purchase Agreement and the Notes, the Company is not permitted to optionally redeem any of the Notes until August 19, 2025; and

WHEREAS, the Company has requested that the Investors and the Collateral Agent agree to waive the restriction on the optional redemption of the Notes prior to August 19, 2025 in order to permit the repurchase and redemption of the Notes contemplated by this Agreement and, subject to the terms and conditions of this Agreement, the Investors and the Collateral Agent have agreed to waive such restriction with respect to the repurchase and redemption of the Notes contemplated by this Agreement.

NOW THEREFORE, in consideration of the foregoing and the mutual agreements and covenants contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. <u>Waiver of Restriction on Redemption</u>. Subject to the terms and conditions of this Agreement, the Investors and the Collateral Agent hereby waive the restriction on the optional redemption of the Notes prior to August 19, 2025 as set forth in Section 8.1(a) of the Notes solely for the purposes of permitting the repurchase and redemption of the Notes contemplated by this Agreement and for no other purpose. The waiver contained in this <u>Section 1</u> is a limited waiver and (a) shall only be relied upon and used for the specific purpose set forth herein, and (b) shall not constitute nor be deemed to constitute a waiver of (i) any Event of Default under the Securities Purchase Agreement or any Note or (ii) any term or condition of the Securities Purchase Agreement or any Note other than as specifically set forth herein.

2. <u>Waiver Fee</u>. In consideration of each Investor's agreement to waive the restriction on the optional redemption of the Notes prior to August 19, 2025 as set forth in Section 8.1(a) of the Notes with respect to the repurchase and redemption of the Notes contemplated by this Agreement, the Company hereby agrees to pay each Investor a waiver fee, payable in cash to each Investor on the date hereof, in the amount set forth opposite such Investor's name under the heading "Waiver Fee" on <u>Schedule I</u> hereto (with respect to each such Investor, such Investor's "*Waiver Fee*").

3. <u>Repurchase of Notes</u>. The Company hereby agrees to repurchase and redeem from each Investor and each Investor hereby agrees to sell to the Company, in each case on the terms and conditions set forth herein:

(a) First Closing Notes in an aggregate principal amount set forth opposite such Investor's name under the heading "First Closing Notes (Principal and Interest)" on <u>Schedule I</u> hereto (with respect to each such Investor, such Investor's "*Repurchased First Closing Notes*") for an aggregate cash purchase price equal to the sum of (x) the amount set forth opposite such Investor's name under the heading "First Closing Notes (Closing Purchase Price)" on <u>Schedule I</u> hereto (with respect to each such Investor's "*Repurchased First Closing Notes* (Closing Purchase Price)", which represents the aggregate outstanding principal amount of such Investor's Repurchased First Closing Notes as of the date hereof, *plus* (y) the amount set forth opposite such Investor's name under the heading "First Closing Notes as of the date hereof, *plus* (y) the amount set forth opposite such Investor's name under the heading "First Closing Notes as of the date hereof, *plus* (y) the amount set forth opposite such Investor's name under the heading "First Closing Notes (Deferred Purchase Price)" on <u>Schedule I</u> hereto (with respect to each such Investor's Repurchased First Closing Notes Price)", which represents the aggregate amount of accrued and unpaid interest in respect of such Investor's Repurchased First Closing Notes as of the date hereof;

(b) Second Closing Notes in an aggregate principal amount set forth opposite such Investor's name under the heading "Second Closing Notes (Principal and Interest)" on <u>Schedule I</u> hereto (with respect to each such Investor, such Investor's "*Repurchased Second Closing Notes*") for an aggregate cash purchase price equal to the sum of (x) the amount set forth opposite such Investor's "*Repurchased Second Closing Notes*") for an aggregate cash purchase Price)" on <u>Schedule I</u> hereto (with respect to each such Investor, such Investor's "*Repurchased Second Closing Notes*") for an aggregate outstanding principal amount of such Investor's "*Repurchased Second Closing Notes Closing Purchase Price*"), which represents the aggregate outstanding principal amount of such Investor's Repurchased Second Closing Notes as of the date hereof, *plus* (y) the amount set forth opposite such Investor's name under the heading "Second Closing Notes (Deferred Purchase Price)" on <u>Schedule I</u> hereto (with respect to each such Investor's Repurchased Second Closing Notes as of the aggregate amount of accrued and unpaid interest in respect of such Investor's Repurchased Second Closing Notes as of the date hereof; and

(c) Third Closing Notes in an aggregate principal amount set forth opposite such Investor's name under the heading "Third Closing Notes (Principal and Interest)" on <u>Schedule I</u> hereto (with respect to each such Investor, such Investor's "*Repurchased Third Closing Notes*"; and together with such Investor's Repurchased First Closing Notes and Repurchased Second Closing Notes, collectively, such Investor's "*Repurchased Notes*") for an aggregate cash purchase price equal to the sum of (x) the amount set forth opposite such Investor's "*Repurchased Third Closing Notes (Closing Purchase Price*") on <u>Schedule I</u> hereto (with respect to each such Investor, such Investor's "*Repurchased Third Closing Notes Closing Purchase Price*"; and together with such Investor's "*Repurchased Third Closing Notes Closing Purchase Price*"; and together with such Investor's "*Aggregate Repurchased Notes Closing Purchase Price*"), which represents the aggregate outstanding principal amount of such Investor's Repurchased Third Closing Notes (Deferred Purchase Price)" on <u>Schedule I</u> hereto (with respect to each such Investor's Repurchased Third Closing Notes (Deferred Purchase Price)" on <u>Schedule I</u> hereto (with respect to each such Investor's "*Repurchase Price*"), which represents the aggregate outstanding principal amount of such Investor's Repurchased Third Closing Notes as of the date hereof, *plus* (y) the amount set forth opposite such Investor's "*Repurchased Third Closing Notes*") on <u>Schedule I</u> hereto (with respect to each such Investor's "*Repurchase Third Closing Notes Closing Notes*") on <u>Schedule I</u> hereto?; and together with such Investor's Repurchased First Closing Notes (Deferred Purchase Price)" on <u>Schedule I</u> hereto (with respect to each such Investor's usch Investor's "*Repurchased Third Closing Notes*"), which represents the aggregate amount of such Investor's "*Repurchase Price*"; and together with such Investor's Repurchased First Closing Notes Deferred Purchase Price, collectively, such Investor's "*Repurchas*

4. <u>Closing of Repurchase of Repurchased Notes; Payment of Waiver Fee and Purchase Price</u>.

(a) The closing of the repurchase and redemption of the Repurchased Notes hereunder shall occur on the date hereof (the "Closing").

(b) At the Closing, the Company shall deliver to each Investor, by wire transfer of immediately available funds to an account specified by each such Investor, cash in an aggregate amount equal to the sum of (a) such Investor's Aggregate Repurchased Notes Closing Purchase Price, plus (b) such Investor's Waiver Fee.

(c) On January 2, 2025, the Company shall deliver to each Investor, by wire transfer of immediately available funds to an account specified by each such Investor, cash in an aggregate amount equal to such Investor's Aggregate Repurchased Notes Deferred Purchase Price.

(d) The provisions of Section 11.1(e) of the Notes, as applicable, shall apply to the repurchase and redemption of the Repurchased Notes hereunder.

5. <u>Miscellaneous</u>. Except as specifically waived herein, the Securities Purchase Agreement, the Notes and all other Transaction Documents are and shall continue to be in full force and effect and are hereby in all respects ratified and confirmed. Except as specifically set forth in <u>Section 1</u>, the execution, delivery and effectiveness of this Agreement shall not operate as a waiver of any right, power or remedy of the Investors or the Collateral Agent under the Securities Purchase Agreement, the Notes or any other Transaction Documents, nor constitute a waiver of any provision of the Securities Purchase Agreement, the Notes or any other Transaction Documents. This Agreement may be amended or modified only pursuant to a written instrument executed by all of the Parties. This Agreement and the rights and obligations of the parties under this Agreement shall be governed by, and construed and interpreted in accordance with, the law of the State of New York (without reference to its choice of law rules). Section 8.9 of the Securities Purchase Agreement is incorporated herein, mutatis mutandis, as if a part hereof. This Agreement may be executed in any number of counterparts and by different parties hereto in separate counterparts, each of which when so executed and delivered shall be deemed to be an original and all of which taken together shall constitute but one and the same agreement. Delivery of an executed counterpart of a signature page to this Agreement electronically shall be effective as delivery of a manually executed counterpart of this Agreement.

[Signatures Follow]

IN WITNESS WHEREOF, the parties hereto have executed, acknowledged and delivered this Agreement effective as of the day and year first above written.

COMPANY:

FENNEC PHARMACEUTICALS INC.

By: //s/ Robert Andrade

INVESTORS:

PETRICHOR OPPORTUNITIES FUND I LP

By: Petrichor Opportunities Fund I GP, LLC

By: /s/ Tad Wessel

PETRICHOR OPPORTUNITIES FUND I INTERMEDIATE LP

By: Petrichor Opportunities Fund I GP, LLC

By: /s/ Tad Wessel

COLLATERAL AGENT:

PETRICHOR OPPORTUNITIES FUND I LP

By: Petrichor Opportunities Fund I GP, LLC

By:

/s/ Tad Wessel

SCHEDULE I

Repurchased Notes

SCHEDULE I

Repurchased Notes

Investor Petrichor Opportunities	 r Fee	First Closing Notes (Principal and Interest)	First Closing Notes (Closing Purchase Price)	First Closing Notes (Deferred Purchase Price)	Second Closing Notes (Principal and Interest)	Second Closing Notes (Closing Purchase Price)		(Principal	Third Closing Notes (Closing <u>Purchase Price)</u>	Third Closing Notes (Deferred Purchase Price)	Aggregate Repurchased	
Fund I LP Petrichor Opportunities Fund I Intermediate	\$ 1.00	\$3,833,583.27	\$3,730,754.351	\$ 102,828.92	\$1,375,546.54	\$1,334,225.88 ²	² \$41,320.66	\$3,971,319.77	\$ 3,971,319.77 ³	\$ 0.00	\$ 9,036,301.00	\$ 144,149.58
LP	\$ 1.00	\$1,681,570.33	\$1,636,465.264	\$ 45,105.07	\$ 603,372.38	\$ 585,247.415	5 \$18,124.97	\$1,741,987.33	\$ 1,741,987.336	\$ 0.00	\$ 3,963,701.00	\$ 63,230.04

¹ Represents an aggregate initial principal amount of \$3,475,500.00 plus an aggregate of \$ in PIK Interest that has been added to the outstanding principal amount of the First Closing Notes prior to the date hereof

² Represents an aggregate initial principal amount of \$ plus an aggregate of \$ in PIK Interest that has been added to the outstanding principal amount of the Second Closing Notes prior to the date hereof

³ Represents an aggregate initial principal amount of \$ plus an aggregate of \$ in PIK Interest that has been added to the outstanding principal amount of the Third Closing Notes prior to the date hereof

4 Represents an aggregate initial principal amount of \$ plus an aggregate of \$ in PIK Interest that has been added to the outstanding principal amount of the First Closing Notes prior to the date hereof

5 Represents an aggregate initial principal amount of \$ plus an aggregate of \$ in PIK Interest that has been added to the outstanding principal amount of the Second Closing Notes prior to the date hereof

6 Represents an aggregate initial principal amount of \$ plus an aggregate of \$ in PIK Interest that has been added to the outstanding principal amount of the Third Closing Notes prior to the date hereof



FENNEC PHARMACEUTICALS ANNOUNCES EARLY PARTIAL REPAYMENT OF ITS OUTSTANDING CONVERTIBLE DEBT FACILITY WITH PETRICHOR HEALTHCARE CAPITAL MANAGEMENT

~ \$13 Million Convertible Debt Repayment from Available Cash ~

~ Elimination of Approximately \$1.5 Million in Annual Interest Expense and Potential Equity Overhang of Approximately 1.6 Million Shares ~

Research Triangle Park, NC, December 19, 2024 – Fennec Pharmaceuticals Inc. (NASDAQ:FENC; TSX: FRX), a specialty pharmaceutical company, today announced the early repayment of \$13 million of the Company's approximately \$32 million outstanding convertible debt facility with Petrichor Healthcare Capital Management ("Petrichor"). Pro forma for today's announced repayment, the convertible debt facility with Petrichor will be approximately \$19 million and maintain a maturity of September 2027. This early partial repayment was financed entirely with available cash.

"We are pleased to announce the early partial repayment of a significant portion of our debt to Petrichor in a financial and strategic action that optimizes the Company's balance sheet and overall capital structure, while effectively saving approximately \$1.5 million in future annual interest payments and eliminating potential dilutive shares," said Jeff Hackman, chief executive officer of Fennec Pharmaceuticals. "This financial milestone underscores the confidence we continue to have in our business and reflects our commitment to maintaining a strong and sustainable operating model that enables us to accelerate our commercialization plans for PEDMARK^O. We thank Petrichor for their continued support of Fennec and believe that we are well positioned for near-term and sustainable growth."

As previously reported in Fennec's third quarter 2024 earnings and inclusive of this announcement, the Company anticipates that its cash, cash equivalents and investment securities will be sufficient to fund planned operations into 2026.

Further information will be set forth in the Current Report on Form 8-K to be filed by the Company with the U.S. Securities and Exchange Commission (the "SEC") on or about December 20, 2024.

About Fennec Pharmaceuticals

Fennec Pharmaceuticals Inc. is a specialty pharmaceutical company focused on the development and commercialization of PEDMARK[®] to reduce the risk of platinum-induced ototoxicity in pediatric patients. Further, PEDMARK received FDA approval in September 2022 and European Commission approval in June 2023 and U.K. approval in October 2023 under the brand name PEDMARQSI^O. PEDMARK has received Orphan Drug Exclusivity in the U.S. and PEDMARQSI has received Pediatric Use Marketing Authorization in Europe which includes eight years plus two years of data and market protection. For more information, please visit <u>www.fennecpharma.com</u>.

About Petrichor

Petrichor partners with world-class healthcare managers and businesses to provide customized investment structures and support. Petrichor has completed over 125 investments representing more than \$6 billion in invested capital and has held over 50 board seats. Petrichor maintains a deep in-house understanding of healthcare products and services, including scientific, technical, and commercial expertise. This healthcare expertise, together with a breadth of experience investing across sectors, geographies, and capital structures, provides a unique combination to help build successful companies. For more information on Petrichor, please visit www.petrichorcap.com.

PEDMARK[®] (sodium thiosulfate injection)

PEDMARK[®] is the first and only U.S. Food and Drug Administration (FDA) approved therapy indicated to reduce the risk of ototoxicity associated with cisplatin treatment in pediatric patients with localized, non-metastatic, solid tumors. It is a unique formulation of sodium thiosulfate in single-dose, ready-to-use vials for intravenous use in pediatric patients.⁷ PEDMARK is also the first and only therapeutic agent with proven efficacy and safety data with an established dosing regimen, across two open-label, randomized Phase 3 clinical studies, the Children's Oncology Group (COG) Protocol ACCL0431 and SIOPEL 6.

In the U.S. and Europe, it is estimated that, annually, more than 10,000 children may receive platinum-based chemotherapy. The incidence of ototoxicity depends upon the dose and duration of chemotherapy, and many of these children require lifelong hearing aids. There is currently no established preventive agent for this hearing loss and only expensive, technically difficult, and sub-optimal cochlear (inner ear) implants have been shown to provide some benefit. Infants and young children that suffer ototoxicity at critical stages of development lack speech language development and literacy, and older children and adolescents lack socialemotional development and educational achievement.

PEDMARK has been studied by co-operative groups in two Phase 3 clinical studies of survival and reduction of ototoxicity, COG ACCL0431 and SIOPEL 6. Both studies have been completed. The COG ACCL0431 protocol enrolled childhood cancers typically treated with intensive cisplatin therapy for localized and disseminated disease, including newly diagnosed hepatoblastoma, germ cell tumor, osteosarcoma, neuroblastoma, medulloblastoma, and other solid tumors. SIOPEL 6 enrolled only hepatoblastoma patients with localized tumors.

Indications and Usage

PEDMARK[®] (sodium thiosulfate injection) is indicated to reduce the risk of ototoxicity associated with cisplatin in pediatric patients 1 month of age and older with localized, non-metastatic solid tumors.

Limitations of Use

The safety and efficacy of PEDMARK have not been established when administered following cisplatin infusions longer than 6 hours. PEDMARK may not reduce the risk of ototoxicity when administered following longer cisplatin infusions, because irreversible ototoxicity may have already occurred.

Important Safety Information

PEDMARK is contraindicated in patients with history of a severe hypersensitivity to sodium thiosulfate or any of its components.

Hypersensitivity reactions occurred in 8% to 13% of patients in clinical trials. Monitor patients for hypersensitivity reactions. Immediately discontinue PEDMARK and institute appropriate care if a hypersensitivity reaction occurs. Administer antihistamines or glucocorticoids (if appropriate) before each subsequent administration of PEDMARK. PEDMARK may contain sodium sulfite; patients with sulfite sensitivity may have hypersensitivity reactions, including anaphylactic symptoms and life-threatening or severe asthma episodes. Sulfite sensitivity is seen more frequently in people with asthma.

PEDMARK is not indicated for use in pediatric patients less than 1 month of age due to the increased risk of hypernatremia or in pediatric patients with metastatic cancers.

Hypernatremia occurred in 12% to 26% of patients in clinical trials, including a single Grade 3 case. Hypokalemia occurred in 15% to 27% of patients in clinical trials, with Grade 3 or 4 occurring in 9% to 27% of patients. Monitor serum sodium and potassium levels at baseline and as clinically indicated. Withhold PEDMARK in patients with baseline serum sodium greater than 145 mmol/L.

Monitor for signs and symptoms of hypernatremia and hypokalemia more closely if the glomerular filtration rate (GFR) falls below 60 mL/min/1.73m².

Administer antiemetics prior to each PEDMARK administration. Provide additional antiemetics and supportive care as appropriate.

The most common adverse reactions (\geq 25% with difference between arms of >5% compared to cisplatin alone) in SIOPEL 6 were vomiting, nausea, decreased hemoglobin, and hypernatremia. The most common adverse reaction (\geq 25% with difference between arms of >5% compared to cisplatin alone) in COG ACCL0431 was hypokalemia.

Please see full Prescribing Information for PEDMARK® at: www.PEDMARK.com.

Forward Looking Statements

Except for historical information described in this press release, all other statements are forward-looking. Words such as "believe," "anticipate," "plan," "expect," "estimate," "intend," "may," "will," or the negative of those terms, and similar expressions, are intended to identify forward-looking statements. These forward-looking statements include statements about our business strategy, timeline and other goals, plans and prospects, including our commercialization plans respecting PEDMARK[®], the market opportunity for and market impact of PEDMARK[®], its potential impact on patients and anticipated benefits associated with its use, and potential access to further funding after the date of this release. Forward-looking statements are subject to certain risks and uncertainties inherent in the Company's business that could cause actual results to vary, including the risks and uncertainties that regulatory and guideline developments may change, scientific data and/or manufacturing capabilities may not be sufficient to meet regulatory standards or receipt of required regulatory clearances or approvals, clinical results may not be replicated in actual patient settings, unforeseen global instability, including political instability, for an outbreak of pandemic or contagious disease, such as the novel coronavirus (COVID-19), or surrounding the duration and severity of an outbreak, protection offered by the Company's patents and patient applications may be challenged, invalidated or circumvented by its competitors, the available market for the Company's products will not be able to penetrate one or more targeted markets, revenues will not be sufficient to fund further development and clinical studies, our ability to obtain necessary capital when needed on acceptable terms or at all, the Company way not meet its future capital requirements in different countries and municipalities, and other risks detailed form time to time in the Company's filings with the Securities and Exchange Commission including its Annual Re

For a more detailed discussion of related risk factors, please refer to our public filings available at www.sec.gov and www.sedar.com.

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For further information, please contact:

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