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): August 11, 2022

Landos Biopharma, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-39971**	**81-5085535**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

PO Box 11239, Blacksburg, Virginia	**24062**
(Address of Principal Executive Offices)	**(Zip Code)**

(540) 218-2232
(Registrant's Telephone Number, Including Area Code)

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 Securities Exchange Act of 1934:

Title of each class	Trading symbol	Name of each exchange on which registered
Common Stock, par value $0.01 per share	**LABP**	**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 2.02 Results of Operations and Financial Condition.

On August 11, 2022, Landos Biopharma, Inc. (the "**Company**") issued a press release announcing its financial results for the three months ended June 30, 2022. A copy of this press release is furnished as Exhibit 99.1 hereto.

The information in this Item 2.02 and Exhibit 99.1 hereto are being 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 Securities Act of 1933, as amended (the "**Securities Act**"), or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 7.01 Regulation FD Disclosure.

On August 11, 2022, the Company posted a presentation on the Company's website summarizing data from the Phase1b trial of NX-13 (the "**NX-13 Presentation**"), which the Company may use from time to time in conversations with investors, analysts or other third parties. The NX-13 Presentation is furnished as Exhibit 99.2 hereto.

The information in this Item 7.01 and Exhibit 99.2 hereto are being furnished and shall not be deemed "filed" for purposes of Section 18 of 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 Securities Act or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d). Exhibits

Exhibit No.	Description
99.1	Press Release, dated August 11, 2022.
99.2	NX-13 Presentation, dated August 11, 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, as amended, the Company has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Landos Biopharma, Inc.

Dated: August 11, 2022

By: /s/ Gregory Oakes
Gregory Oakes
Chief Executive Officer

Landos Biopharma Reports Second Quarter 2022 Results and Provides Business Update

Positive Top-Line Results From NX-13 Phase 1b Trial in Ulcerative Colitis Demonstrate a Favorable Safety and Tolerability Profile Across Range of Once-Daily Oral Doses, as well as Promising Early Efficacy Signals

Phase 2 Proof of Concept Clinical Trial for NX-13 in Ulcerative Colitis Planned

On Track to Complete Comprehensive Review of Clinical Development Plans Later this Year

NEW YORK, August 11, 2022 — Landos Biopharma, Inc. (NASDAQ: LABP), a clinical-stage biopharmaceutical company developing novel, oral medicines for patients with autoimmune diseases, today announced financial results for the second quarter ended June 30, 2022, and provided a business update.

"Landos continues to make progress advancing our clinical-stage programs – omilancor, NX-13 and LABP-104 – and positioning the Company for the future," said Gregory Oakes, President and CEO of Landos. "We announced positive top-line results from our NX-13 Phase 1b trial, which showed a favorable safety and tolerability profile in ulcerative colitis (UC) patients across a range of doses, as well as promising early efficacy signals. The results support our belief that NX-13 has the potential to be an important new oral, once-daily treatment for UC. These positive results also highlight our sharpened strategic focus on pursuing what we believe are the most promising molecules and target indications."

"As we finalize our comprehensive review of the Company's clinical development plans, Landos is well positioned to advance our clinical stage assets and deliver on our mission of addressing the therapeutic gap for patients with autoimmune diseases. We look forward to providing a comprehensive update on our pipeline later this year," continued Mr. Oakes.

Clinical Development Updates

Omilancor

Omilancor is a novel, oral, gut-restricted LANCL2 agonist in development for the treatment of UC as a once-daily oral treatment.

- Landos continues to optimize drug product formulation, including a dose selection assessment. The Company expects to announce both the timing and next steps in the development of omilancor later this year.

NX-13

NX-13 is a novel, oral, gut-restricted NLRX1 agonist in development for the treatment of UC as a once-daily oral treatment.

- The Company recently announced top-line results from its Phase 1b trial in UC patients. The data showed favorable safety and tolerability across a range of doses, as well as signals of clinical improvement as soon as two weeks in patients' symptoms and four weeks by endoscopy in exploratory endpoints.

- The Company provided additional information regarding results of the NX-13 Phase 1b trial in a supplemental presentation posted on the Company's investor relations website.
- Landos plans to initiate a Phase 2 proof of concept clinical trial of NX-13 in UC patients to evaluate the safety, efficacy, and optimal dosing.

LABP-104

LABP-104 is a novel, oral, systemically distributed LANCL2 agonist in development for the treatment of systemic lupus erythematosus (SLE) and/or rheumatoid arthritis (RA) as a once-daily oral treatment.

- Landos conducted a Phase 1a trial of LABP-104 in healthy volunteers and expects topline results to be reported later this year. The Company expects to announce both the timing and next steps in the development of LABP-104 later this year.

Summary of Second Quarter 2022 Results

Cash, Cash Equivalents and Marketable Securities:

As of June 30, 2022, the Company had cash, cash equivalents and marketable securities of $55.8 million, which it believes will be sufficient to fund its planned operations for at least the next 12 months. Upon completion of its portfolio prioritization review later this year, the Company will provide further details into its operating plans and capital resources.

Research and Development Expenses:

Research and development expenses were $6.6 million for the second quarter of 2022, compared to $11.5 million in the second quarter of 2021. The decrease was primarily attributed to a reduction in contract research and clinical data management costs following the planned termination of further enrollment in two clinical trials of omilancor for the treatment of Crohn's Disease. This was partially offset by an increase in consulting and temporary labor costs for the three months ended June 30, 2022.

General and Administrative Expenses:

General and administrative expenses were $4.7 million for the second quarter of 2022, compared to $2.6 million in the second quarter of 2021. The increase was primarily attributable to increases in employee-related expenses, including stock-based compensation, as well as an increase in recruiting and legal fees.

About Landos Biopharma

Landos Biopharma is a clinical-stage biopharmaceutical company focused on the discovery and development of oral therapeutics for patients with autoimmune diseases. We believe we were the first to identify and target LANCL2, NLRX1 and PLXDC2, which are immunometabolic pathways or targets. We have identified seven novel immunometabolic pathways or targets based on predictions of immunometabolic function using a proprietary advanced artificial intelligence-based integrated computational and experimental precision medicine platform. Our near-term focus is on our clinical-stage programs including omilancor for the treatment of UC, NX-13 for the treatment of UC, and LABP-104 for the potential treatment of systemic lupus erythematosus and rheumatoid arthritis.

For more information, please visit www.landosbiopharma.com.

Cautionary note on Forward-Looking Statements

Statements in this press release about future expectations, plans and prospects for Landos Biopharma, Inc. (the "Company"), including statements about the Company's strategy, clinical development and regulatory plans for its product candidates, including omilancor, NX-13 and LABP-104, and other statements containing the words "anticipate", "plan", "expect", "may", "will", "could", "believe", "look forward", "potential", the negatives thereof, variations thereon and similar expressions, or any discussions of strategy constitute forward-looking statements. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties inherent in the initiation and enrollment of future clinical trials, expectations of expanding ongoing clinical trials, availability and timing of data from ongoing clinical trials, expectations for regulatory approvals, other matters that could affect the availability or commercial potential of the Company's product candidates and other similar risks. Risks regarding the Company's business are described in detail in its Securities and Exchange Commission ("SEC") filings, including in its Annual Reports on Form 10-K and Quarterly Reports on Form 10-Q, which are available on the SEC's website at www.sec.gov. Additional information will be made available in other filings that the Company makes from time to time with the SEC. Such risks may be amplified by the impacts of the COVID-19 pandemic. In addition, the forward-looking statements included in this press release represent the Company's views only as of the date hereof. The Company anticipates that subsequent events and developments will cause the Company's views to change. However, while the Company may elect to update these forward-looking statements at some point in the future, the Company specifically disclaims any obligation to do so, except as may be required by law. These forward-looking statements should not be relied upon as representing the Company's views as of any date subsequent to the date hereof.

Contacts

Tanner Kaufman / Kara Sperry
Joele Frank, Wilkinson Brimmer Katcher
212-355-4449

Landos Biopharma, Inc. Unaudited Condensed Consolidated Statements of Operations (in thousands, except share and per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue - license fee:	$ —	$ 18,000	$ —	$ 18,000
Operating expenses:				
Research and development	$ 6,604	$ 11,522	$ 17,404	$ 18,776
General and administrative	4,662	2,596	8,815	5,241
Total operating expenses	11,266	14,118	26,219	24,017
(Loss) income from operations	(11,266)	3,882	(26,219)	(6,017)
Other (loss) income, net	(18)	215	71	296
Net (loss) income	$ (11,284)	$ 4,097	$ (26,148)	$ (5,721)
Net (loss) income per share, basic and diluted	$ (0.28)	$ 0.12	$ (0.65)	$ (0.19)
Weighted-average shares used to compute net (loss) income per share, basic	40,254,890	33,639,481	40,254,890	29,875,877
Weighted-average shares used to compute net (loss) income per share, diluted	40,254,890	34,384,784	40,254,890	29,875,877

Landos Biopharma, Inc. Condensed Consolidated Balance Sheets (in thousands)

	June 30, 2022 (Unaudited)	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 19,241	$ 8,305
Marketable securities, available-for-sale	36,510	82,575
Prepaid expenses and other current assets	2,287	1,266
Total current assets	58,038	92,146
Property and equipment, net	—	707
Other assets	—	26
Total assets	$ 58,038	$ 92,879
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,711	$ 12,908
Accrued liabilities	1,799	3,703
Total current liabilities	6,510	16,611
Total liabilities	6,510	16,611
Commitments and contingencies		
Stockholders' equity:		
Common stock	403	403
Additional paid-in capital	171,816	170,241
Accumulated other comprehensive loss	(392)	(225)
Accumulated deficit	(120,299)	(94,151)
Total stockholders' equity	51,528	76,268
Total liabilities and stockholders' equity	$ 58,038	$ 92,879

Exhibit 99.2

LANDOS
BIOPHARMA

NX-13 Phase 1b Clinical Trial Data

AUGUST 2022

Forward Looking Statements

This presentation contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this presentation, including statements regarding our strategy, future operations, prospects, plans and objectives of management, are forward-looking statements. The words “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “predict,” “project,” “target,” “potential,” “will,” “would,” “could,” “should,” “continue,” and similar expressions are intended to identify forward looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements are subject to a number of risks, uncertainties and assumptions. Risks regarding our business are described in detail in our Securities and Exchange Commission filings, including in our Annual Report on Form 10-K for the year ended December 31, 2021. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. The forward-looking statements contained in this presentation reflect our current views with respect to future events, and we assume no obligation to update any forward-looking statements except as required by applicable law.

Positive Top-Line Results Highlight Strong Company Momentum

Support potential of NX-13 as important, new treatment for Ulcerative Colitis (UC)

- NX-13 targets a novel pathway
- NX-13 showed a favorable safety and tolerability profile in UC patients across a range of oral, once-daily doses
- Results indicate promising early signals regarding efficacy*

Validate sharpened strategic focus on pursuing the most promising target indications

- Strong scientific foundation and promising pipeline of oral, once-daily clinical-stage assets — omilancor, NX-13 and LABP-104

Comprehensive review of clinical development plans near completion

- Focused on optimizing successful outcomes for clinical stage assets, strengthening team and advancing mission of addressing therapeutic gap for patients with autoimmune diseases
- On track to provide update later this year

*Study was not designed or powered for exploratory clinical endpoints therefore results are hypothesis-generating only.

Roadmap for NX-13 Development

What we learned in the Phase 1b trial:

- Favorable safety profile and tolerability in active UC across the study
- Indications of clinical improvement signals* seen as soon as
  - 2 weeks in patient symptoms; and
  - 4 weeks by endoscopy in exploratory endpoints

What we still need to determine:

- Conducting further analysis of clinical, pharmacokinetic, and pharmacodynamic data
  - Guidance on doses and population stratification
  - Site and mechanism of drug action

What's next:

Announcing timing and study design for Phase 2 proof of concept trial later this year

*Study was not designed or powered for exploratory clinical endpoints therefore results are hypothesis-generating only.


NX-13 Phase 1b
Clinical Trial Data

NX-13 Overview

Mechanism of Action

Targets NLRX1 pathway, a mitochondrial-associated regulatory NOD-like receptor

Drug Profile

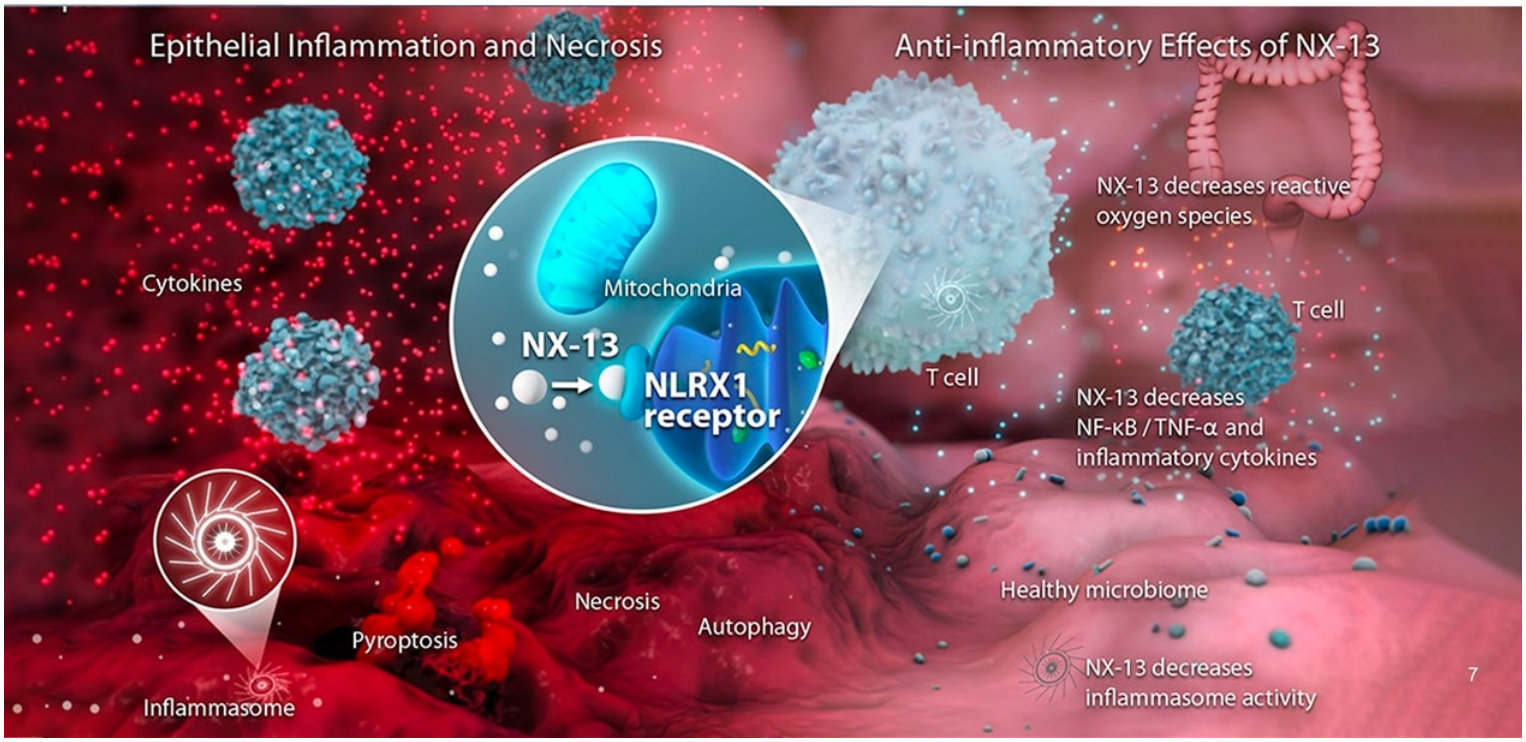
Orally active and gut-restricted, allowing target engagement within the GI tract

Recent & Upcoming Milestones

Recently completed successful Phase 1b trial

Announcing timing and study design for Phase 2 proof of concept trial later this year

NX-13 Selectively Targets Novel Target NLRX1 in the Gut



Phase 1b Study Design of NX-13 in Active UC

Primary Objective:

To assess the safety and tolerability of NX-13 after multiple oral dose administration in subjects with active ulcerative colitis (UC)

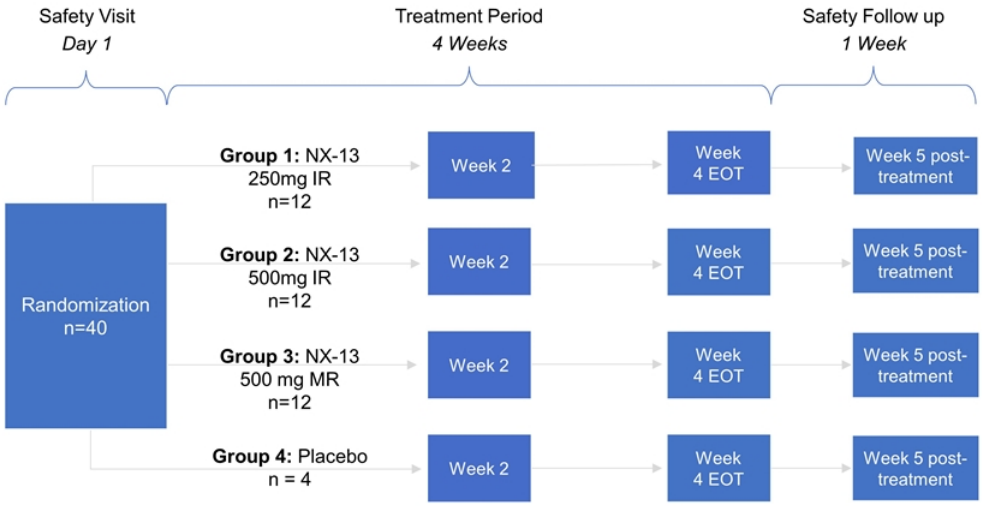
Key Inclusion Criteria:

- Male and female subjects 18-75 years old;
- Active UC >90days;
- Total Mayo Score of 4 to 10 (enrolled population average 7.6);
- MES ≥ 2 (confirmed by central reader);
- Baseline fecal calprotectin >250ug/g;
- 5-aminosalicylates stable for >1month, throughout trial;
- Bio-naïve or 8-week washout period if previously on biologics

Phase 1b Study Design of NX-13 in Active UC

Primary endpoints: Evaluate safety and pharmacokinetics of multiple dose levels

Promising signals of clinical efficacy despite relatively short trial duration



IR = Immediate Release; MR = Modified Release
*Study was not designed or powered for exploratory clinical endpoints therefore results are hypothesis-generating only

NX-13 was Well-Tolerated and Shows Promising Efficacy Signals in Active UC

Safety: NX-13 was generally well tolerated, consistent with non-clinical, Phase 1a data

- No Serious Adverse Events
- 3 unrelated Adverse Events (AEs) of note

Pharmacokinetics: Plasma levels were generally low

- Modified Release tablet produced a flattened, prolonged exposure profile
- Tissue levels fell below the limit of quantification in a portion of patients in all dose groups, suggesting need for higher sensitivity assay

Efficacy: 4 weeks of low dose, immediate release NX-13 (250mg IR) once daily induced:

- Clinical response in 8/11 patients
- Clinical remission in 3/11 patients
- Endoscopic response in 4/11 patients
- Symptomatic Remission (Stool Frequency=0, Rectal Bleeding=0) in 8/11 patients
- Fecal Calprotectin Normalization in 5/11 patients

*Study was not designed or powered for exploratory clinical endpoints therefore results are hypothesis-generating only

NX-13 Phase 1b Trial Safety Evaluations

	Placebo (n = 4)	NX-13 250mg (n=11)	NX-13 500mg (n=10)	NX-13 500mg MR (n=11)
Serious AEs	**0**	**0**	**0**	**0**
Mild/Moderate TEAEs	1 (20%)	2 (18.2%)	3 (27.3%)	6 (54.5%)
GI *(abdominal pain, UC worsening, pancreatitis, constipation)*	1 (20%)	0	1 (9.1%)	3 (27.3%)
Renal *(congenital PCKD, increased creatinine, kidney stones)*	0	0	0	1 (9.1%)
General/Cardiac *(A.Fib, Anemia, Weakness, Dizziness)*	1 (20%)	0	2 (18.2%)	0
Clinical Chemistry *(GGT increase, HLD, hypocalcemia, hypophosphataemia)*	0	1 (9.1%)	2 (18.2%)	2 (18.2%)
Infections / Infestations *(UTI, COVID)*	0	1 (9.1%)	0	1 (9.1%)

HLD = hyperlipidaemia; GGT = Gamma-Glutamyltransferase

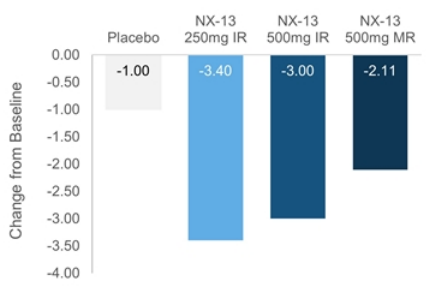
3 unrelated AEs of note:

- UC Flare (withdrew)
- A.Fib/Panic attack (withdrew)
- Mild pancreatitis (continued)

No additional changes noted in clinical chemistry, hematology, vital signs, physical exam and ECG from baseline

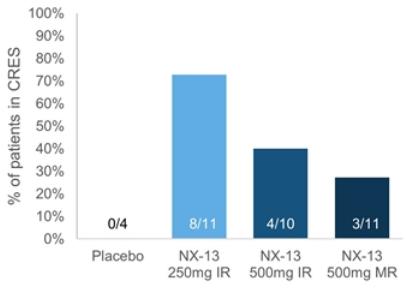
NX-13 Treated Patients Experienced Reductions in Total Mayo Score after 4 weeks

Total Mayo Score Change from Baseline



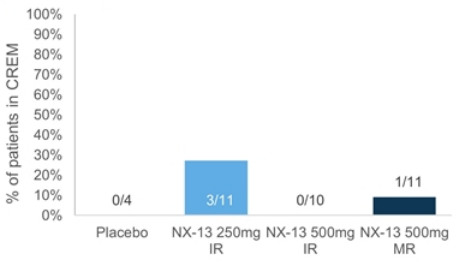
Clinical Response

Defined as CFB of -3, or -30% in Mayo Score



Clinical Remission

Defined as Mayo Score less than 2, with no subscore above 1

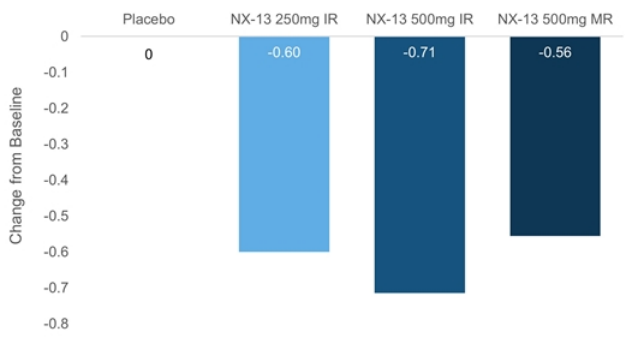


- Patients who received the 250mg dose experienced the greatest reduction of Total Mayo Score: -3.40 (range -7, 0), representing an average 48% reduction from baseline score.
  - 500mg patients also experienced clinically meaningful reductions of -3.00 and -2.11 on the IR and MR doses, respectively
- 72% (8/11) of the 250mg group achieved clinical response; 27% (3/11) achieve clinical remission after just 4 weeks of treatment

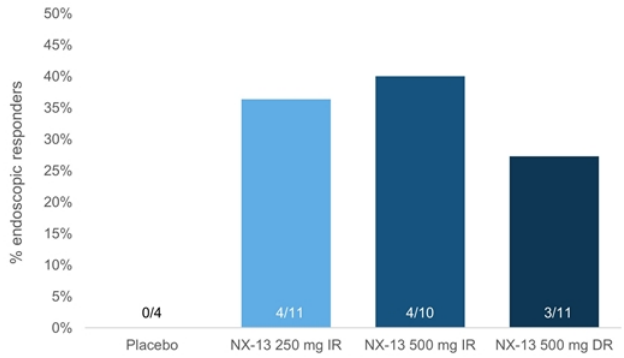
IR= Immediate Release; MR= modified release designed to dissolve at the terminal ileum
*Study was not designed or powered for exploratory clinical endpoints therefore results are hypothesis-generating only

Endoscopic Improvement at All Doses Driving Reduction of Mayo Score

Mayo Endoscopy Score Change from Baseline



Endoscopic Response (MES CFB -1)

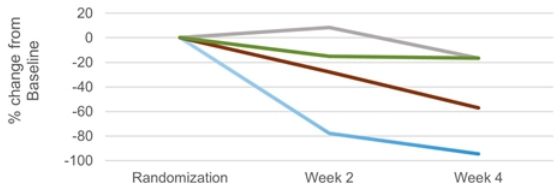


- Patients treated with ALL doses of NX-13 experienced reductions in MES on average
  - 27-40% endoscopic response **after just 4 weeks** of treatment across dosage groups

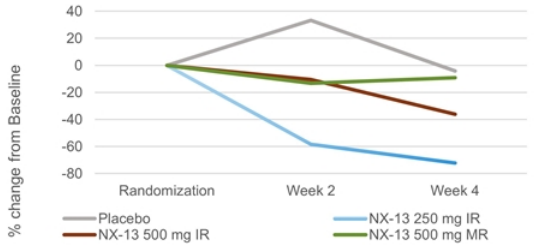
FCP = Fecal Calprotectin; Normalization defined as an FCP score reduction to below 250.
MES = Mayo Endoscopy Score; PROs = Patient Reported Outcomes
*Study was not designed or powered for exploratory clinical endpoints therefore results are hypothesis-generating only

NX-13 Supported Symptomatic Remission in Rectal Bleeding and Stool Frequency

Rectal Bleeding Change from Baseline



Stool Frequency Change from Baseline



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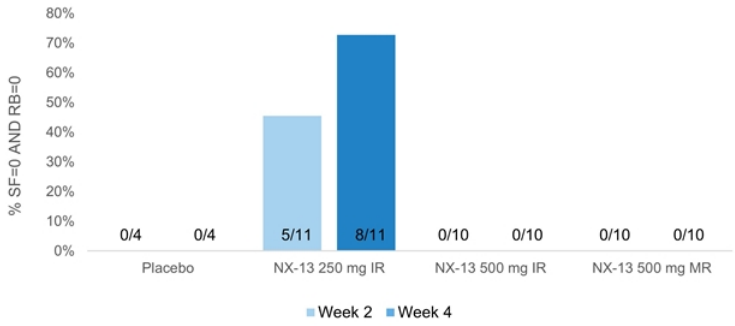
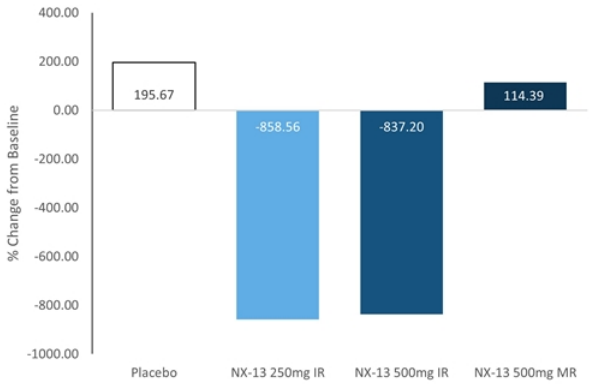
Resolution of SF + RB



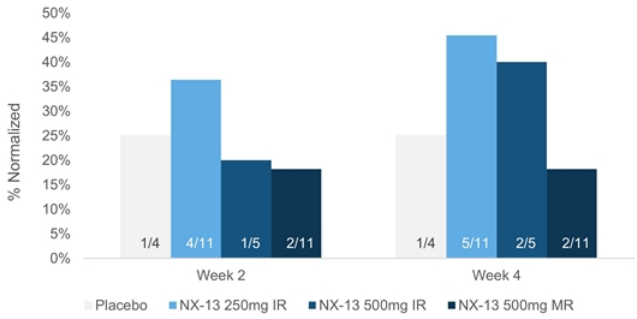
- Patients in the 250mg group had the greatest reduction of Rectal Bleeding and Stool Frequency at 2 weeks, with further reduction at 4 weeks
  - Majority of patients saw complete resolution of BOTH rectal bleeding and stool frequency after 4 weeks of treatment with NX-13 250mg, once daily

Fecal Calprotectin (FCP) Change and Normalization

Week 4 FCP Change from Baseline



FCP Normalization (FCP decrease to <250)



- Immediate release (IR) groups had the greatest decrease of Fecal Calprotectin at 4 weeks on average
- Rates of Fecal Calprotectin Normalization mirrored Clinical Remission and Endoscopic response
  - Changes were seen as early as 2 weeks

FCP = Fecal Calprotectin; Normalization defined as an FCP score reduction to below 250.
*Study was not designed or powered for exploratory clinical endpoints therefore results are hypothesis-generating only

NX-13 was Well-Tolerated and Shows Promising Efficacy Signals in Active UC

Safety: NX-13 was generally well tolerated, consistent with non-clinical, Phase 1a data

- No Serious Adverse Events
- 3 unrelated Adverse Events (AEs) of note

Pharmacokinetics: Plasma levels were generally low

- Modified Release tablet produced a flattened, prolonged exposure profile
- Tissue levels fell below the limit of quantification in a portion of patients in all dose groups, suggesting need for higher sensitivity assay

Efficacy: 4 weeks of low dose, immediate release NX-13 (250mg IR) once daily induced:

- Clinical response in 8/11 patients
- Clinical remission in 3/11 patients
- Endoscopic response in 4/11 patients
- Symptomatic Remission (Stool Frequency=0, Rectal Bleeding=0) in 8/11 patients
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*Study was not designed or powered for exploratory clinical endpoints therefore results are hypothesis-generating only