

**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): November 07, 2022

CinCor Pharma, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-41201
(Commission File Number)

36-4931245
(IRS Employer
Identification No.)

**230 Third Avenue
6th Floor
Waltham, Massachusetts**
(Address of Principal Executive Offices)

02451
(Zip Code)

Registrant's Telephone Number, Including Area Code: 844 531-1834

(Former Name or Former Address, if Changed Since Last Report)

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(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.00001 par value per share	CINC	The NASDAQ Stock Market LLC

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.

Item 7.01 Regulation FD Disclosure.

On November 7, 2022, CinCor Pharma, Inc. (the “Company”) issued a press release regarding its previously announced late-breaking presentation of data from its Phase 2 BrigHtn clinical trial evaluating its lead clinical candidate, baxdrostat, in treatment-resistant hypertension at the 2022 American Heart Association Scientific Sessions. The Company will host a conference call and webcast to discuss the data at 7:00 a.m., Eastern Time, on November 8, 2022. A live audio webcast of the presentation will be available under “Events and Presentations” in the “Investors” section of the Company’s website at www.cincor.com. The webcast will be archived on the Company’s website for at least 30 days following the call. The Company’s website and the information contained on, or that can be accessed through, the Company’s website will not be deemed to be incorporated by reference in, and are not considered part of, this Current Report.

Separately, on November 7, 2022, the Company issued a press release regarding the publication of data from its Phase 2 BrigHtn clinical trial in the New England Journal of Medicine.

Copies of the above-referenced press releases are attached hereto as Exhibits 99.1 and 99.2, respectively, and are hereby incorporated by reference.

The information in this Current Report on Form 8-K, including Exhibits 99.1 and 99.2 attached hereto, is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release issued by CinCor Pharma, Inc., dated November 7, 2022
99.2	Press Release issued by CinCor Pharma, Inc., dated November 7, 2022
104	Cover Page Interactive Data File (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.

Cincor Pharma, Inc.

Date: November 8, 2022

By: /s/ Michael W. Kalb
Michael W. Kalb, Executive Vice President and Chief Financial
Officer

CinCor Pharma Announces Late-Breaking Presentation of Phase 2 BrigHtn Data on Baxdrostat in Treatment-Resistant Hypertension at the 2022 American Heart Association Scientific Sessions

Aldosterone and renin biomarker activity clinically demonstrate how baxdrostat mechanistically achieves selective blood pressure lowering effects with no impact on cortisol

20.3 mmHg reduction in systolic blood pressure, or 11 mmHg (p-value < 0.0001) placebo-adjusted decline at the 2 mg dose

Well-tolerated profile and differentiated mechanism of action supports combination approaches

Conference call and live webcast Tuesday November 8th, 2022 at 7 AM Eastern Time

WALTHAM, MA, November 7, 2022 (GLOBE NEWSWIRE) -- CinCor Pharma, Inc. ("CinCor") announced the presentation today of Phase 2 data from its BrigHtn trial as part of the late-breaking science session at the 2022 American Heart Association (AHA) Scientific Sessions. Baxdrostat is a highly selective, once daily oral small molecule inhibitor of aldosterone synthase.

"We were honored to present our Phase 2 BrigHtn data as part of a late-breaking session focused on new treatments for the increasingly recognized unmet needs in resistant hypertension at this year's AHA conference," said Mason Freeman, M.D, Chief Medical Officer at CinCor. "Baxdrostat significantly decreases aldosterone in plasma and urine, while increasing plasma renin as a physiological compensatory change. These changes in aldosterone and renin following treatment with baxdrostat reflect less salt exposure to the kidney and reduced blood pressure over time. And, unlike earlier generations of aldosterone synthase inhibitors, serum cortisol levels were not reduced, once again confirming the highly selective mechanism of baxdrostat. Collectively these findings demonstrate how baxdrostat uniquely helps address a known cause of elevated blood pressure, potentially offering a much needed treatment option for patients with tough to control hypertension."

BrigHtn Trial Highlights

Aldosterone and renin activity reinforce the biological mechanism of baxdrostat

- Dose-dependent reduction in both plasma and urine aldosterone support inhibition of aldosterone synthase and the mechanism of action of baxdrostat
 - Urine aldosterone levels 24-hours post-treatment quantitatively measure total body aldosterone production with less variation than plasma to provide direct evidence of baxdrostat's aldosterone lowering capabilities
 - Dose-dependent changes in renin activity support physiological salt response
 - No meaningful impact on cortisol confirms baxdrostat is highly selective for aldosterone synthase
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Clinically meaningful and dose-dependent reduction in blood pressure with baxdrostat

- BrigHtn successfully met its primary endpoint, demonstrating a statistically significant change from baseline in mean seated systolic blood pressure (SBP) versus placebo:
 - Dose-dependent reductions in SBP of -20.3 mmHg (2-mg), -17.5 mmHg (1-mg), and -12.1 mmHg (0.5-mg)
 - Statistically significant placebo-adjusted decreases of -11.0 (2-mg, P = 0.0001) and -8.1 (1-mg, P = 0.003)
- Secondary endpoint results included baxdrostat significantly lowering diastolic blood pressure (DBP) by 5.2 mmHg in the 2mg dose arm, and approximately 46% of patients in the 2 mg dose arm achieving blood pressure control (SBP less than 130mmHg)
- Patient demographics and baseline characteristics were diverse and well-balanced across treatment arms

Clinical safety and tolerability of baxdrostat support a well-tolerated profile

- No drug related serious adverse events (SAEs) observed or major safety concerns were reported across all three dose cohorts tested after 12 weeks of treatment
- Transient and manageable adverse events of special interest included hypotension, hyponatremia, or elevated potassium levels
- Low discontinuation rate of less than 1% (2 patients) due to transient treatment-related adverse events; all patients completed the study on drug
- Well-tolerated profile and differentiated mechanism of action supports combination approaches

The BrigHtn trial was a Phase 2 randomized, double-blind, placebo-controlled dose-ranging clinical trial designed to assess the safety and efficacy of baxdrostat in subjects who have not achieved their target blood pressure despite receiving three or more antihypertensive agents at their maximally tolerated doses, one of which must be a diuretic. The trial evaluated three active doses of baxdrostat (0.5 mg, 1.0 mg, and 2.0 mg) compared to placebo control in 275 patients randomized across all four dosing cohorts, with 248 patients completing. The primary endpoint of BrigHtn was the change in mean seated SBP from randomization to trial end after 12 weeks of treatment.

Conference Call and Webcast Information

CinCor management will hold a conference call and webcast Tuesday November 8th 2022 at 7 AM Eastern Time to provide an update on additional results from the Phase 2 BrigHtn trial presented at AHA 2022. The dial-in number for the conference call is 877-407-9039 (U.S./Canada) or 201-689-8470 (international). The conference ID for all callers is 13734379. The live webcast and replay may be accessed by visiting the CinCor website at <https://www.cincor.com/events-presentations>. The replay will be available for 30 days following the call.

About CinCor

CinCor, founded in 2018, is a clinical-stage biopharmaceutical company with a mission to bring innovation to the pharmaceutical treatment of cardio-renal diseases. Its lead asset, baxdrostat (CIN-107), a highly selective, oral small molecule inhibitor of aldosterone synthase, is in clinical development for the treatment of hypertension and primary aldosteronism.

About Baxdrostat (CIN-107)

Baxdrostat is a highly selective, oral small molecule inhibitor of aldosterone synthase, the enzyme responsible for the synthesis of aldosterone in the adrenal gland, in development for patient populations with significant unmet medical needs, including treatment-resistant hypertension and primary aldosteronism. Hypertension, which is defined by the American College of Cardiology and the American Heart Association as resting blood pressure above 130/80 mm Hg, is generally acknowledged to be one of the most common preventable risk factors for premature death worldwide. Though often asymptomatic, hypertension significantly increases the risk of heart disease, stroke, and kidney disease, amongst other diseases. It is estimated that as much as 20% of the global population suffers from hypertension, including nearly one-half of the adult population in the U.S., or 116 million hypertensive patients.

Forward-Looking Statements

This press release contains certain forward-looking statements, including, but not limited to, statements related to CinCor's business in general; the therapeutic potential of baxdrostat (CIN-107), including its potential to be an effective treatment for patients with treatment-resistant hypertension, uncontrolled hypertension and CKD, and the ability of baxdrostat to address multiple unmet needs in patients; the potential of baxdrostat to emerge as a new mechanism of action in the hypertension treatment paradigm; and other statements that are not historical facts. Because such statements are subject to risks and uncertainties, actual results may differ from those expressed or implied by such forward-looking statements. Words such as "anticipates," "believes," "expected," "intends," "plan," "may," "will," "project", "estimate", "continue," "advance" and "future" or similar expressions are intended to identify forward-looking statements. These forward-looking statements are based on CinCor's current plans, objectives, estimates, expectations and intentions, involve assumptions that may never materialize or may prove to be incorrect and inherently involve significant risks and uncertainties, including factors beyond CinCor's control, that could cause actual results, performance, or achievement to differ materially and adversely from those anticipated or implied in the statements, including, without limitation, CinCor has incurred significant operating losses since its inception; CinCor has a limited operating history and no history of commercializing products; CinCor will require substantial additional funding to finance its operations; CinCor's business is entirely dependent at this time on the success of one drug, baxdrostat; initial, interim, "top-line" and preliminary data from clinical trials announced or published from time to time may change; CinCor may not be successful in its efforts to expand its pipeline beyond baxdrostat; success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials; enrollment and retention of patients in clinical trials could be delayed; CinCor relies and will rely on third parties to conduct, supervise and monitor existing clinical trials and potential future clinical trials;

developments from the company's competitors and the marketplace for the company's products; and CinCor's business, operations and clinical development timelines and plans may be adversely affected by the evolving and ongoing COVID-19 pandemic, geopolitical events, including the ongoing military conflict between Russia and Ukraine and related sanctions against Russia, and macroeconomic conditions, including rising inflation and uncertain credit and financial markets, and matters related thereto; and other risks and uncertainties affecting the company, including those described under the caption "Risk Factors" and elsewhere in CinCor's Annual Report on Form 10-K for the year ended December 31, 2021 filed with the Securities and Exchange Commission (SEC) on March 22, 2022, CinCor's Quarterly Report on Form 10-Q for the three months ended September 30, 2022 filed with the SEC on November 3, 2022, and other filings and reports that CinCor may file from time to time with the SEC. Other risks and uncertainties of which CinCor is not currently aware may also affect the company's forward-looking statements and may cause actual results and the timing of events to differ materially from those anticipated. All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. CinCor undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law.

Contacts:

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EVP and CFO

Investors:

Bob Yedid
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CinCor Pharma Announces Publication in the New England Journal of Medicine of Phase 2 BrigHtn Data on Selective Aldosterone Synthase Inhibitor Baxdrostat in Treatment-Resistant Hypertension

Clinically significant and dose-dependent reduction in blood pressure with baxdrostat

Highly selective mechanism of action with no meaningful impact on cortisol supports first-in-class potential

Potential treatment for the 10-12 million patients in the US alone with treatment-resistant hypertension

WALTHAM, MA, November 7, 2022 (GLOBE NEWSWIRE) -- CinCor Pharma, Inc. ("CinCor") announced that detailed results from the Phase 2 BrigHtn trial evaluating the safety and efficacy of baxdrostat in treatment-resistant hypertension were published online today in the New England Journal of Medicine. Baxdrostat is a highly selective, once daily oral small molecule inhibitor of aldosterone synthase.

"Publication of the Phase 2 BrigHtn data in the world-renowned New England Journal of Medicine highlights to the medical community that resistant hypertension is an important unmet need with inadequate treatment options that fail to bring blood pressure under control," said Mason Freeman, M.D, Chief Medical Officer at CinCor. "The clinical biomarker activity of aldosterone and renin provide mechanistic insight into how baxdrostat achieves selective blood pressure lowering effects with no impact on cortisol. These findings further reinforce the robust blood pressure lowering capabilities in hypertensive patients on three or more medications, the well-tolerated profile supportive of long-term use and combinability with other agents, and the potential to treat the 10-12 million patients in the US alone with treatment-resistant hypertension."

The BrigHtn trial was a Phase 2 randomized, double-blind, placebo-controlled, dose-ranging clinical trial designed to assess the safety and efficacy of baxdrostat in subjects who have not achieved their target blood pressure despite receiving three or more antihypertensive agents at their maximally tolerated doses, one of which must be a diuretic. The trial evaluated three active doses of baxdrostat (0.5 mg, 1.0 mg, and 2.0 mg) compared to placebo control in 275 patients randomized across all four dosing cohorts, with 248 patients completing. The primary endpoint of BrigHtn was the change in mean seated systolic blood pressure from randomization to trial end after 12 weeks of treatment.

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