

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): January 24, 2023

22nd Century Group, Inc.
(Exact Name of Registrant as Specified in Charter)

Nevada
(State or Other Jurisdiction of
Incorporation)

001-36338
(Commission File Number)

98-0468420
(I.R.S. Employer
Identification No.)

500 Seneca Street, Suite 507, Buffalo, New York
(Address of Principal Executive Office)

14204
(Zip Code)

Registrant's telephone number, including area code: (716) 270-1523

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))

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

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.

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol	Name of each exchange on which registered
Common Stock, \$0.00001 par value	XXII	NASDAQ Capital Market

Item 7.01. Regulation FD Disclosure.

On January 24, 2023, 22nd Century Group, Inc. (the "Company") issued a press release regarding its acquisition of privately held RX Pharmatech Ltd (RXP), a United Kingdom distributor of cannabinoids. The Company is attaching a copy of such press release as Exhibit 99.1 hereto, which is incorporated by reference herein.

Forward-Looking Statements

This report contains forward-looking statements and other information relating to matters that are not historical facts. These forward-looking statements involve certain risks and uncertainties that could cause actual results to differ materially from those expressed or implied by these statements. These risks and uncertainties include the factors detailed from time to time in the reports we file with the SEC, including those described under "Risk Factors" in our Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q. These forward-looking statements speak only as of the date of this report. We expressly disclaim any obligation or undertaking to disseminate any updates or revisions to any forward-looking statement contained herein to reflect any change in our expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based.

Item 9.01(d). Financial Statements and Exhibits.

99.1 [Press Release, dated January 24, 2023.](#)

104 Cover Page Interactive Data File - The cover page XBRL tags are embedded within the inline XBRL document.

SIGNATURES

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.

22nd Century Group, Inc.

Date: January 24, 2023

/s/ Peter Ferola

Peter Ferola

General Counsel and Secretary

22nd Century Group (XXII) Acquires RX Pharmatech Ltd, Greatly Strengthening UK and EU Market Position

Immediately Accretive Addition to the Hemp/Cannabis Business with Positive EBITDA

1,276 Novel Food Applications for Cannabinoid Products to Accelerate Growth in the U.K. and EU Food and Nutraceuticals Markets

BUFFALO, N.Y., January 24, 2023 (Globe Newswire)— 22nd Century Group, Inc. (Nasdaq: **XXII**), a leading biotechnology company dedicated to improving health with reduced nicotine tobacco, hemp/cannabis and hops advanced plant technologies, today announced the acquisition of privately held RX Pharmatech Ltd (RXP), a leading United Kingdom distributor of cannabinoids with 1,276 novel food applications with the U.K. Food Standards Agency (FSA). Terms of the agreement include an up-front payment of \$650,000 in cash and stock and a three-year equity earn-out based on revenue milestones.

“The acquisition of RXP establishes GVB as the leader in the U.K. Consumer Products isolate market, which is expected to reach an estimated \$1.26 billion by 2025 and secures direct access to key European markets for CBD products,” stated James A. Mish, chief executive officer of 22nd Century Group. “RXP has exclusively utilized GVB’s technical data and worked closely with the FSA on developing their highly effective application and compliance programs that secured 1,276 novel food applications, the second most CBD products to pass through the first round of approval. We look forward to leveraging their leadership team’s vast cannabis industry experience and strong relationships with U.K. and EU regulatory agencies as we move forward.”

Mr. Mish continued, “We expect the addition of RXP will be immediately accretive to the company and facilitate significant operating efficiencies leading to additional revenue and gross margin improvement. In particular, the addition of RXP with our recently opened distribution facility in the Netherlands will allow us to scale our operations and capture more market share in the growing European Consumer Products market.”

RXP’s products include CBD isolate and numerous variations of finished products like gummies, oils, drops, candies, tinctures, sprays, capsules and others. The U.K. is not accepting new novel food applications for cannabinoid products at this time and denied tens of thousands of product applications earlier in 2022 during the FSA’s first round of screening. This market dynamic will could allow 22nd Century to open new opportunities to land highly accretive contracts with multinationals for quality CBD and hemp-derived consumer products dependent on the novel food licenses.

Since 2019, the U.K. Government regulation of hemp ingredients, including popular cannabinoids such as cannabidiol (CBD), has been administered under a novel food scheme regulated by the FSA, making the U.K. the only market in the world with a clear regulatory regime for CBD at the federal level. Additionally, the U.S. Food and Drug Administration (FDA) is expected to establish a daily threshold safety level for CBD consumption in 2023. This threshold is also expected to be quickly adopted by the U.K. and the EU. This regulatory action will enable multinational, well-recognized brands to enter the U.S., U.K. and EU nutraceutical, food and beverage market, greatly increasing CBD demand and requiring novel food licenses.

About GVB Biopharma

GVB Biopharma, a 22nd Century company, is a global-scale specialty ingredient supplier and contract development & manufacturing organization (CDMO) with manufacturing locations in Nevada and Oregon. GVB is the largest merchant provider of cannabinoid extracts and isolates in North America with a focus on cannabidiol (CBD) and cannabigerol (CBG) extracted and refined at an industrial scale into distillates and isolates. GVB Biopharma’s facilities are NSF International audited and are cGMP Registered for dietary supplements manufacturing. GVB is widely regarded as a best-in-class operator with a leading position in the hemp-derived active ingredients market, with around 15% market share and growing. GVB is also a white-label contract manufacturer of tinctures, gel capsules, gummies, mints, tablets, topical, and vape offerings.

About 22nd Century Group, Inc.

22nd Century Group, Inc. (Nasdaq: **XXII**) is a leading agricultural biotechnology company focused on tobacco harm reduction, reduced nicotine tobacco and improving health and wellness through plant science. With dozens of patents allowing it to control nicotine biosynthesis in the tobacco plant, the Company has developed proprietary reduced nicotine content (RNC) tobacco plants and cigarettes, which have become the cornerstone of the FDA’s [Comprehensive Plan](#) to address the widespread death and disease caused by smoking. The Company received the first and only FDA Modified Risk Tobacco Product (MRTP) authorization of a combustible cigarette in December 2021. In tobacco, hemp/cannabis and hop plants, 22nd Century uses modern plant breeding technologies, including genetic engineering, gene-editing, and molecular breeding to deliver solutions for the life science and consumer products industries by creating new, proprietary plants with optimized alkaloid and flavonoid profiles as well as improved yields and valuable agronomic traits.

Learn more at xxiicentury.com, on [Twitter](#), on [LinkedIn](#), and on [YouTube](#).

Learn more about VLN[®] at tryvln.com.

Cautionary Note Regarding Forward-Looking Statements

Except for historical information, all of the statements, expectations, and assumptions contained in this press release are forward-looking statements. Forward-looking statements typically contain terms such as “anticipate,” “believe,” “consider,” “continue,” “could,” “estimate,” “expect,” “explore,” “foresee,” “goal,” “guidance,” “intend,” “likely,” “may,” “plan,” “potential,” “predict,” “preliminary,” “probable,” “project,” “promising,” “seek,” “should,” “will,” “would,” and similar expressions. Actual results might differ materially from those explicit or implicit in forward-looking statements. Important factors that could cause actual results to differ materially are set forth in “Risk Factors” in the Company’s Annual Report on Form 10-K filed on March 1, 2022, and in the Company’s Quarterly Report filed on November 8, 2022. All information provided in this release is as of the date hereof, and the Company assumes no obligation to and does not intend to update these forward-looking statements, except as required by law.

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