

**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: September 13, 2021
(Date of earliest event reported)

COHBAR, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-38326
(Commission
File Number)

26-129952
(I.R.S. Employer
Identification No.)

1455 Adams Drive, Suite 2050
Menlo Park, CA 94025
(Address of principal executive offices and zip code)

(650) 446-7888
(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 (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(b) under the Exchange Act (17 CFR 240.14a-12(b))
- 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	CWBR	Nasdaq Capital 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.

COHBAR, INC.

FORM 8-K

Item 8.01 Other Events.

On September 13, 2021, CohBar, Inc. has prepared investor presentation materials with information about the Company, which it intends to use as part of investor presentations. A copy of the investor presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibits are furnished herewith and this list is intended to constitute the exhibit index:

99.1	CohBar, Inc. presentation dated September 13, 2021.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

Signature

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.

COHBAR, INC.
(Registrant)

September 13, 2021
(Date)

By: /s/ Jeffrey F. Biunno
Jeffrey F. Biunno
Chief Financial Officer



Breakthrough Mitochondrial Science

A Source for Novel Therapeutics

HCW Conference

September 2021

Forward Looking Statements

This presentation contains forward-looking statements which are not historical facts within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are based only on our current beliefs, expectations and assumptions regarding the future of our business, future plans and strategies, projections, anticipated events and other future conditions. In some cases you can identify these statements by forward-looking words such as "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "could," "should," "would," "project," "plan," "expect," "goal," "seek," "future," "likely" or the negative or plural of these words or similar expressions. Examples of such forward-looking statements include but are not limited to statements regarding our cash forecasts; anticipated outcomes of research and clinical trials for our mitochondria based therapeutic (MBT) candidates; expectations regarding the timing of delivery of data, and the anticipated timing and progression of our lead candidate, CB4211, and our other programs; expectations regarding the growth of MBTs as a significant future class of drug products; and statements regarding anticipated therapeutic properties and potential of our mitochondrial peptide analogs and MBTs, including but not limited to the treatment of COVID-19 ARDS. You are cautioned that such statements are not guarantees of future performance and that actual results or developments may differ materially from those set forth in these forward-looking statements. Factors that could cause actual results to differ materially from these forward-looking statements include: our ability to successfully advance drug discovery and development programs, including the delay or termination of ongoing clinical trials; receipt of unfavorable feedback from regulators regarding the safety or tolerability of CB4211 or the possibility of other developments affecting the viability of CB4211 as a clinical candidate or its commercial potential; results that are different from earlier data results including less favorable than and that may not support further clinical development; our ability to raise additional capital when necessary to continue our operations; our ability to recruit and retain key management and scientific personnel; risks related to the impact on our business of the COVID-19 pandemic or similar public health crises; and our ability to establish and maintain partnerships with corporate and industry partners. Additional assumptions, risks and uncertainties are described in detail in our registration statements, reports and other filings with the Securities and Exchange Commission and applicable Canadian securities regulators, which are available on our website, and at www.sec.gov or www.sedar.com.

You are cautioned that such statements are not guarantees of future performance and that our actual results may differ materially from those set forth in the forward-looking statements. The forward-looking statements and other information contained in this presentation is made as of the date hereof and CohBar does not undertake any obligation to update publicly or revise any forward-looking statements or information, whether as a result of new information, future events or otherwise, unless so required by applicable securities laws. Nothing herein shall constitute an offer to sell or the solicitation of an offer to buy any securities.

CohBar Opportunity

Leader in developing mitochondria based therapeutics

- Novel approach leveraging over a billion years of evolution

Recent clinical milestone

- Positive CB4211 Phase 1a/1b topline data for lead candidate under development for NASH and obesity

Near-term milestone

- IND for CB5138-3 for the potential treatment of Idiopathic Pulmonary Fibrosis (IPF) in 2022

Pipeline targeting chronic diseases














- Initial focus on inflammatory and fibrotic conditions

Comprehensive IP strategy based on first mover advantage

- 13 issued patents; >65 patent filings

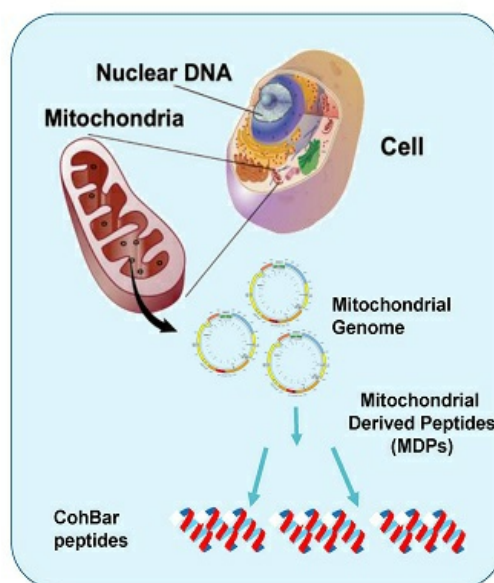


Experienced Team: Successful track record of drug discovery, development and partnerships

Management	Prior Experience	
Joseph Sarret, MD, JD  President & Chief Executive Officer	15+ years of leadership experience with public/private life sciences companies Held several executive management roles at companies ranging from early- to clinical-stage development and initial commercialization. Led multiple partnership and M&A transactions.	   
Kenneth Cundy, PhD.  Chief Scientific Officer	30+ years of drug discovery and development experience Development of 15 drugs with \$100B+ in sales including Hepsera®, Tamiflu®, Viread® and Horizant®. Extensive FDA interactions across 15 INDs and 6 NDAs. Inventor on 47 issued US patents.	  
Jeffrey Biunno, CPA, MBA  Chief Financial Officer, Secretary & Treasurer	30+ years of financial experience Public, small, medium and large-cap companies Participated in three sales transactions	  

CohBar is the leader in developing a new class of peptides: Mitochondria based therapeutics

- **Key insights by CohBar’s founders**
 - Peptide sequences are encoded in the mitochondrial genome
 - Certain peptides regulate multiple organs and systems in the body
- **Published studies demonstrate broad effects in animals**
 - Certain MDPs improve metabolism, reduce tumor growth, impact longevity, etc.
- **Analogous of naturally occurring peptides**
 - Expect improved safety profile
- **CohBar Technology Platform**
 - Identified over 100 peptides and over 1,000 analogs



Pipeline

MBT Programs	Potential Indications	Preclinical	IND Enabling Activities	Phase 1a	Phase 1b
Clinical					
CB4211	NASH				
	Obesity				
Preclinical					
CB5138-3	IPF, Fibrotic Diseases				
Apelin Agonists	ARDS, COVID-19 ARDS				
CXCR4 Inhibitors	Cancer, Other Diseases				
Immunotherapy Peptides	Cancer Immunotherapy				

Targeting opportunities with high unmet need

• NASH and Obesity

- US prevalence of NASH increasing – projected to be 27M by 2030¹
- Global NASH market size estimated to exceed \$50B by 2027²
- No approved treatment for NASH
- Obesity impacts approximately one third of US adults

• IPF and other fibrotic diseases

- Fibrotic diseases of liver, kidney, lungs, heart, etc. account for 45% of all cause mortality³
- Current IPF therapies not well tolerated: nausea, vomiting, diarrhea, skin problems

• Acute Respiratory Distress Syndrome (ARDS)

- Impacts > 2 million patients worldwide, with mortality 30 – 35%⁴
- No currently approved treatments – care is primarily supportive

• CXCR4 inhibitors

- CXCR4 receptor overexpressed in more than 75% of cancers⁵

¹Estes et. al. 2018

²<https://www.reportsanddata.com/report-detail/non-alcoholic-steatohepatitis-nash-market>

³Wynn 2004

⁴<https://www.thoracic.org/patients/lung-disease-week/2011/ards-week/general-info.php>

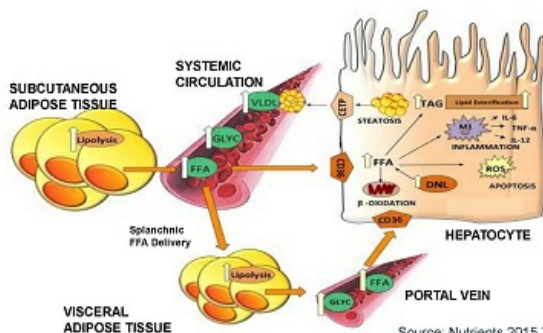
⁵Dubrovskaya et. al. 2012

CB4211: Novel Mechanism of Action Relevant to NASH

Targeting Free Fatty Acid Release from Fat Cells

Inhibition/Regulation of Lipolysis

- NALFD: excess free fatty acid released from abdominal fat cells by lipolysis - flows directly to the liver
- Excess fatty acid in liver leads to NASH: liver fat deposits, inflammation, fibrosis, cirrhosis, and ultimately liver cancer
- Inhibiting lipolysis reduces fatty acid release



Source: Nutrients 2015,7, 9453–9474

Molecular Mechanism – Enhances Insulin Signaling

Regulation of Insulin Signaling

- Insulin receptor and insulin signaling play a central role in metabolic regulation
- CB4211 enhances the action of insulin in vitro:
 - Inhibits lipolysis in fat cells (adipocytes)
 - Decreases free fatty acid release to liver
 - Decreases glucose production by liver cells
 - Increases glucose consumption by muscle cells.
- Molecular mechanism of action presented at ADA in June 2018: *CB4211 is a Potential Treatment for Metabolic Diseases with Novel Mechanism of Action: Sensitization of the Insulin Receptor*
- Further evidence that some MDP's are important regulators of key metabolic pathways in the body

CB4211 Phase 1a: Study Design and Subject Disposition

Phase 1a Study Design

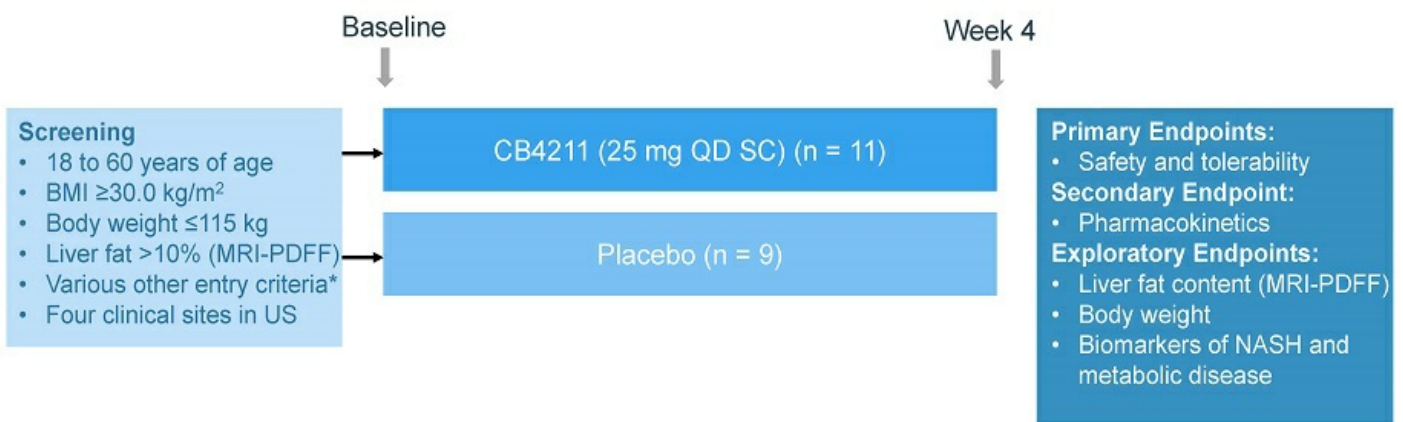
- Randomized, double-blind, placebo-controlled study
- 6 cohorts of Single Ascending Dose (SAD) and 3 cohorts Multiple (7-day) Ascending Dose (MAD)
- Healthy adult volunteers (up to 8 per cohort) randomized (3:1) to CB4211 versus placebo

Phase 1a Subject Disposition

- 65 healthy subjects enrolled and randomized to CB4211 or placebo
- Initially enrolled four single ascending dose (SAD) and one multiple ascending dose (MAD) cohort
- Persistent local deposition of drug at injection site led to interruption of study to modify formulation
- Additional cohorts (two SAD and two MAD) completed with modified formulation
- No subjects discontinued treatment

CB4211 Phase 1b: Study Design

Randomized, Double-blind, Placebo-controlled Study



Subjects were confined for the duration of the study and provided a standardized diet based on baseline energy expenditure

*Inclusion criteria also included history of Fatty Liver Index (FLI) score >60 , FLI score >60 at Screening, or documented history of fatty liver with imaging results (eg, standard positive ultrasound or Fibroscan controlled attenuation parameter (CAP) >300 decibels (dB)/m) indicating liver fat $>10\%$ within 6 months of Screening. For further details see Clinicaltrials.gov record NCT03998514.

Phase 1b Results: Changes in Key PD Biomarkers (Day 28)

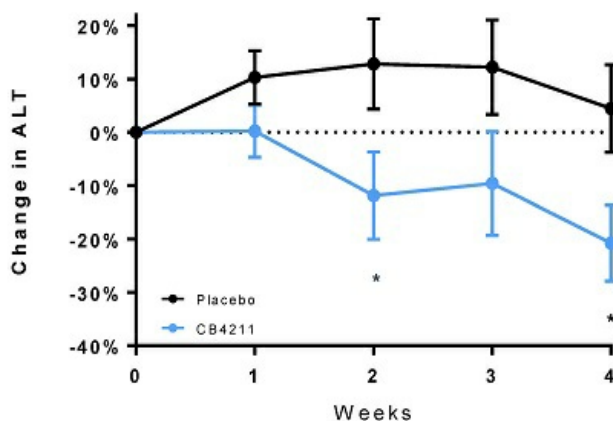
Biomarker	CB4211 (25 mg) (n = 11)	Placebo (n = 9)	Difference from Placebo
ALT (% reduction from baseline)	-21%	4%	-25%*
Proportion of subjects with >17 U/L decrease in ALT ⁽¹⁾	27%	11%	16%
AST (% reduction from baseline)	-28%	-11%	-17%*
Glucose (% reduction from baseline)	-6%	0%	-6%*

*Statistically significant difference, $p < 0.05$ vs. placebo. Data are least square means.

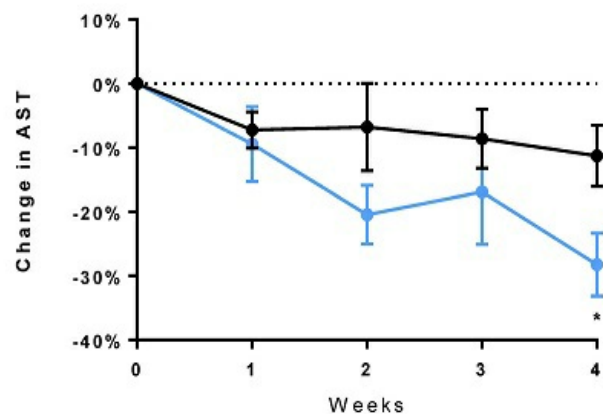
(1) A decrease in ALT by 17 U/L or more is significantly associated with histologic response in NASH. (Loomba R et al. Gastroenterology 2019,156:88-95)

Phase 1b Results: CB4211 Significantly Reduced ALT and AST

Percent Change from Baseline in ALT



Percent Change from Baseline in AST



CB4211 reduced ALT by 21% and AST by 28% at Week 4

*Statistically significant, $p < 0.05$ vs. placebo

Data are mean +/- SEM

Phase 1b Results: Comparison to Historical ALT Data for 4-Week Studies⁽¹⁾

Parameter	CB4211 (CohBar) (25 mg) (SC injection)	MET409 (Metacrine) (50 mg) (oral)	DUR-928 (Durect) (300 mg) (IV injection)	CRV43 (Hepion) (225 mg) (oral)	Currently in Phase 3		
					Ocaliva (Intercept) (50 mg) (oral)	Resmetirom (Madrigal) (100 mg) (oral)	Semaglutide (Novo- Nordisk) (0.4 mg) ⁽²⁾ (SC injection)
# of Subjects	11	10	20	15	21	25	102
% Reduction in ALT at Week 4	-21.0%	-16.5	-17%	-21.1%	Increased at Week 6	-21% at Week 12	-13% at Week 4 of 52 Weeks
Placebo Adjusted % Reduction in ALT	-25%	No placebo arm	No placebo arm	-15.0%	N/A	-13.3% at Week 12	-13% at Week 4 of 52 Weeks

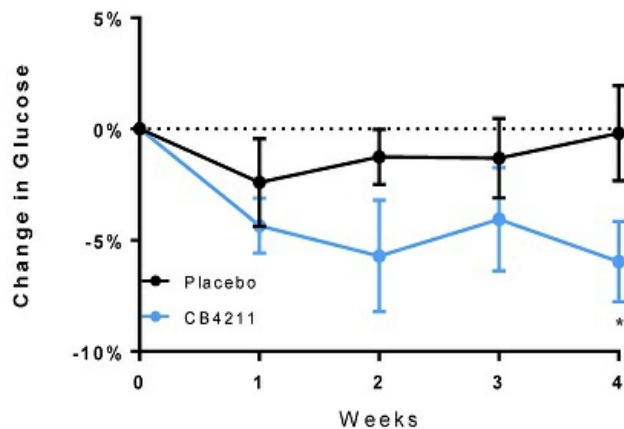
CB4211 reduced ALT as much or more than other NASH candidates

(1) All data regarding third-party studies on this slide are based on public information from third-party studies in different stages of development, and not our own. Conclusions on this slide are not based on head-to-head results.

(2) Data extracted from reports for Week 4 time point in a 52-week study.

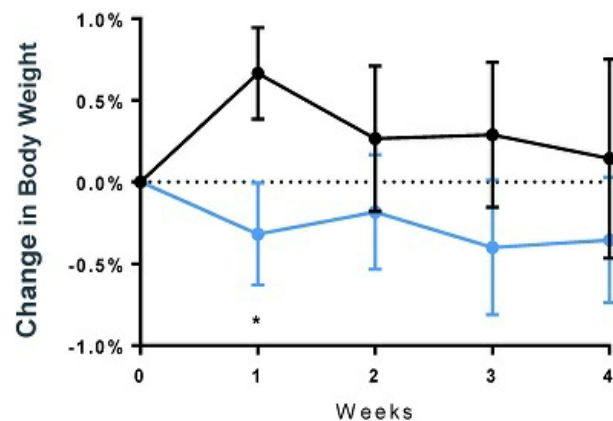
Phase 1b Results: CB4211 Reduced Fasting Glucose Levels

Percent Change from Baseline in Glucose



CB4211 reduced fasting glucose by 6% at Week 4

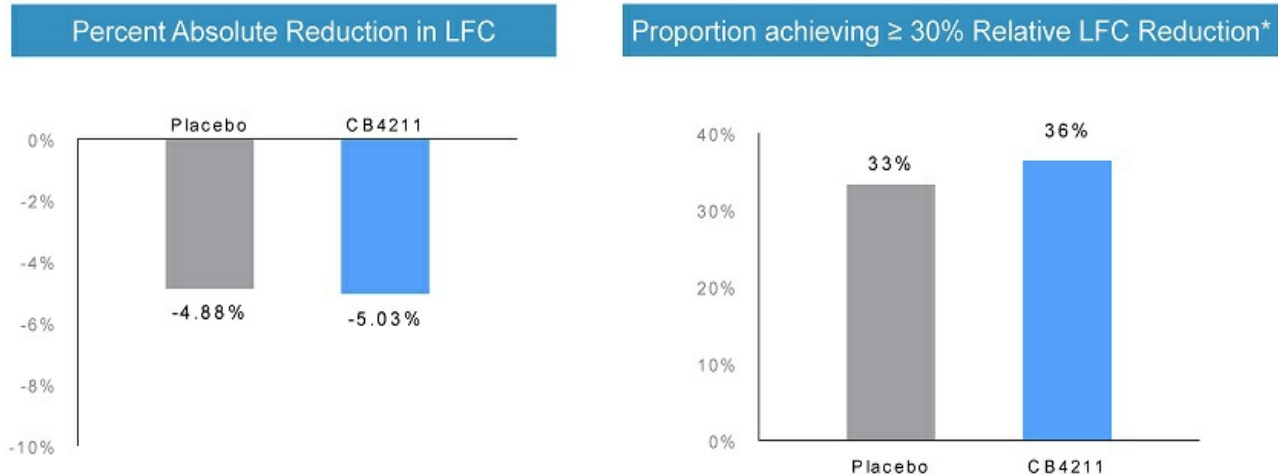
Percent Change from Baseline in Body Weight



CB4211 showed trend to reduced body weight

Data are mean +/- SEM. *Statistically significant, p<0.05 vs. placebo.

Phase 1b Results: Change from Baseline in Liver Fat Content (MRI-PDFF)



Reduction in absolute LFC at Week 4 for CB4211 was comparable to other NASH candidates. However, liver fat content was also reduced in placebo arm - possibly the result of confinement for 4 weeks on a controlled diet

*A relative reduction of 30% in liver fat is associated with a histological response in non-alcoholic steatohepatitis (Patel J et al. Therap Adv Gastroenterol 2016, 9(5): 692-701)

Phase 1a/1b Topline Safety Data: Positive Primary Outcome

Positive Results for Primary Outcome: Safety and Tolerability

- CB4211 was well-tolerated and appeared safe with no serious adverse events
- All adverse events were transient and generally mild to moderate
- AEs occurring in $>10\%$ of subjects treated with CB4211:
 - Injection site reactions: CB4211 (79%) vs Placebo (33%)

Secondary Outcome: Pharmacokinetics – Data pending

Phase 1b Topline Activity Data: Positive Exploratory Outcomes

Positive Results from Exploratory Trend Analysis at 4 Weeks

- Robust and significant reductions in ALT, AST versus placebo
- ALT reduction favorable vs other NASH candidates in 4-week studies
- ALT reduction predictive of potential benefit in NASH resolution
- Significant reduction in glucose – suggests improvement in metabolic homeostasis
- Trend towards lower body weight – corroborating the preclinical results
- Liver fat content was reduced substantially in both active and placebo arms
- Additional analysis of biomarker data is planned

These positive topline data support the further development of CB4211 for NASH

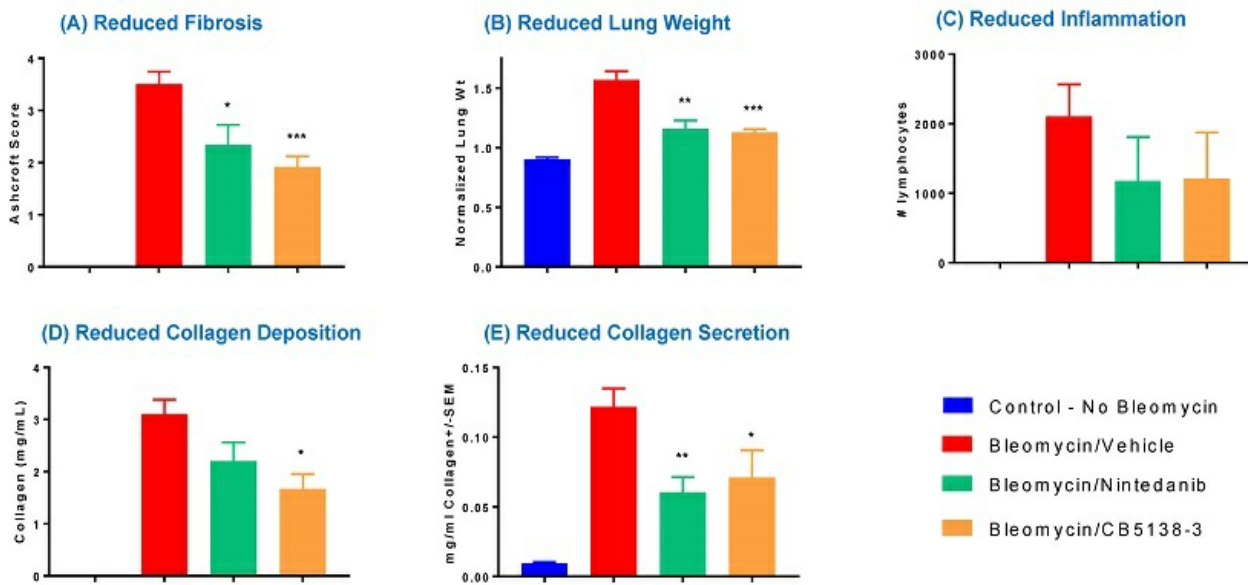
CB4211: Next Steps

- Continue to analyze data from Phase 1a / 1b trial
- Plan to present additional data from this study at an upcoming scientific meeting
- Continue ongoing work to optimize formulation towards commercial form
- Complete necessary steps to move to Phase 2 (e.g., manufacturing, toxicology studies, etc.)
- Obtain input from KOL's and disease area experts on most appropriate clinical path forward
- Design future 12- or 16-week Phase 2a study based on the Phase 1b trial results

CB5138-3: IPF and other fibrotic diseases

- **Demonstrated antifibrotic effects in cultured human cells**
 - Decreased expression of fibrosis biomarkers in co-cultures of lung cells and fibroblasts
 - Inhibit pathological fibrotic process of conversion of fibroblasts to myofibroblasts *in vitro*
- **Anti-fibrotic and anti-inflammatory effects shown in animal models of IPF**
 - Decreased Ashcroft fibrosis score and lymphocytes in lung fluid after 21 days in prophylactic model
 - Demonstrated positive effects on all study outcomes in therapeutic mouse model – number of these effects were greater than the effects seen with nintedanib
- **Initiated IND-enabling studies for CB5138-3 in IPF** – potential First-in-Human study in 2022
- **Exploring potential utility in other fibrotic diseases** using additional animal models

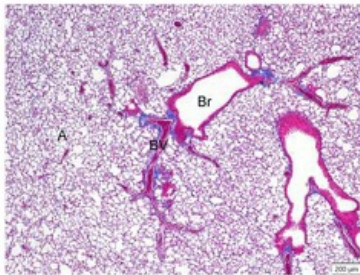
CB5138-3 Showed Efficacy as Monotherapy in Mouse Therapeutic Model of IPF



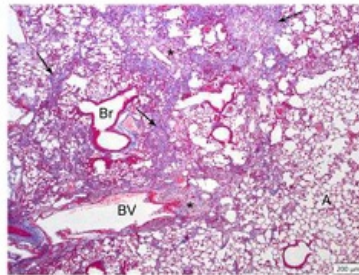
Source: Cundy et al. Poster A2261; American Thoracic Society Meeting, August 5-10, 2020.

CB5138-3 Efficacy in Mouse Therapeutic model of IPF

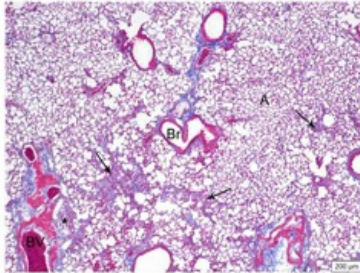
Control – No Bleomycin



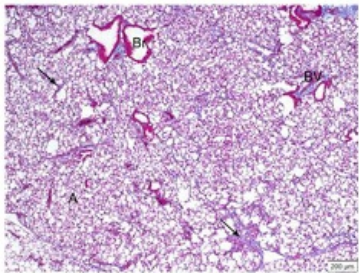
Bleomycin + Vehicle



Bleomycin + Nintedanib



Bleomycin + CB5138-3



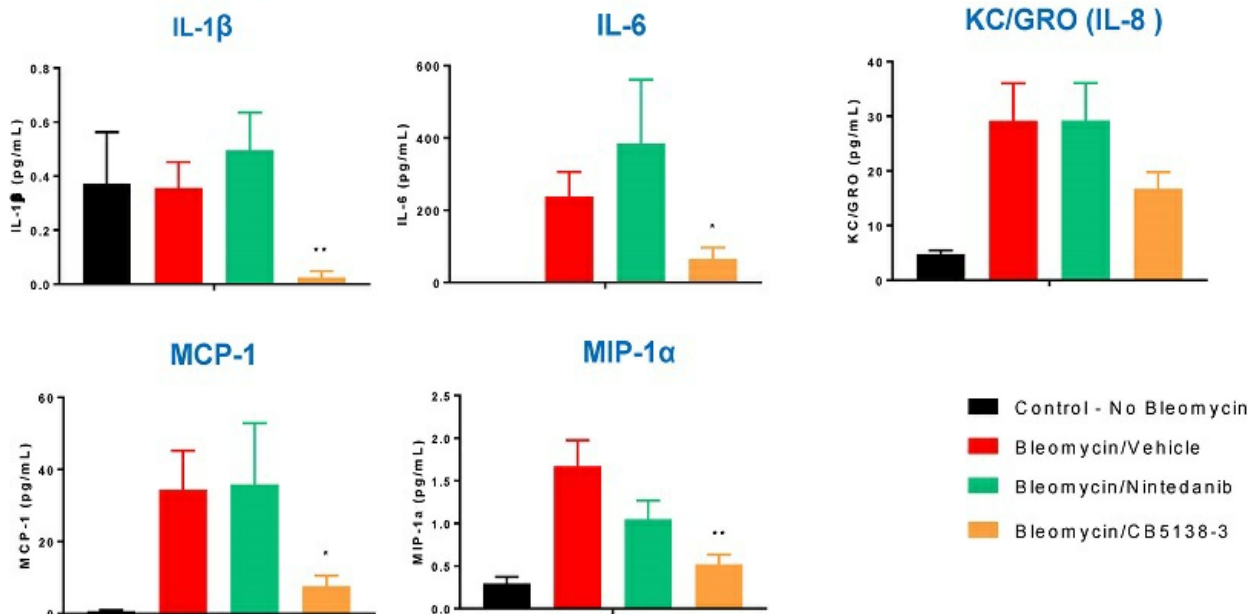
CB5138-3 reduced fibrosis and inflammation in the mouse therapeutic IPF model.

Representative photomicrographs from MT staining of lung tissue.

A - alveoli
Br - bronchiolus
BV - blood vessel
Arrows – fibrosis
Asterisk - lymphocytic infiltrate

Source: Cundy et al. Poster A2261; American Thoracic Society Meeting, August 5-10, 2020.

CB5138-3 Monotherapy Reduced Key Pro-inflammatory Cytokines in BALF in Mouse Therapeutic Model of IPF



Source: CohBar data on file

Potential Milestones 2021 – 2022*

2H2021

- **CB4211**
 - Initiate activities to support next CB4211 clinical study
 - Accelerate partnership discussions

2022

- **CB5138-3 for IPF and other fibrotic diseases:** File new IND and begin first in human clinical trial
- **Third clinical candidate:** Select candidate and initiate IND enabling activities based on study results

*Some activities require additional funding

Financial Summary (as of 6/30/21)

- **Capitalization**
 - **Shares outstanding:** 62.3M; **Fully diluted:** 92.6M
 - **Options:** 10.9M, weighted average exercise price of \$1.78
 - **Warrants:** 19.4M, weighted average exercise price of \$1.62
- **Balance Sheet**
 - **Cash & investments:** \$13.8M; projected to last through Q2 2022
 - **Short Term Debt:** \$350k
- **Insider Ownership:** 20%
- **Operating Cash Flow**
 - **Net cash used in operating activities - 6 mo. ended 6/30/21:** \$8.5M

CohBar Opportunity

Leader in developing mitochondria based therapeutics

- Novel approach leveraging over a billion years of evolution

Recent clinical milestone

- Positive CB4211 Phase 1a/1b topline data for lead candidate under development for NASH and obesity

Near-term milestone

- IND for CB5138-3 for the potential treatment of Idiopathic Pulmonary Fibrosis (IPF) in 2022

Pipeline targeting chronic diseases

- Initial focus on inflammatory and fibrotic conditions

Comprehensive IP strategy based on first mover advantage

- 13 issued patents; >65 patent filings

25



Thank You