

**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 05, 2023

Landos Biopharma, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39971
(Commission File Number)

81-5085535
(IRS Employer
Identification No.)

P.O. Box 11239
Blacksburg, Virginia
(Address of Principal Executive Offices)

24062
(Zip Code)

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

(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, 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 7.01 Regulation FD Disclosure.

On January 5, 2023, Landos Biopharma, Inc. (the “Company”) issued a press release to announce a comprehensive update on its future development plans. A copy of the press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K. The Company also updated its corporate presentation on January 5, 2023 for use in meetings with investors, analysts and others. The presentation is available through the Company’s website and a copy is attached as Exhibit 99.2 to this Current Report on Form 8-K.

The information in this Item 7.01 of this Current Report on Form 8-K (including Exhibits 99.1 and 99.2) is 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, 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 Number	Exhibit Description
99.1	Press Release, dated January 5, 2023.
99.2	Corporate Presentation, dated January 5, 2023.
104	The cover page from Landos Biopharma, Inc.’s Form 8-K filed on January 5, 2023, formatted in Inline XBRL.

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.

Landos Biopharma, Inc.

Date: January 5, 2023

By: /s/ Gregory Oakes

Gregory Oakes

Chief Executive Officer

Landos Biopharma Provides Comprehensive Update on Clinical Development Plans*Advancing NX-13 Clinical Development for Treatment of Ulcerative Colitis**On Track to Initiate Phase 2 Proof-of-Concept Trial for NX-13 in the Second Quarter of 2023 and Report Topline Data by the Fourth Quarter of 2024**Broader, Novel Pipeline Poised for Partnering and Continued Development in the Future;
Significant Optionality for Omilancor, LABP-104 and Four Promising Pre-Clinical Programs**Secures Additional \$16.7 Million Investment**Disciplined Financial Approach Expected to Maintain Cash Runway into First Half of 2025**Company to Host Investor Call at 8:00 AM ET*

NEW YORK, January 5, 2022 – Landos Biopharma, Inc. (NASDAQ: LABP) (“Landos” or the “Company”), a clinical-stage biopharmaceutical company developing novel, oral medicines for patients with autoimmune diseases, today announced a comprehensive update on its future clinical development plans.

The Landos leadership team and Board of Directors have conducted an in-depth review of the Company’s pipeline and overall development plans to ensure that it is pursuing the most promising therapies and target indications. Following the review of Landos’ three clinical stage programs – NX-13, Omilancor and LABP-104 – as well as its four pre-clinical assets, Landos will be focused on advancing NX-13, a novel, oral, gut-selective NLRX1 agonist in development as a once-daily treatment for Ulcerative Colitis (“UC”), including into an upcoming Phase 2 proof-of-concept clinical trial.

“After thorough analysis and careful consideration, we are confident that focusing our resources toward NX-13’s clinical development has the potential to deliver the most value for Landos and our shareholders,” said Gregory Oakes, President and Chief Executive Officer of Landos. “Given the strong clinical data we saw in prior NX-13 trials and our anticipated timeline for the Phase 2 trial, we believe that advancing its development is the right path forward. NX-13, with its unique mechanism of action (“MOA”), favorable safety profile, once-daily dosing, and promising early clinical data, could potentially transform the current treatment paradigm with earlier utilization in moderate-to-severe UC for patients who are either failing or starting to lose efficacy on conventional therapies like 5-ASAs or steroids. Following the positive read-out of the NX-13 Phase 1b trial, we have been finalizing the design for a Phase 2 proof-of-concept clinical trial. Our goal is to generate as much meaningful data as possible, as quickly as possible, to build on our already impressive data foundation. We expect that the NX-13 Phase 2 trial will have two active arms and will be blinded, placebo-controlled, and statistically powered. We have already completed a series of startup activities and are on track for first site activation and patient enrollment in the second quarter of 2023. We look forward to sharing our progress and expect to report topline data by the fourth quarter of 2024.”

Given the strong foundation of data across its broader pipeline, Landos believes Omilancor, LABP-104 and its novel preclinical programs are poised for partnering and continued clinical development in the future. Landos will continue to explore collaborations and other arrangements that would provide additional resources and/or capabilities to advance these promising programs and create value for shareholders.

“Our goal is to evolve Landos from a discovery-based organization into an immunology development powerhouse. We are focused on the successful advancement of our innovative pipeline of multiple pathways and programs with novel MOAs. We continue to see significant optionality for our broader pipeline, including Omilancor for UC, Crohn’s Disease (“CD”), Eosinophilic Esophagitis, Psoriasis, and Atopic Dermatitis; LABP-104 for Systemic Lupus Erythematosus (“SLE”) and Rheumatoid Arthritis (“RA”); as well our preclinical programs: LABP-66 for the treatment of Multiple Sclerosis (“MS”), Alzheimer's Disease, and other debilitating central nervous system (“CNS”) diseases; LABP-73 for Respiratory Inflammatory disease; LABP-69 for RA and Diabetic Nephropathy; and LABP-111 for Nonalcoholic Steatohepatitis (“NASH”) and Diabetes. We believe that potential partners, key opinion leaders, academics, and others are excited about these programs, and we will continue to engage with them to explore opportunities that would create long-term value for our shareholders. As we look ahead, we believe these programs have significant optionality for continued development in the future,” continued Mr. Oakes.

Adding Key Talent and Capabilities

Landos has also been selectively enhancing its leadership team, adding key talent and capabilities to help position the Company for continued success as it advances NX-13 towards a Phase 2 proof-of-concept trial. Landos has added experts with significant clinical drug development expertise in the immunology space, including the appointment of Fabio Cataldi, MD, as Executive Vice President & Chief Medical Officer in September 2022. Dr. Cataldi brings more than twenty years of experience to Landos in the successful development of innovative therapies, including research expertise in gastroenterology and immunology, particularly in UC.

Partnership with LianBio

As announced in 2021, Landos entered into an exclusive collaboration and license agreement with LianBio for the development and commercialization of NX-13 and Omilancor in Greater China, including mainland China, Hong Kong, Taiwan, and Macau, as well as other select Asian markets. Of note, the Company continues to maintain rights to Japan, which Landos believes is a significant and growing market opportunity.

Clinical Stage Programs

NX-13

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

- Landos announced top-line results from its NX-13 Phase 1b trial in UC patients in August 2022. The data showed favorable safety and tolerability profiles 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. This early signal, as well as the data from long-term toxicology studies, support the potential of NX-13 as an important new treatment for UC.
 - Landos is continuing an in-depth analysis of the clinical, pharmacokinetic (“PK”), and pharmacodynamic (“PD”) data for NX-13. A preliminary analysis demonstrated promising signals of both target engagement and molecular dose response among the 250mg and 500mg IR doses.
 - Landos will be conducting a Phase 2 proof-of-concept clinical trial for NX-13, which will be dose ranging, blinded, placebo-controlled, and statistically powered.
 - The Company is on track for first site activation and patient enrollment for the NX-13 Phase 2 trial in the second quarter of 2023. The Company expects to report topline data from the trial by the fourth quarter of 2024.
 - In addition to UC, the Company believes NX-13 has the potential to treat CD.
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Omilancor

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

- Landos has completed a global Phase 2 trial in mild-to-moderate UC, which confirmed the safety and tolerability characteristics observed in the Phase 1a trial. While this study showed a clinical remission rate of over 30%, it did not reach statistical significance due to a higher-than-expected placebo remission rate of over 20%.
- A pre-specified disease severity analysis, however indicated clinical efficacy in more severe UC patients, and that an enhanced formulation may further improve Omilancor efficacy in future trials.
- The Company is evaluating whether an enhanced formulation may improve absorption and local bioavailability of Omilancor to the colonic mucosa, and potentially increasing durable efficacy.

LABP-104

LABP-104 is a novel, oral, systemically distributed LANCL2 agonist in development for the once-daily treatment of SLE and/or RA.

- Today, Landos announced that it recently completed a successful Phase 1a clinical trial of LABP-104, which was well-tolerated in healthy volunteers and did not result in any serious adverse events.
- The Phase 1a clinical trial results for LABP-104 support its potential as a treatment for SLE and/or RA, and the Company is evaluating whether future formulations may provide enhanced absorption characteristics to maximize drug effects.

Pre-Clinical Programs

The Company also has four promising, novel pre-clinical programs in its portfolio, including:

- **LABP-66:** A novel NLRX1 agonist in development for the treatment of MS, Alzheimer's Disease, and other debilitating CNS diseases.
 - o As announced in August 2021, Landos entered into a research collaboration with Dr. Peter Calabresi, Director of the Multiple Sclerosis Center and Professor of Neurology at Johns Hopkins University School of Medicine. The research is funded by the National Institute of Health and is focused on further validating the NLRX1 immunometabolic pathway in MS. Since inception, the study has progressed from in vitro analysis of the role of NLRX1 activation in glial cells to mouse studies to validate and expand the initial findings in preclinical models of MS. Dr. Calabresi's team recently presented their data at the National MS Society Tykeson Fellows Conference and the Race to Erase MS Symposium.
 - **LABP-73:** A novel NLRX1 agonist in development for the treatment of Asthma and Chronic Obstructive Pulmonary Disease.
 - **LABP-69:** A novel PLXCD2 agonist in development for the treatment of RA and Diabetic Nephropathy. LABP-69 aims to increase IL-10 secretion and down regulate pro-inflammatory signals and angiogenesis, supporting its potential as a novel therapy for RA and Diabetic Nephropathy.
 - **LABP-111:** A novel LANCL2 agonist in development for the treatment of NASH and Diabetes.
-

Financial Update

Today, Landos also separately announced that it has secured a \$16.7 million investment at market price, from its largest shareholder, Perceptive Advisors. With this additional funding, the Company expects to have sufficient cash, cash equivalents and marketable securities to fund its planned operations into the first half of 2025.

“We believe this successful financing underscores our shareholders’ confidence and excitement in our path forward and the significant value that we expect to deliver as we advance NX-13. We look forward to executing on our strategic plan, leveraging the strength of Landos’ assets to drive value for patients and shareholders alike,” said Mr. Oakes.

Consistent with its enhanced focus, the Company has actively reprioritized Landos’ key initiatives and taken steps to right-size its cost structure. The Company has realized substantial operating cost efficiencies over the past year. As the Company transitions from the clinical conduct and close-out activities of previous trials, to finalizing the design and launch of the new NX-13 trial, Landos expects its cash requirements to remain relatively constant in future periods.

Corporate Update Conference Call

The Company will host a live webcast to provide a comprehensive update on Landos’ clinical development plans at 8:00 AM ET today.

The webcast can be accessed through the Company’s investor relations website at <https://ir.landosbiopharma.com/>, or by dialing 800-225-9448 (Toll Free) or 203-518-9708 (International). For those who cannot listen to the live webcast, a replay will be made available on the Company’s investor relations website.

About Landos Biopharma

Landos Biopharma is a clinical stage biopharmaceutical company focused on the development of first-in-class therapeutics for patients with autoimmune disease. The Company’s mission is to create safer and more effective treatments that address the therapeutic gap in the current treatment paradigm.

Landos has a portfolio of three novel targets anchoring libraries of immunometabolic modulation pathways, including seven potentially first-in-class, once-daily therapies targeting 14 indications in the immunology space. This includes our three clinical stage programs: NX-13 for Ulcerative Colitis and Crohn’s Disease; Omilancor for Ulcerative Colitis, Crohn’s Disease and Eosinophilic Esophagitis; and LABP-104 for Systemic Lupus Erythematosus and Rheumatoid Arthritis

The Company is currently focused on advancing the clinical development of NX-13 in Ulcerative Colitis.

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 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, including the planned Phase 2 trial of NX-13, availability and timing of data from ongoing clinical trials, expectations regarding the reformulation for Omilancor, expectations for regulatory approvals, other matters that could affect the availability or commercial potential of the Company’s product candidates, the Company’s anticipated cash runway, potential partnering opportunities 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.

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Corporate Overview

January 5, 2023



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.

This presentation includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties as well as our own estimates of potential market opportunities. All of the market data used in this prospectus involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such data. Industry publications and third party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information. Our estimates of the potential market opportunities for our product candidates include several key assumptions based on our industry knowledge, industry publications, third-party research and other surveys, which may be based on a small sample size and may fail to accurately reflect market opportunities. While we believe that our internal assumptions are reasonable, no independent source has verified such assumptions.



Landos:
The Next
Immunology
Development
Powerhouse



2017: Founding
Pioneering Drug Discovery
Computational & Immunometabolic Expertise
Academic, Entrepreneurial Culture
Foundational IP Portfolio



**2023: Globally Focused
Clinical-Stage BioPharma**
Innovative Clinical Development
Novel Immunology Pipeline
Strong IP Position
Sufficient Cash to Fund Planned
Operations into first half of 2025

Note: Cash includes cash, cash equivalents and marketable securities

3 Novel target (NLRX1, LANCL2, PLXDC2) libraries of immunometabolic modulation pathways

7 Potentially first-in-class, once-daily, oral therapeutics upstream of multiple canonical inflammatory/regulatory pathways

14 Indications in the immunology space targeted by broadly applicable MOAs



Broad Portfolio of Clinical & Pre-clinical Programs

Three Promising Clinical Stage Programs

- **NX-13:** A novel, oral, gut-selective NLRX1 agonist in development for the treatment of Ulcerative Colitis and Crohn's Disease as a once-daily treatment
- **Omilancor:** A novel, oral LANCL2 agonist in development for the treatment of Ulcerative Colitis, Crohn's Disease, Eosinophilic Esophagitis, Psoriasis, and Atopic Dermatitis as a once-daily treatment
- **LABP 104:** A novel, oral, systemically distributed LANCL2 agonist in development for the treatment of lupus and/or rheumatoid arthritis (RA) as a once-daily treatment

Four High Potential Pre-Clinical Programs

- **LABP-66:** An oral, once-daily, product candidate targeting NLRX1 in development for Multiple Sclerosis and Alzheimer's Disease
- **LABP-73:** An oral, once-daily, product candidate targeting NLRX1 in development for Asthma and COPD
- **LABP-111:** An oral, once-daily, product candidate targeting LANCL2 in development for Type I Diabetes and NASH
- **LABP-69:** An oral, once-daily, product candidate targeting PLXCD2 in development for Rheumatoid Arthritis and Diabetic Nephropathy



**Our Focus: Advancing
NX-13 Clinical
Development in UC**

Broader Portfolio with Significant Optionality for Partnering & Continued Development in the Future



Strategic Review:

Focused on the Most Value-Enhancing Near and Long-Term Opportunities

The Landos management team and Board of Directors conducted an **in-depth review of the Company's pipeline and development plans** to ensure that it is pursuing **the most promising therapies and target indications**



Shifting our focus away from being a discovery-based organization towards becoming an immunology development powerhouse



Pursue the most promising therapies and target indications



Align our resources with pipeline assets that offer the greatest potential impact and value to shareholders and stakeholders



Leverage smart, well-designed clinical trials to advance the strongest programs through clinical development



Landos Strategy: Advancing NX-13 in UC is the Focus

Advancing NX-13 is the Top Priority

- **NX-13** has the potential to be an important new treatment for UC patients
- We believe favorable market dynamics, combined with unique and promising clinical profiles, provide attractive entry point for commercialization

Impressive & Emerging Data Foundation Supports Dual Focus

- **NX-13:** Phase 1b results showed a favorable safety and tolerability profile; promising signals of clinical improvement as soon as two weeks in patients' symptoms and four weeks by endoscopy in exploratory endpoints*

Clear Path Forward Defines Next Steps

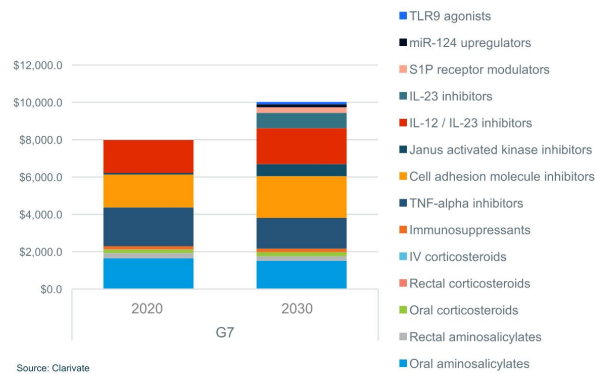
- **NX-13:** Key Phase 2 design principles: Dose-ranging, Blinded, Powered, and Placebo-controlled. On-track to initiate Phase 2 trial in Q2 2023; topline data readout expected by Q4 2024
- Broader Portfolio with Significant Optionality for Partnerships & Continued Development in the Future

*NX-13 Phase 1b study was not designed or powered for exploratory clinical endpoints therefore results are hypothesis-generating only

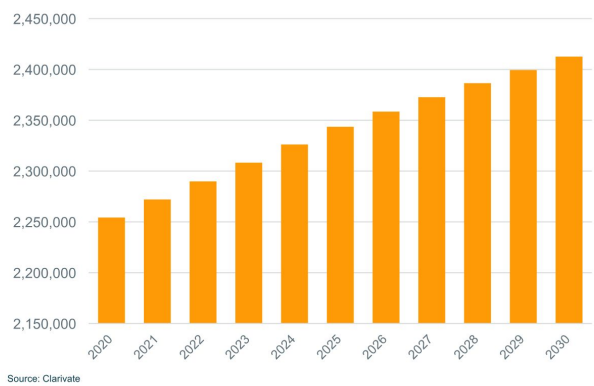


UC is an Attractive & Growing Market Opportunity

Global UC Sales (\$M): 2020 – 2030



Global UC Diagnosed Patients: 2020 – 2030



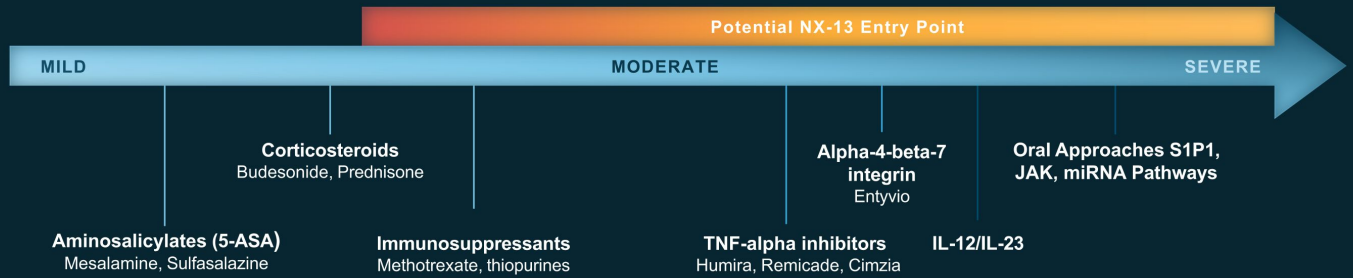
Source: 2022 Decision Resource Group (Clarivate) UC Disease Landscape and Forecast including 2030 projected data



Clear, Sustainable Entry Point for NX-13

Potential benefits that may help to transform the current treatment paradigm:

- Oral, once-daily dosing with comparable efficacy to advanced therapies
- Greater mucosal healing
- Improved efficacy and safety for long-term use





Landos' Path Forward

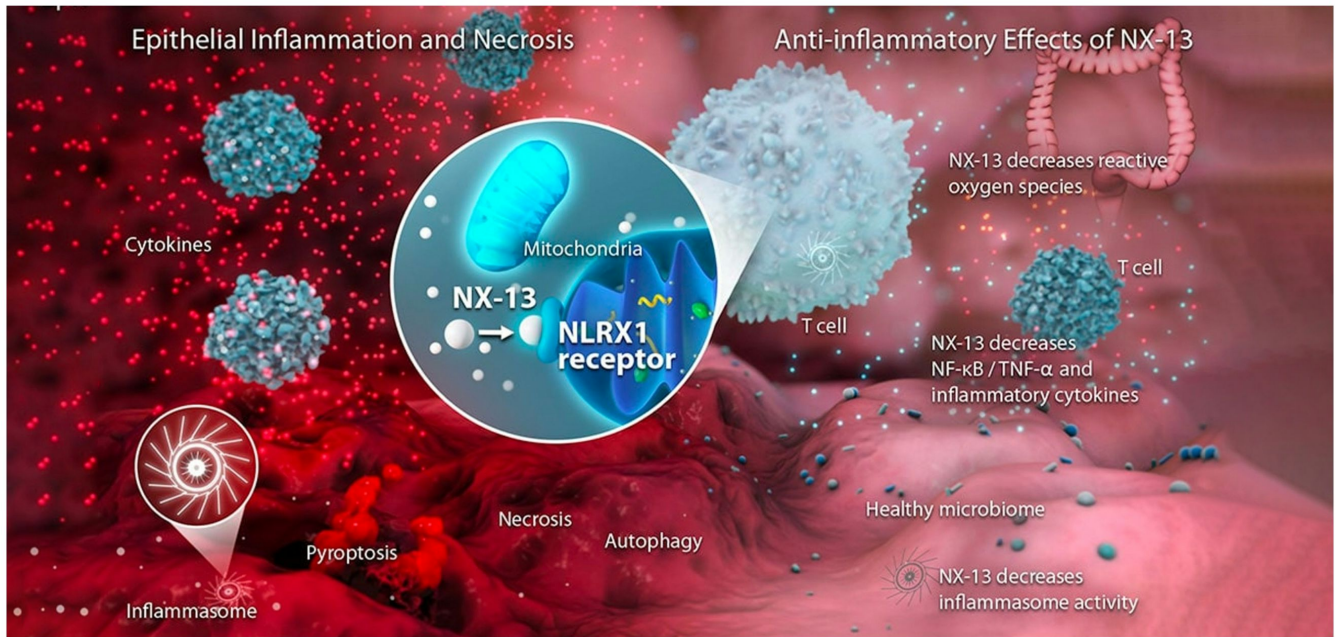
- Strategic focus on NX-13 clinical advancement provides roadmap that aligns with our current resources
 - Phase 2 proof of concept trial for NX-13 on-track to start **Q2 2023**; top-line data expected in **Q4 2024**
- Broader portfolio with significant optionality for partnerships, development, and investment in the future
 - Impressive stable of preclinical programs within 3 novel immunometabolic pathways for broad immunology indications
- Continued collaboration with KOLs, academics and others that are excited about our novel MOA libraries
- Sufficient cash to fund planned operations into first half of 2025*
- Agile approach allows for pivot based on changes to capital resources

*Cash includes cash, cash equivalents and marketable securities



NLRX1 Library

NLRX1 Activation Reduces Inflammatory Cytokines, Cells & Signaling Pathways





- Novel NLRX1 Agonist MOA
 - Designed to decrease reactive oxygen species and oxidative stress; decreases pro-inflammatory signals
- Administration Route
 - Oral, once-daily
- Pharmacokinetics & Safety in clinical trials to date
 - No on-target toxicities associated with NLRX1
 - No observed effects from limited systemic immunomodulation
 - AE incidence similar to placebo

Our Focus: Advancing NX-13 in UC			
Drug	Indication	Distribution	Stage
NX-13	UC	Gut-selective	Ph2
NX-13	CD	Gut-selective	Ph1b/2a
LABP-66	MS	Systemic (CNS)	PreClinical
LABP-66	Alz.D	Systemic (CNS)	PreClinical
LABP-73	Asthma	Systemic	PreClinical
LABP-73	COPD	Systemic	PreClinical
Significant Optionality for Partnering & Continued Development in the Future			



NLRX1 GI Anti-Inflammatory: NX-13 Profile



Mechanism of Action

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

Bimodal MOA aims to decrease reactive oxygen species and oxidative stress, while decreasing pro-inflammatory signals



Drug Profile

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

In development for Ulcerative Colitis & Crohn's Disease



Recent & Upcoming Milestones

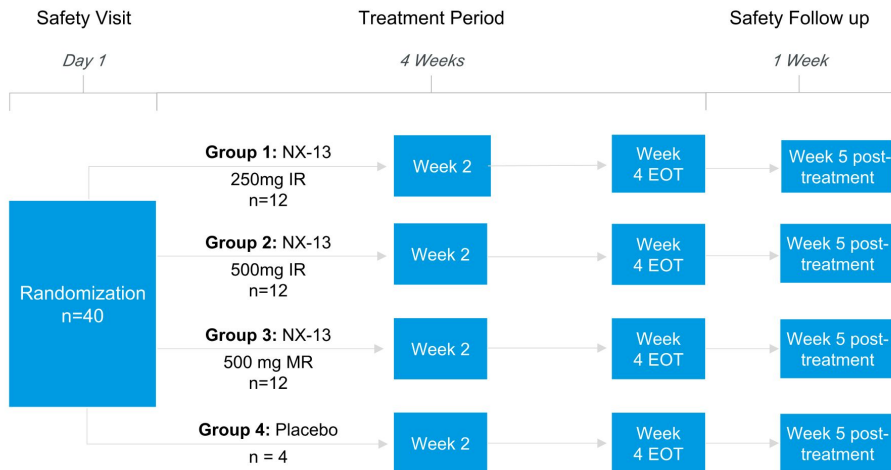
Recently completed successful Phase 1b trial

Finalizing design of Phase 2 proof-of-concept trial

Note: Advancing NX-13 in UC is the Company's current focus and top priority



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



IR = Immediate Release; MR = Modified Release

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



PRIMARY ENDPOINTS

Evaluate safety and pharmacokinetics of multiple dose levels



INCLUSION

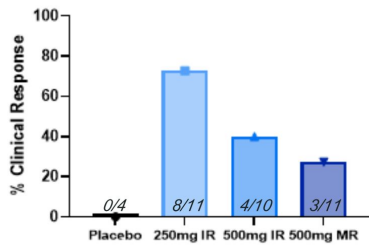
Total Mayo 4-10; MES 2-3;
FCP>250



NX-13 Treated Patients Experienced Reductions in Multiple Clinical Measures after 4 weeks

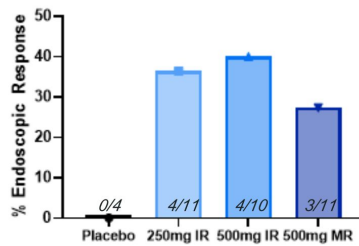
Clinical Response

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



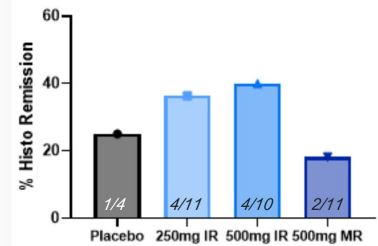
Endoscopic Response

MES CFB of at least -1



Histologic Remission

Geboes <3.1, no increased neutrophils in the LP



Patients receiving NX-13 IR doses responded best:

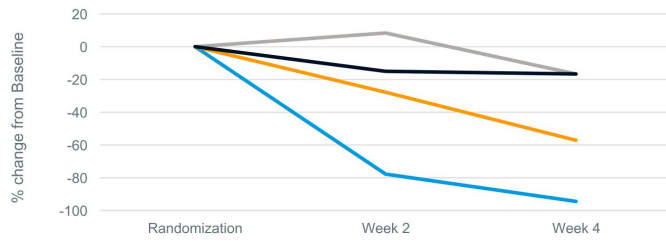
- 72% (8/11) of the 250mg group achieved clinical response; 40% of the 500mg IR group was in clinical remission
- 36-40% endoscopic response after just 4 weeks of treatment across IR dosage groups
- 36-40% of patients receiving IR achieved histologic remission after 4 weeks of treatment
 - Placebo patient started trial with Geboes <3.1

IR= Immediate Release; MR= modified release designed to dissolve at the terminal ileum

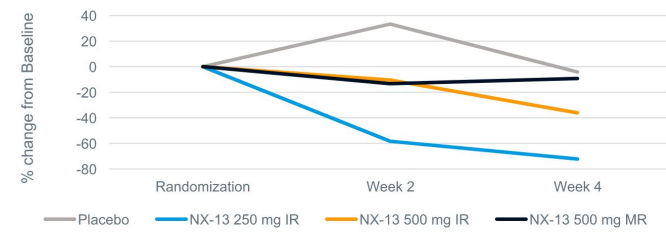
Note: Study was not designed or powered for exploratory clinical endpoints therefore results are hypothesis-generating only

NX-13 Supported **Symptomatic Remission** in Rectal Bleeding & Stool Frequency

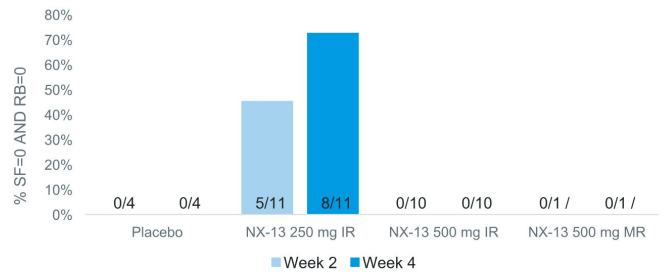
Rectal Bleeding Change from Baseline



Stool Frequency Change from Baseline



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

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



NX-13 was Well-Tolerated & Shows Promising Signs of Clinical Improvement in Active UC



Safety

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, once daily treatment induced:

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

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



What's Next: Study Design for NX-13 Phase 2 Proof of Concept Trial

OUR GOAL | Generate as much meaningful data as possible — as quickly as possible — to build on our already impressive data foundation.

TIMING | On-track to initiate Phase 2 trial in Q2 2023; Expecting to report topline data by Q4 2024

Key Design Principles:



Blinded



Powered



Placebo Controlled



Dose-Ranging



Preclinical Programs in the NLRX1 Agonist Library

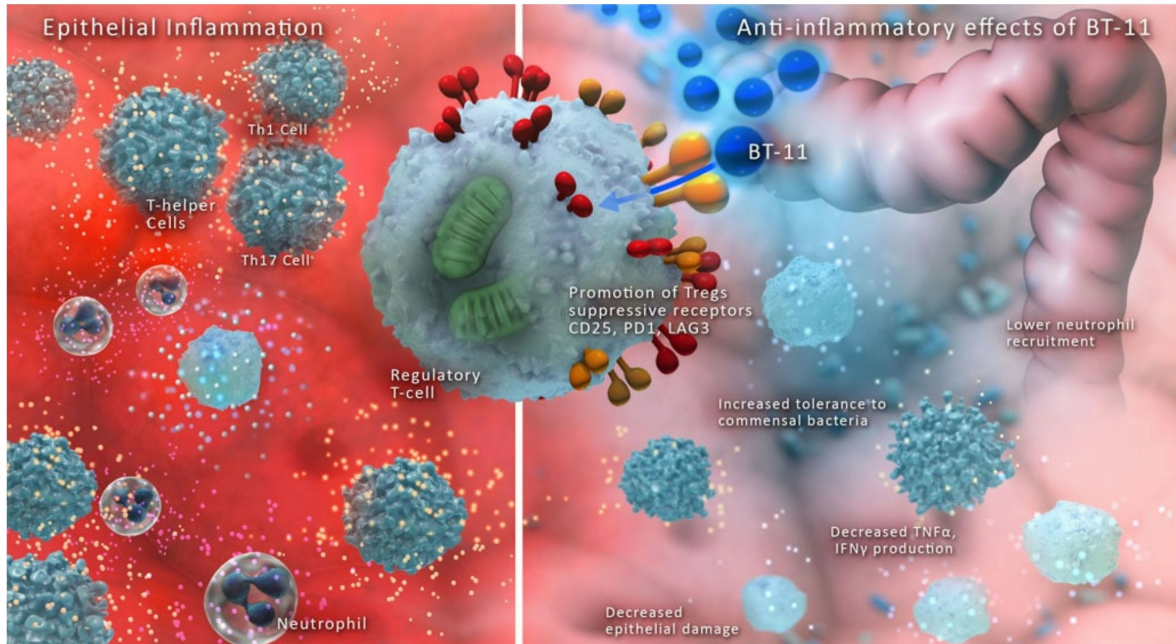
	LABP-73 for Respiratory Inflammation	LABP-66 for CNS Inflammation
Key Indications	Asthma, COPD	MS, AlzD
Administration	Oral, once-daily	Oral, once-daily
Development Stage	Preclinical Development	Preclinical Development
Additional Information	MOA supported by efficacy in 3 respiratory inflammation mouse models Systemic PK profile established	MOA supported by efficacy in 2 MS mouse models

Note: Advancing NX-13 in UC is the Company's current focus and top priority
COPD: Chronic Obstructive Pulmonary Disease; MS: Multiple Sclerosis; AlzD: Alzheimer's Disease



LANCL2 Library

LANCL2 Activity Exerts Anti-Inflammatory Effects within GI Tract





- Novel LANCL2 Agonist MOA
 - Downregulation of pro-inflammatory signals
 - Increase in T regs and anti-inflammatory signals
- Administration Route
 - Oral, once-daily
- Pharmacokinetics & Safety in clinical trials to date
 - No on-target toxicities associated with LANCL2
 - No observed effects of immunosuppression
 - AE incidence similar to placebo

Note: EoE - Eosinophilic Esophagitis; ODD - Orphan Drug Designation

Our Focus: Advancing NX-13 in UC			
Drug	Indication	Distribution	Stage
Omilancor	UC	Gut-restrictive	Ph2
Omilancor	CD	Gut-restrictive	Ph2
Omilancor	EoE	Gut-restrictive	ODD-enabling
Omilancor	Psoriasis	Topical	PreClinical
Omilancor	A.Derm	Topical	PreClinical
LABP-104	SLE	Systemic	Ph1b/2a
LABP-104	RA	Systemic	Ph1b/2a
LABP-111	NASH	Systemic	PreClinical
LABP-111	T1 Diabetes	Systemic	PreClinical
Significant Optionality for Partnering & Continued Development in the Future			



LANCL2 Oral GI Anti-Inflammatory: Omilancor Profile



Mechanism of Action

Targets LANCL2 pathway, a G-coupled protein receptor on the cell surface

Bimodal MOA aims to stabilize regulatory T cell activity while down-regulating proinflammatory cytokine expression



Drug Profile

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

In development for Ulcerative Colitis, Crohn's Disease, EoE



Recent Milestones

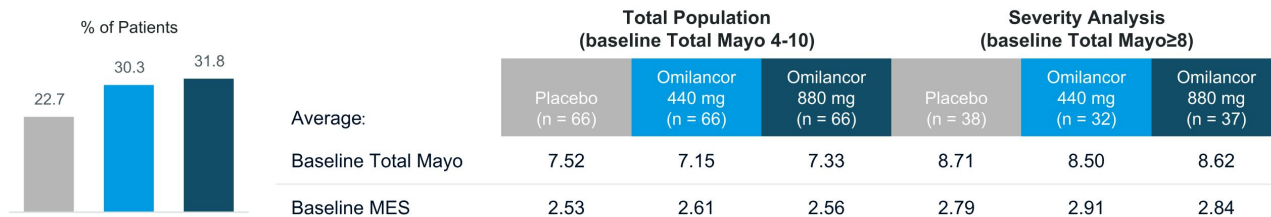
Completed Phase 2 trial* showing better results in moderate-to-severe UC population in a prespecified disease severity analysis

*Higher than expected placebo remission rates in the study population led to Omilancor not reaching statistical significance in the induction phase

Note: Advancing NX-13 in UC is the Company's current focus and top priority



Total Population Clinical Remission

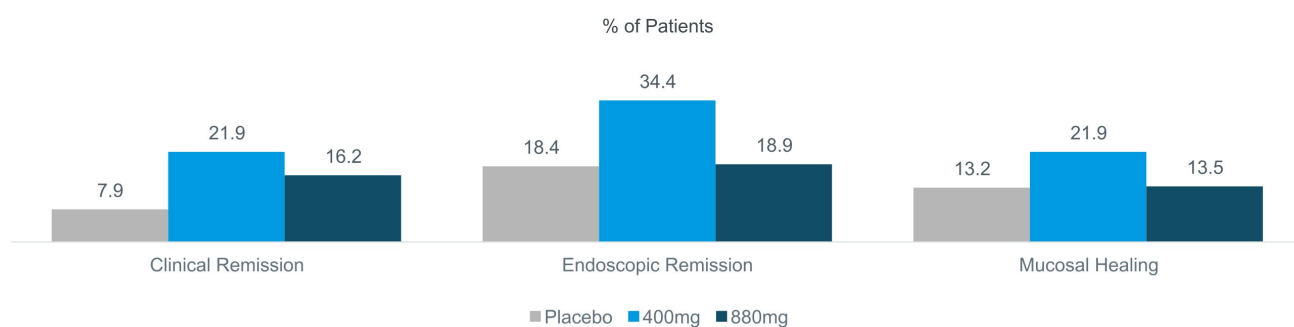


Omilancor was highly active and induced high levels (>30%) of clinical remission*

- Higher than expected placebo remission rates led to omilancor not achieving statistical significance during the induction phase
- Statistical Analysis Plan prescribed a severity sub-analysis of patients with baseline Total Mayo Score in the upper half of the study range (baseline total mayo ≥ median value)
 - Baseline Total Mayo and MES were similar across the 3 dose groups in both the whole population and the more severe subgroup

*Clinical Remission defines as Mayo Score less than or equal to 2, with no subscore above 1

Omilancor was Active in a More Severe UC population (Total Mayo ≥ 8)



Prespecified Severity Analysis:
In a more severe population,
low dose (440mg) Omilancor
produced high rates in the
induction phase of (>20%) of:

- Clinical remission* (Delta 14 versus placebo)
- Endoscopic remission* (Delta 16 versus placebo)
- Mucosal Healing* (Delta 8.7 versus placebo)

*Clinical Remission defines as Mayo Score less than or equal to 2, with no subscore above 1; endoscopic remission MES \leq 1; Mucosal healing MES \leq 1, Geboes \leq 3.1



Omilancor GI Summary & Next Steps

What we learned in the phase 2 trial:

- Omilancor was highly active and induced high levels (>20%) of both clinical and endoscopic remission, including mucosal healing, in a more severe population
- LANCL2 was successfully targeted and upregulated upon treatment with Omilancor, balancing the immune response
- Tissue Concentrations of Omilancor are correlated with disease remission

What we still need to determine:

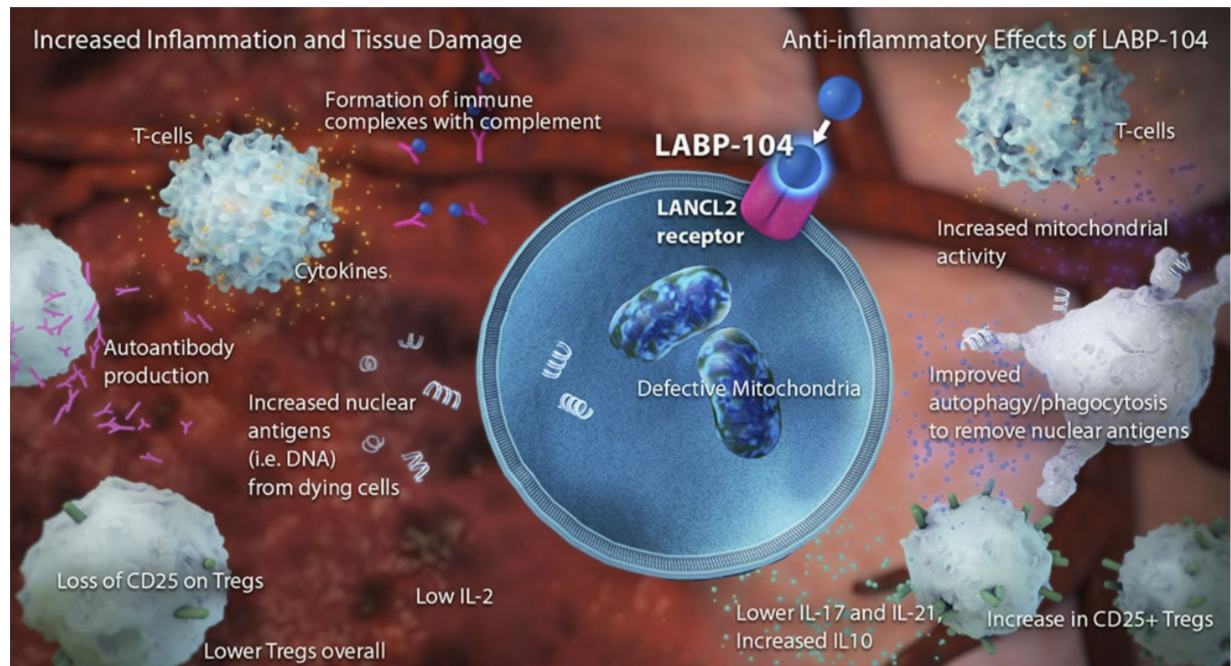
- Formulation optimization to increase reliable absorption in order to improve tissue concentrations and clinical response

WHAT'S NEXT

Continue to Assess Reformulation to Improve Efficacy & Replicability of Response

Note: Advancing NX-13 in UC is the Company's current focus and top priority

Systemic LANCL2 Activation Aims to Enhance Tolerability & Restore Homeostasis in Immune Cells





LANCL2 Oral Systemic Anti-Inflammatory: LABP-104 Profile



Mechanism of Action

Targets LANCL2 pathway, a G-coupled protein receptor on the cell surface



Drug Profile

Orally active with systemic distribution, allowing broad target engagement

In development for Systemic Lupus Erythematosus (SLE) & Rheumatoid Arthritis (RA)



Recent & Upcoming Milestones

Favorable safety and tolerability in Phase 1a trial (No AE clusters or trends)

PK and absorption profile indicated systemic exposure

Assess formulation enhancement and plan long-term toxicology studies

Note: Advancing NX-13 in UC is the Company's current focus and top priority



Preclinical Programs in the LANCL2 Agonist Library

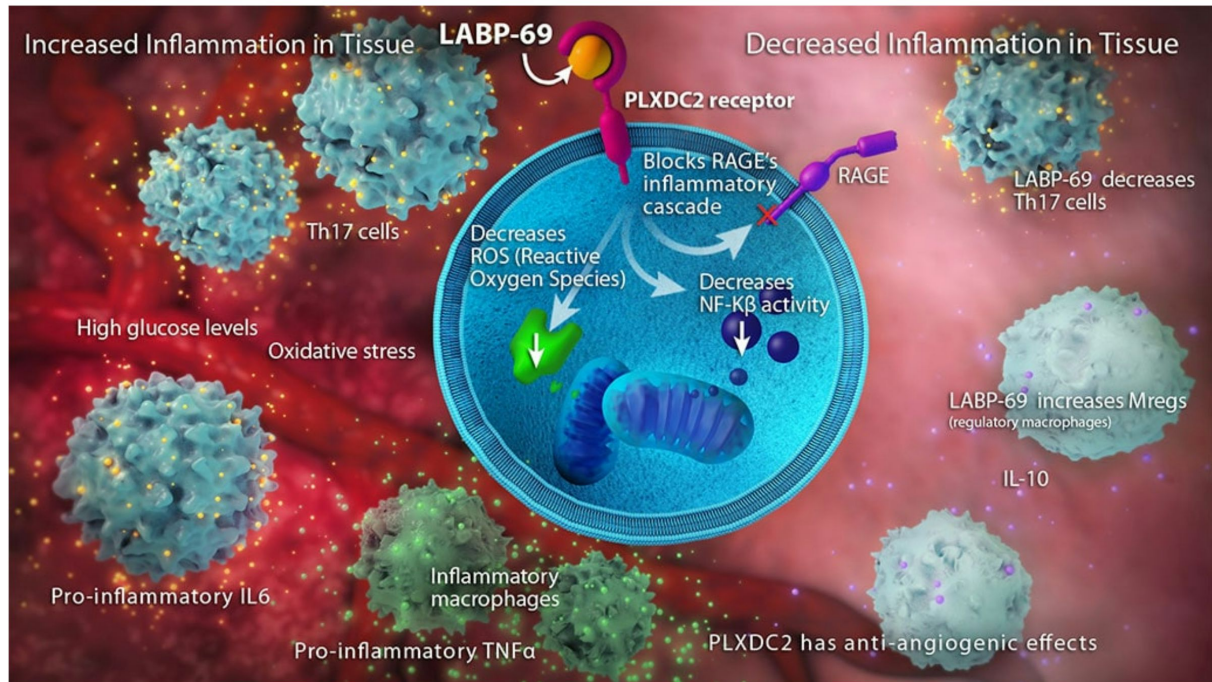
	TOPICAL OMILANCOR for Dermatological Inflammation	LABP-111 for Metabolic Inflammation
Key Indications	PsO, A.Derm	NASH, T1D
Administration	Topical, once-daily	Oral, once-daily
Development Stage	Preclinical Development	Preclinical Development
Additional Information	MOA supported by efficacy in 2 PsO mouse models Topical PK profile with no systemic exposure 12-week dermal toxicology complete	MOA supported by efficacy in 2 NASH mouse models

Note: Advancing NX-13 in UC is the Company's current focus and top priority
PsO: Psoriasis, A.Derm: Atopic Dermatitis, NASH: Non-Alcoholic Steatohepatitis, T1D: Type 1 Diabetes



PLXDC2 Family

Activation of PLXDC2 in Immune & Non-Immune Cells Suppresses Inflammation & Angiogenesis





PLXDC2 Anti-Inflammatory: LABP-69 Profile

Novel PLXDC2 Agonist MOA



- Designed to decrease reactive oxygen species, oxidative stress, pro-inflammatory signals & angiogenesis

Key Indications



- Rheumatoid Arthritis
- Diabetic Nephropathy

Ongoing Preclinical Development



- MOA: Evidence in 2 RA rodent models
- Next Step:
 - IND-enabling toxicology

Administration Route



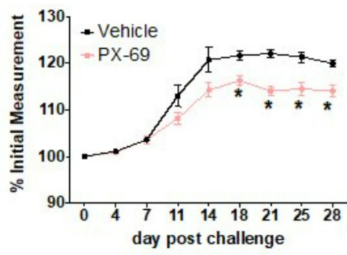
- Oral, once-daily

Note: Advancing NX-13 in UC is the Company's current focus and top priority

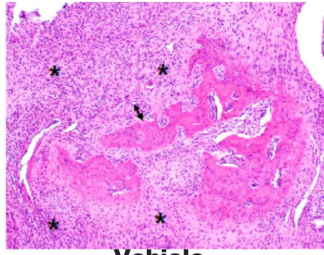


LABP-69 Reduced Disease Severity In Rat Model Of Rheumatoid Arthritis

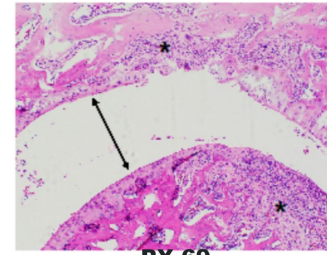
Hind Paw Size



Histologic Disease Severity



Vehicle



PX-69

Oral LABP-69 treatment resulted in:

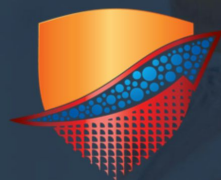
- Decreased paw swelling as an indication of inflammation within the joint
- Reduced histologic cartilage damage, disorganization, and pannus formation within the ankle joint
- Reduced immune cell infiltration of the ankle joint
- Maintenance of joint space



Landos' Path Forward

- Strategic focus on NX-13 clinical advancement provides roadmap that aligns with our current resources
 - Phase 2 proof of concept trial for NX-13 on-track to start **Q2 2023**; top-line data expected in **Q4 2024**
- Broader portfolio with significant optionality for partnerships, development, and investment in the future
 - Impressive stable of preclinical programs within 3 novel immunometabolic pathways for broad immunology indications
- Continued collaboration with KOLs, academics and others that are excited about our novel MOA libraries
- Sufficient cash to fund planned operations into first half of 2025*
- Agile approach allows for pivot based on changes to capital resources

*Cash includes cash, cash equivalents and marketable securities



LANDOS
BIOPHARMA