UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 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 6, 2023**

INNOVIVA, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**000-30319**	**94-3265960**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification Number)

1350 Old Bayshore Highway,
Suite 400
Burlingame, California 94010
(650) 238-9600
(Addresses, including zip code, and telephone numbers, including area code, of principal executive offices)

(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 (see General Instruction A.2. below):

☐ 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, par value $0.01 per share	INVA	The NASDAQ Global Select 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 ☐

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 6, 2023, Innoviva, Inc. (the "Company") made available on its website a presentation discussing topline data from the Phase 3 clinical trial of Zoliflodacin (the "Zoliflodacin Clinical Data Presentation"). A copy of the Zoliflodacin Clinical Data Presentation is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

The information included in this Current Report on Form 8-K that is furnished pursuant to this Item 7.01, including the information contained in Exhibit 99.1 hereto, shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. In addition, the information included in this Current Report on Form 8-K that is furnished pursuant to this Item 7.01, including the information contained in Exhibit 99.1 hereto, shall not be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing, unless expressly incorporated by specific reference into such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

99.1	Zoliflodacin Clinical Data Presentation, dated November 6, 2023
104	Cover Page Interactive File (the cover page tags are embedded within the Inline XBRL document)

SIGNATURE

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

INNOVIVA, INC.

Date: November 6, 2023

By: /s/ Pavel Raifeld
Pavel Raifeld
Chief Executive Officer

INNOVIVA Specialty Therapeutics™

Zoliflodacin Phase 3 clinical trial topline data

November 6, 2023

Top line summary: positive zoliflodacin Phase 3 results

- An estimated 82 million patients contract gonorrhea each year[1], with rising rates of resistance to standard of care regimens in many countries[2].
- We, in collaboration with GARDP, conducted a global pivotal phase 3 trial to evaluate the efficac single 3g oral dose of zoliflodacin in treatment of uncomplicated gonorrhea compared to treatm with a combination of intramuscular injection of ceftriaxone and oral azithromycin.
- Zoliflodacin met the primary efficacy endpoint and was non-inferior to the comparator arm in participants with urogenital disease (point estimate 5.3% (95% confidence interval: 1.4%, 8.7%))
- For the key secondary analyses of infections at rectal and pharyngeal sites, rates of cure in the zoliflodacin arm were comparable to those observed in the comparator arm, though these analy were not powered for statistical significance.
- In this study, zoliflodacin was safe and generally well-tolerated; majority of adverse events were to moderate with no discontinuations due to adverse events, serious adverse events, or deaths.
- The study outcome could provide an important therapeutic option for patients and is a positive milestone in the development of zoliflodacin and the fight against antimicrobial resistance.

1 – WHO global antimicrobial resistance suveillance. Lancet Microbe 2021; 2: e627–36
2 – Lancet 2023; 9: e332-33

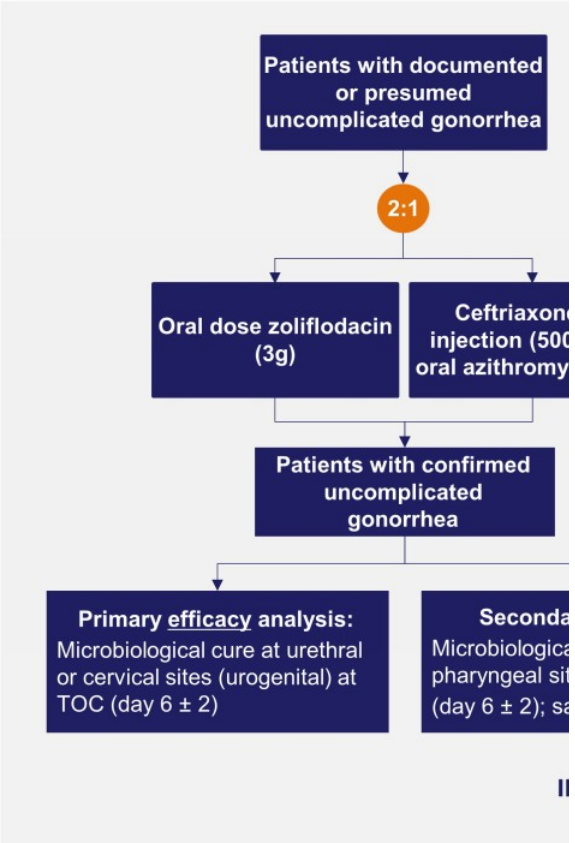
Zoliflodacin Phase 3 registration study design

The zoliflodacin pivotal Phase 3 registration trial was conducted to evaluate the efficacy of a single 3g oral dose of zoliflodacin in treatment of uncomplicated gonorrhea compared to treatment with intramuscular injection of ceftriaxone and oral azithromycin, a current global standard of care regimen.

The primary efficacy endpoint was microbiological test of cure at urethral or cervical sites (urogenital) in participants who had a positive culture for gonorrhea at baseline.

Secondary analyses were microbiological cure at rectal or pharyngeal sites and safety. The trial was designed with a 90% power and a 10% noninferiority margin.

This was a global study, conducted at 16 sites in the United States, South Africa, Belgium, Netherlands, and Thailand.



Abbreviations: CRO-AZI – ceftriaxone and azithromycin; IM – intramuscular injection

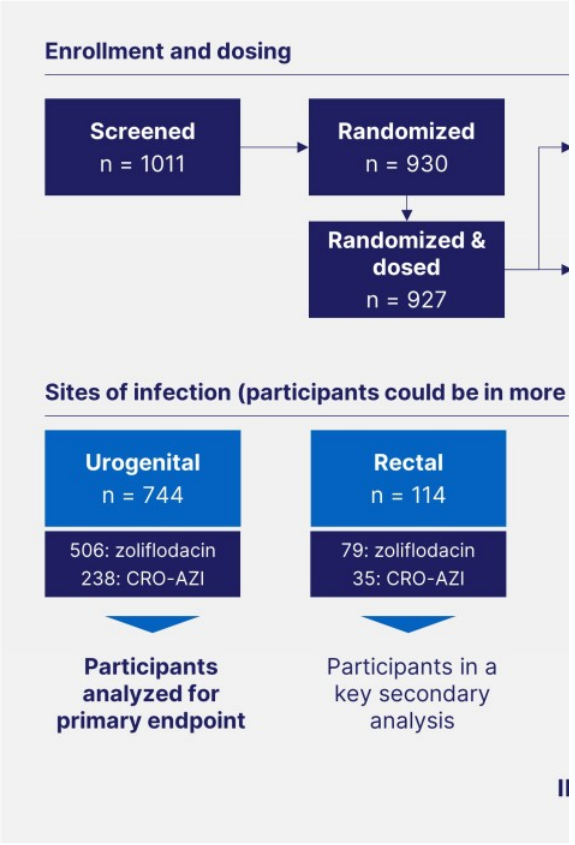
Study enrollment

1011 patients were initially screened, with 927 randomized and dosed.

The majority of participants (744) presented with urogenital infections, followed by rectal infections (114) and pharyngeal infections (81). Participants could be in more than one group.

Overall, the trial participants were 87% male, 13% female, 55% Black or Black African, and 20% were positive for human immunodeficiency virus (HIV).

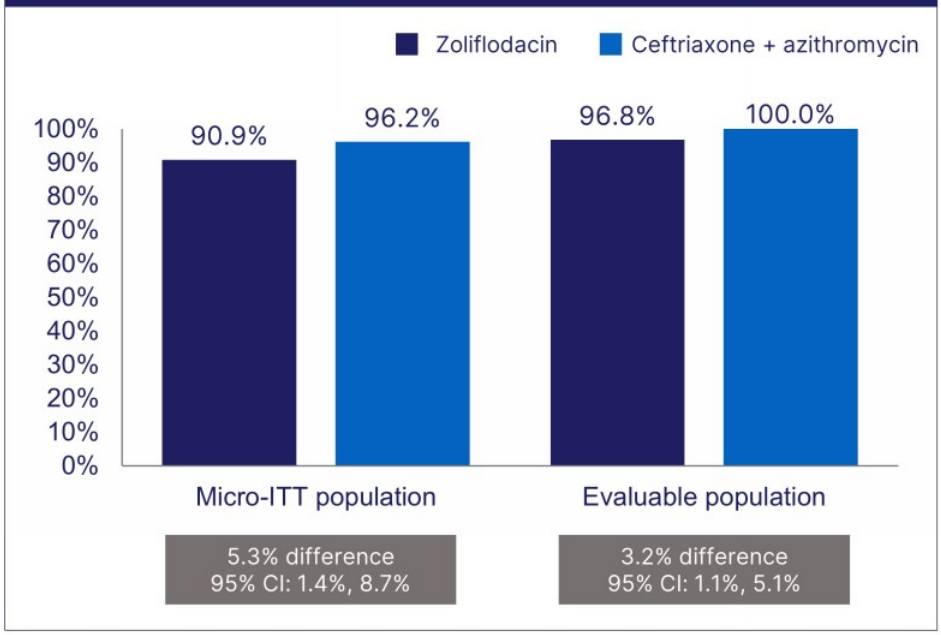
Abbreviations: CRO-AZI – ceftriaxone and azithromycin



The primary endpoint was achieved

A high microbiological cure rate (>90% in both arms) was observed

Microbiological cure rate at test of cure visit



Zoliflodacin met the primary effica
was non-inferior to the comparato
5.3% (95% confidence interval (CI

The intent to treat analysis includ
with a positive baseline culture fo
who missed the test of cure cultu
window, or had demonstrated mic
were recorded as failures.

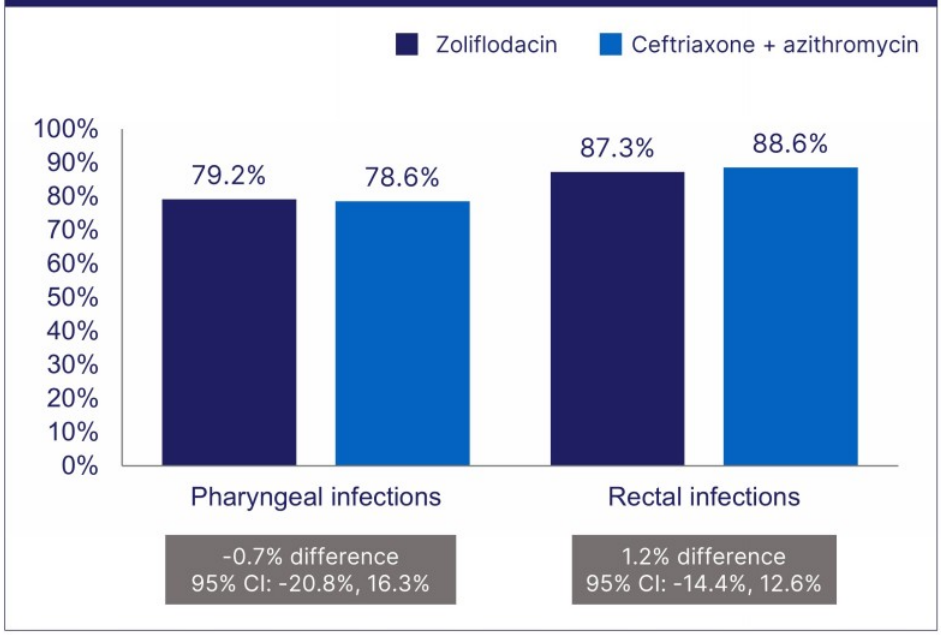
When participants who had both
up cultures were evaluated, the p
reduced to 3.2% (95% CI, 1.1%, 5.

Clinical cure rates, as assessed b
symptoms in the subset of male p
urogenital disease, were also com
zoliflodacin and the comparator a

II

Key secondary analyses showed comparable results in comparison to ceftriaxone and azithromycin

Microbiological cure rate at test of cure visit



Key secondary analysis included
pharyngeal and rectal gonorrhea.
cure for these populations have b
those observed in urogenital dise

Rates of cure in the zoliflodacin a
comparable to those observed in
arm.

These secondary analyses were
statistical significance.

Favorable safety and tolerability profile in this study

In this study, zoliflodacin was safe and generally well-tolerated

The overall rate of adverse events was comparable between the two arms

The majority of adverse events were mild to moderate

There were no discontinuations reported due to adverse events, serious adverse events, or deaths

	Zoliflodacin N=619 n (%)
All TEAEs	286 (46.2)
Drug-related TEAEs	117 (18.9)
SAEs	0
Drug-related SAEs	0
Withdrawals due to adverse events	0
TEAEs leading to death	0

TEAE	Zoliflodacin
Headache	61 (9.9)
Neutropenia	42 (6.8)
Leukopenia	24 (3.9)
Neutrophil count decreased	21 (3.4)
Dizziness	21 (3.4)
Nausea	16 (2.6)
Diarrhea	15 (2.4)

Abbreviations: TEAE – Treatment emergent adverse event; SAE – Serious adverse event; CRO-AZI – ceftriaxone and azithromycin