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): December 15, 2022

SYNLOGIC, INC.
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-37566**	**26-1824804**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

301 Binney St. **Suite 402** **Cambridge, Massachusetts**	**02142**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (617) 401-9975

Not applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	SYBX	The NASDAQ Global Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR § 230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR § 240.12b-2).

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 8.01 Other Events.

On December 15, 2022, Synlogic, Inc. (the "Company") issued a press release announcing that SYNB8802 has demonstrated proof of concept through clinically significant lowering of urinary oxalate in a Phase 1b study in patients with a history of gastric bypass surgery. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated by reference herein. The Company also provided slides to accompany its press release, a copy of which is furnished as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated by reference herein.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated December 15, 2022.
99.2	Slide Presentation dated December 15, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

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

Date: December 15, 2022

Synlogic, Inc.

By: /s/ Michael Jensen
Name: Michael Jensen
Title: Chief Financial Officer

Synlogic Announces Achievement of Proof of Concept for SYNB8802 in Enteric Hyperoxaluria Based on Urinary Oxalate Lowering in Phase 1b Study

Results include -38% reduction in urinary oxalate compared to placebo in Roux-en-Y gastric bypass patients

Favorable safety and tolerability, with frequency and severity of adverse events similar across placebo and active arms

Synlogic to host webcast today at 8:30 am. ET with Dr. Kyle Wood, Associate Professor, Urology,University of Alabama at Birmingham

Cambridge, Mass. December 15, 2022 – Synlogic, Inc. (Nasdaq: SYBX), a clinical-stage biotechnology company developing medicines for metabolic and immunological diseases through its proprietary approach to synthetic biology, today announced that SYNB8802 has demonstrated proof of concept through clinically significant lowering of urinary oxalate in a Phase 1b study in patients with a history of gastric bypass surgery.

Top-line Findings:

- In the Phase 1b SYNB8802-CP-002 study, SYNB8802 demonstrated a dose-related reduction in urinary oxalate.
- The -38% urinary oxalate reduction observed at the $3x10^{11}$ live cell dose three times a day exceeds the level of urinary oxalate reduction (-20%) that has been associated with reduced risk of kidney stones in analyses based on observational data.[1]
- SYNB8802 was generally well tolerated. There were no serious adverse events (SAEs). All GI-related adverse events (AEs) were mild, and their frequency and severity were similar in the active and placebo group.

“Given the profound need for a medical treatment for enteric hyperoxaluria, we are delighted to demonstrate meaningful reductions in urinary oxalate in the Roux-en-Y gastric bypass patient population,” said Aoife Brennan, M.B. Ch.B., Synlogic President and Chief Executive Officer. “In addition, this important milestone represents the third positive clinical data readout this year in three different diseases, following our positive Phase 2 results for SYNB1934 for phenylketonuria and positive Phase 1 results for SYNB1353 for homocystinuria.”

“A subset of enteric patients have repeated kidney stones and life-altering disease that is particularly challenging to manage,” said Kyle Wood, MD, Associate Professor of Urology at the University of Alabama at Birmingham. “A therapeutic approach that lowers urinary oxalate in patients with underlying GI malabsorption is badly needed. The innovative mechanism of SYNB8802 and the strength of the data generated to date support the potential for SYNB8802 to be a highly meaningful first-in-category biotherapeutic.”

The SYNB8802-CP-002 Study

This Phase 1b study was a double-blind, randomized, placebo-controlled, inpatient study evaluating the safety and tolerability of SYNB8802 in subjects with a history of Roux-en-Y gastric bypass surgery. The primary endpoint was safety and tolerability. After a three-day diet and placebo run in, patients were randomized to either placebo or SYNB8802 for a 12-day dosing period. The dosing period included a dose escalation plan with the first six days at the lower dose of 1×10^{11} live cells, followed by six days at the 3×10^{11} live cell dose. Each six-day treatment period included a stepwise increase in dose frequency. To enable a controlled assessment of SYNB8802’s effects on oxalate, patients consumed a controlled diet for the duration of the inpatient stay. Urine was also collected for a 24-hour sample for each patient, each day.

The study enrolled 11 patients; 7 received SYNB8802 and 4 received placebo. SYNB8802 was well tolerated, with no SAEs. The most common AEs were GI-related, mild, and transient. The GI-related AEs occurred at a similar frequency in active and placebo groups. One patient in the placebo group discontinued during dosing due to the need for antibiotics.

Dosing with SYNB8802 was associated with a dose-dependent reduction in urinary oxalate. In a pharmacometric analysis that takes into account all patients’ data, dose level and dose frequency, there was a -28% (-37.2, -18.2) change from baseline in urinary oxalate vs. placebo at the $1x10^{11}$ TID dose, and a -38% (-46.4, -28.7) change from baseline in urinary oxalate vs. placebo at the $3x10^{11}$ TID dose.

In addition to the completed SYNB8802-CP-002 study, SYNB8802 is also being evaluated in an ongoing, outpatient study (SYNB8802-CP-001). Full results from both studies will be presented at a future medical meeting.

Conference Call & Webcast

Synlogic will host a conference call and live webcast at 8:30 a.m. ET today, December 15, 2022. Joining will be Dr. Kyle Wood, a specialist in kidney stone-related disease in his role as Associate Professor, Urology, University of Alabama at Birmingham. **To access the webcast, please register here. To access the call by phone** please dial (646) 307-1963 or for a toll-free option in the U.S. and Canada dial (800) 715-9871. **The event ID is: 4065357.** You can also access this information on the “Events Calendar” section of the Investors & Media webpage. For those unable to participate in the conference call or webcast, a replay will be available for 30 days on the Synlogic website here.

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About Enteric Hyperoxaluria and SYNB8802

Enteric hyperoxaluria (EH) is a metabolic disease and well-recognized cause of recurrent kidney stones, typically caused by a chronic underlying GI disorder associated with malabsorption, which predisposes patients to excessive absorption of oxalate. Elevated oxalate in the circulation leads to oxalate crystal formation in the kidney, causing excruciating pain and progressive renal damage. There is no FDA-approved treatment for enteric hyperoxaluria. SYNB8802 is a novel, orally administered, non-systemically absorbed drug candidate being developed for the treatment of enteric hyperoxaluria. SYNB8802 was designed using precision genetic engineering of the well-characterized probiotic E. coli Nissle to metabolize oxalate in GI tract, preventing its absorption and resultant crystal formation, lowering levels of urinary oxalate.

References

[1] D'Costa et al. *Nephrol Dial Transplant* (2020) 1–8.

About Synlogic

Synlogic is a clinical-stage biotechnology company developing medicines through its proprietary approach to synthetic biology. Synlogic's pipeline includes its lead program in phenylketonuria (PKU), which has demonstrated proof of concept with plans to start a pivotal, Phase 3 study in the first half of 2023, and additional novel drug candidates designed to treat homocystinuria (HCU), enteric hyperoxaluria and gout. The rapid advancement of these potential biotherapeutics, called Synthetic Biotics, has been enabled by Synlogic's reproducible, target-specific drug design. Synlogic uses programmable, precision genetic engineering of well-characterized probiotics to exert localized activity for therapeutic benefit, with a focus on metabolic and immunological diseases. In addition to its clinical programs, Synlogic has a research collaboration with Roche on the discovery of a novel Synthetic Biotic for the treatment of inflammatory bowel disease or IBD. Synlogic has also developed two drug candidates through a research collaboration with Ginkgo Bioworks: SYNB1353, designed to consume methionine for the potential treatment of HCU, and SYNB2081, designed to lower uric acid for the potential treatment of gout. For additional information visit www.synlogictx.com.

Forward-Looking Statements

This press release contains “forward-looking statements” that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this press release regarding strategy, future operations, clinical development plans, future financial position, future revenue, projected expenses, prospects, plans and objectives of management are forward-looking statements. In addition, when or if used in this press release, the words “may,” “could,” “should,” “anticipate,” “believe,” “look forward,” “estimate,” “expect,” “intend,” “on track,” “plan,” “predict” and similar expressions and their variants, as they relate to Synlogic, may identify forward-looking statements. Examples of forward-looking statements, include, but are not limited to, statements regarding the potential of Synlogic’s approach to Synthetic Biotics to develop therapeutics to address a wide range of diseases including: inborn errors of metabolism and inflammatory and immune disorders; our expectations about sufficiency of our existing cash balance; the future clinical development of Synthetic Biotics; the approach Synlogic is taking to discover and develop novel therapeutics using synthetic biology; and the expected timing of Synlogic’s clinical trials of SYNB1618, SYNB1934, SYNB1353, SYNB8802 and SYNB2081 and availability of clinical trial data. Actual results could differ materially from those contained in any forward-looking statements as a result of various factors, including: the uncertainties inherent in the clinical and preclinical development process; the ability of Synlogic to protect its intellectual property rights; and legislative, regulatory, political and economic developments, as well as those risks identified under the heading “Risk Factors” in Synlogic’s filings with the U.S. Securities and Exchange Commission. The forward-looking statements contained in this press release reflect Synlogic’s current views with respect to future events. Synlogic anticipates that subsequent events and developments will cause its views to change. However, while Synlogic may elect to update these forward-looking statements in the future, Synlogic specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Synlogic’s view as of any date subsequent to the date hereof.

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Exhibit 99.2

Transforming Medicine Through Synthetic Biology

Proof of Concept for SYNB8802 for Enteric Hyperoxaluria

Top-Line Results from Phase 1b Study

December 15, 2022

Forward Looking Statements

This presentation contains "forward-looking statements" that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this presentation regarding strategy, future operations, clinical development plans, future financial position, future revenue, projected expenses, prospects, plans and objectives of management are forward-looking statements. In addition, when or if used in this presentation, the words "may," "could," "should," "anticipate," "believe," “look forward,” "estimate," "expect," "intend," "on track,” "plan," "predict" and similar expressions and their variants, as they relate to Synlogic, may identify forward-looking statements. Examples of forward-looking statements, include, but are not limited to, statements regarding the potential of Synlogic's approach to Synthetic Biotics to develop therapeutics to address a wide range of diseases including: inborn errors of metabolism and inflammatory and immune disorders; our expectations about sufficiency of our existing cash balance; the future clinical development of Synthetic Biotics; the approach Synlogic is taking to discover and develop novel therapeutics using synthetic biology; and the expected timing of Synlogic's clinical trials of SYNB1618, SYNB1934, SYNB1353, SYNB8802 and SYNB2081 and availability of clinical trial data. Actual results could differ materially from those contained in any forward-looking statements as a result of various factors, including: the uncertainties inherent in the clinical and preclinical development process; the ability of Synlogic to protect its intellectual property rights; and legislative, regulatory, political and economic developments, as well as those risks identified under the heading "Risk Factors" in Synlogic's filings with the U.S. Securities and Exchange Commission. The forward-looking statements contained in this presentation reflect Synlogic's current views with respect to future events. Synlogic anticipates that subsequent events and developments will cause its views to change. However, while Synlogic may elect to update these forward-looking statements in the future, Synlogic specifically disclaims any obligation to do so. These forward-looking statements should not be relied upon as representing Synlogic's view as of any date subsequent to the date hereof.

Speakers

Aoife Brennan, MB ChB
President & CEO

Kyle Wood, MD
Associate Professor, Urology,
University of Alabama
at Birmingham

Caroline Kurtz, PhD
Chief Development Officer

Dave Hava, PhD
Chief Scientific Officer

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Opening Remarks

Dr. Aoife Brennan
President & CEO

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Enteric Hyperoxaluria & the Burden of Recurrent Kidney Stones

POC Achieved with Urinary Oxalate Lowering from Phase 1b Study

SYNB8802: Potential for First Approved Treatment for Enteric Hyperoxaluria

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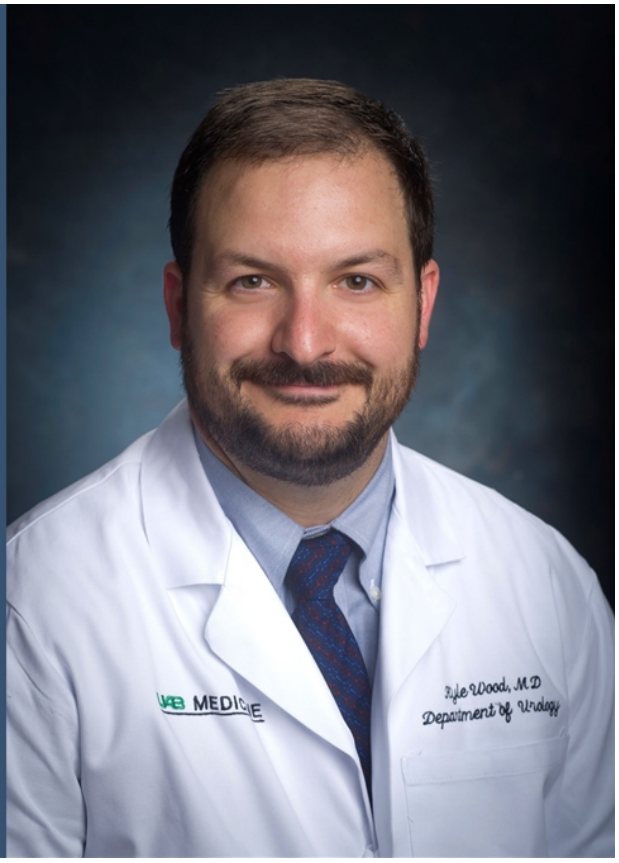
Enteric Hyperoxaluria & Recurrent Kidney Stones: An Overview

Dr. Kyle Wood
Associate Professor, Urology
University of Alabama at Birmingham



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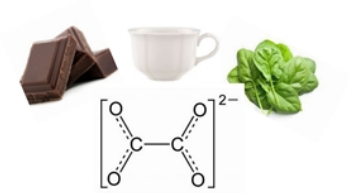
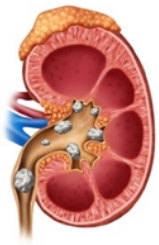
Enteric Hyperoxaluria (EH) & Recurrent Kidney Stones



Dietary Oxalate*: plant-derived; in excess, **absorbed from GI tract** into circulation



Circulating **oxalate results in crystal formation** and chronic, recurrent kidney stones

Excruciating Pain

- Oxalate **crystals damage kidneys**, impair renal function
- Can lead to CKD, ESRD, nephrocalcinosis, systemic oxalosis

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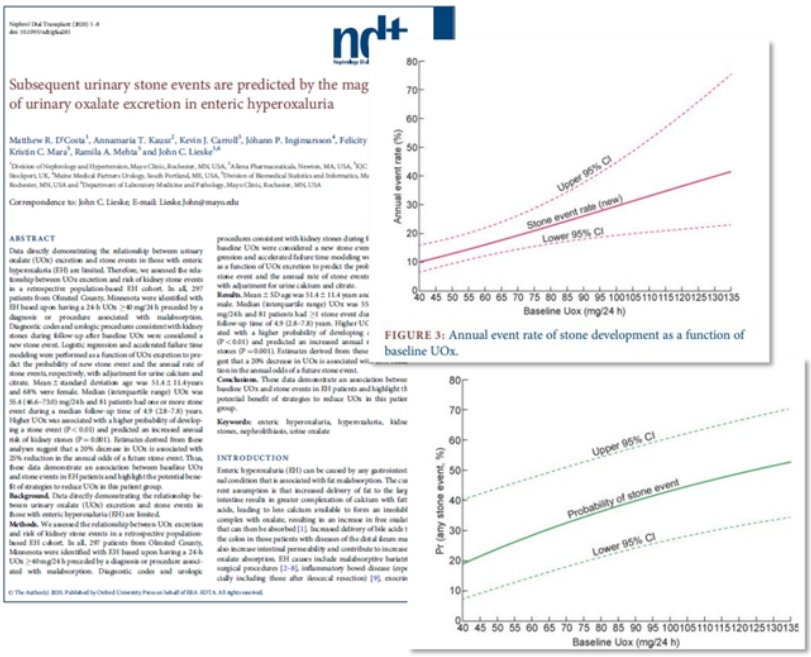
GI = gastrointestinal, CKD = chronic kidney disease, ESRD = end stage renal disease. 1. D'Costa, et al. Nephrol Dial Transplant (2020)

Urinary Oxalate Levels: Recognized Predictor of Recurrent Stones

Higher urinary oxalate (UOx) levels predict stone events in EH patients, with **~~~20%~~ decrease in UOx** associated with **~~~25%~~** reduction in annual stone event risk[1]



Subsequent urinary stone events are predicted by the mag of urinary oxalate excretion in enteric hyperoxaluria

Matthew R. D'Costa[1], Annamaria T. Kausz[2], Kevin J. Carroll[3], Johann P. Ingimarsson[4], Felicity Kristin C. Mara[5], Ramila A. Mehta[5] and John C. Lieske[1,6]

Correspondence to: John C. Lieske; E-mail: Lieske.John@mayo.edu

ABSTRACT

Data directly demonstrating the relationship between urinary oxalate (UOx) excretion and stone events in those with enteric hyperoxaluria (EH) are limited. Therefore, we assessed the rela tionship between UOx excretion and risk of kidney stone events in a retrospective population-based EH cohort. In all, 297 patients from Olmsted County, Minnesota were identified with EH based upon having a 24-h UOx ≥40 mg/24 h preceded by a diagnosis or procedure associated with malabsorption. Diagnostic codes and urologic procedures consistent with kidney stones during follow-up after baseline UOx were considered a new stone event. Logistic regression and accelerated failure time modeling were performed as a function of UOx excretion to pre dict the probability of new stone event and the annual rate of stone events, respectively, with adjustment for urine calcium and citrate. Mean ± standard deviation age was 51.4 ± 11.4 years and 68% were female. Median (interquartile range) UOx was 51.4 (46.6–73.0) mg/24 h and 81 patients had one or more stone event during a median follow-up time of 4.9 (2.8–7.8) years. Higher UOx was associated with a higher probability of develop ing a stone event ($P < 0.01$) and predicted an increased annual risk of kidney stones ($P = 0.001$). Estimates derived from these analyses suggest that a 20% decrease in UOx is associated with 25% reduction in the annual odds of a future stone event. Thus, these data demonstrate an association between baseline UOx and stone events in EH patients and highlight the potential bene fit of strategies to reduce UOx in this patient group.

Background. Data directly demonstrating the relationship be tween urinary oxalate (UOx) excretion and stone events in those with enteric hyperoxaluria (EH) are limited.

Methods. We assessed the relationship between UOx excretion and risk of kidney stone events in a retrospective population-based EH cohort. In all, 297 patients from Olmsted County, Minnesota were identified with EH based upon having a 24-h UOx ≥40 mg/24 h preceded by a diagnosis or procedure associ ated with malabsorption. Diagnostic codes and urologic procedures consistent with kidney stones during f baseline UOx were considered a new stone even gression and accelerated failure time modeling we as a function of UOx excretion to predict the prob stone event and the annual rate of stone events with adjustment for urine calcium and citrate.

Results. Mean ± SD age was 51.4 ± 11.4 years and male. Median (interquartile range) UOx was 51 mg/24 h and 81 patients had ≥1 stone event dur follow-up time of 4.9 (2.8–7.8) years. Higher UO ated with a higher probability of developing ($P < 0.01$) and predicted an increased annual stones ($P = 0.001$). Estimates derived from these got that a 20% decrease in UOx is associated wit tion in the annual odds of a future stone event.

Conclusion. These data demonstrate an association betwee baseline UOx and stone events in EH patients and highlight th potential benefit of strategies to reduce UOx in this patie group.

Keywords: enteric hyperoxaluria, hyperoxaluria, kidne stones, nephrolithiasis, urine oxalate

INTRODUCTION

Enteric hyperoxaluria (EH) can be caused by any gastrointest nal condition that is associated with fat malabsorption. The cu rent assumption is that increased delivery of fat to the larg intestine results in greater complexation of calcium with fat acids, leading to less calcium available to form an insoluble complex with oxalate, resulting in an increase in free oxalat that can then be absorbed [1]. Increased delivery of bile acids t the colon in those patients with diseases of the distal ileum ma also increase intestinal permeability and contribute to increase oxalate absorption. EH causes include malabsorptive bariatri surgical procedures [2–8], inflammatory bowel disease (espe cially including those after ileocecal resection) [9], excessi

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FIGURE 3: Annual event rate of stone development as a function of baseline UOx.

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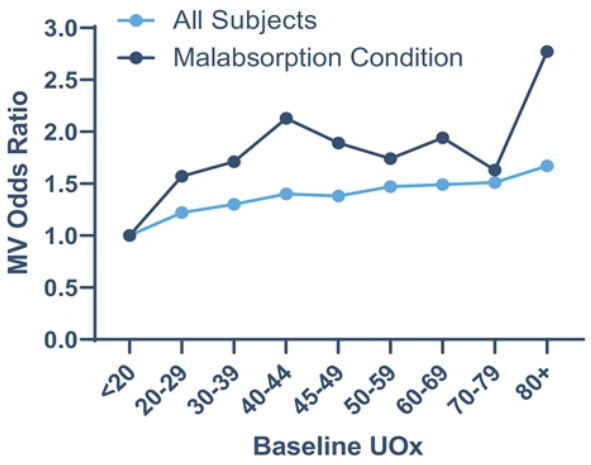
1. D'Costa, et al. Nephrol Dial Transplant (2020)

Urinary Oxalate Levels – and GI Malabsorption - Also Increase Risk for CKD

Incident CKD Risk vs. Baseline Urinary Oxalate & GI Malabsorption



Methodology

- Largest population-based study on the relationship of urinary oxalate levels and incident CKD to date
  - Dataset includes 426,896 patients without CKD at baseline and includes 12,522 with GI malabsorption

Findings

- Among patients without a history of CKD, higher urine oxalate is associated with higher risk of developing incident CKD
  - Prevalence of CKD was twice as high in patients with UOx ≥ 80 mg/d compared with < 20 mg/d
  - Risk is substantially higher among those with an underlying malabsorptive condition

synlogic Puurunen et al, Data presented at ASN in November 2021

Hyperoxaluria May Have Genetic or Enteric Etiology

	Primary Hyperoxaluria (PH)	Enteric Hyperoxaluria (EH)
Pathology	Rare genetic condition	Dietary oxalate hyperabsorption
Onset	Pediatric	Adult
Etiology	Genetic liver enzyme deficiency	Underlying insult to bowel: including IBD, bariatric surgery, other chronic GI conditions
UOx. Levels	90 – 500 mg / 24 hrs (~10x normal)	45 – 130 mg / 24 hrs (~3x normal)

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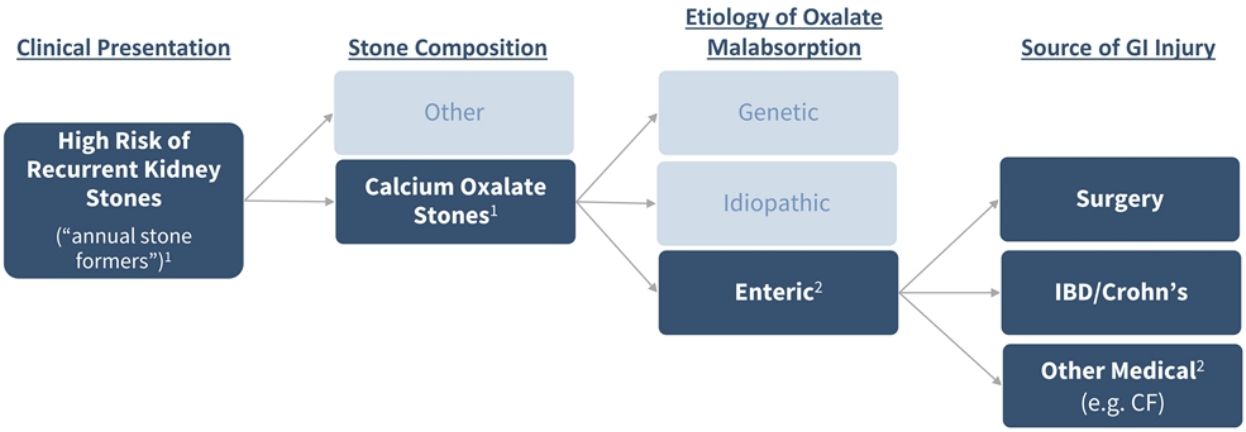
Clinical Path: Differential Diagnosis to Enteric Hyperoxaluria



Estimated U.S. Population:[1,2]

(>3mm)	**x**	**(~75%)**	**x**	**(~10%)**	**=**	**~200,000-300,000**

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Today, Treatment for EH is Limited to Dietary Restrictions

Stone Etiology	*Current Management Strategy*
Low Volume	Increase fluid intake
Hypocitraturia	Citrate supplements
Hyperoxaluria	Low oxalate diet, calcium supplements, change IBD Tx (if applicable)
Hypercalciuria	May include low sodium diet or thiazide diuretics
High Uric Acid	Increase fluid intake

- Modest efficacy
- Avoids healthy foods (e.g. green vegetables)
- Calcium supplements can exacerbate hypercalciuria
- **Treatment is even less effective for *enteric* hyperoxaluria**

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Source: Synlogic 2022 Qualitative Market Research, In-depth interviews with U.S. stone clinic physicians treating patients with recurrent stones

Proof of Concept Data for SYNB8802

Caroline Kurtz, PhD.
Chief Development Officer

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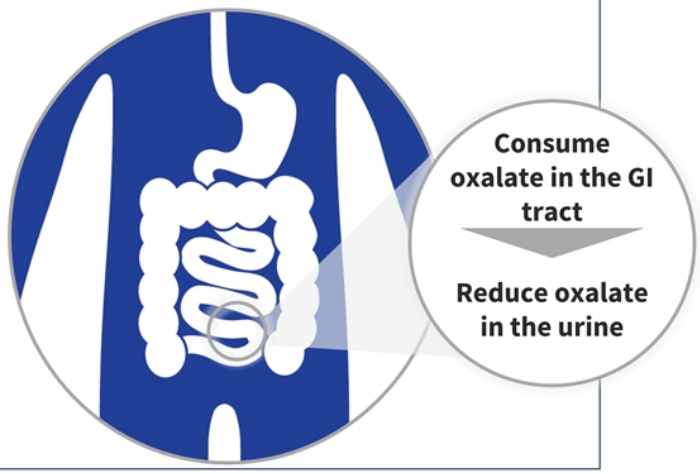
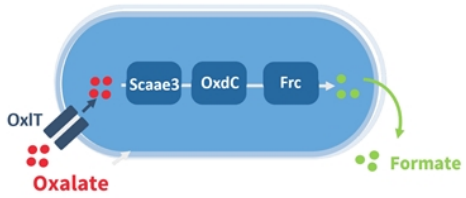
SYNB8802: Consuming Oxalate in the GI Tract to Prevent Absorption

Our Approach

Oral therapy



Precision Engineering of Probiotic



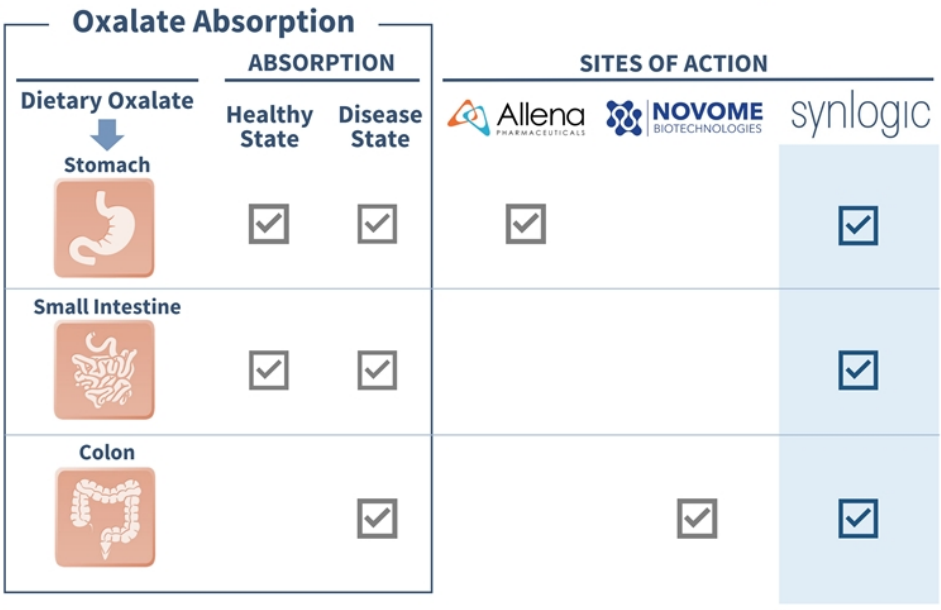
Gut lumen

Intestinal epithelium

Consumes Oxalate Throughout GI Tract

synlogic GI = gastrointestinal

SYNB8802 Differentiation: Targeting Oxalate Throughout the GI Tract



- SYNB8802 consumes oxalate throughout the GI tract
- **Extends duration of action, increasing oxalate-lowering** efficacy potential

synlogic GI=gastrointestinal

SYNB8802-CP-002 Phase 1b Study Design

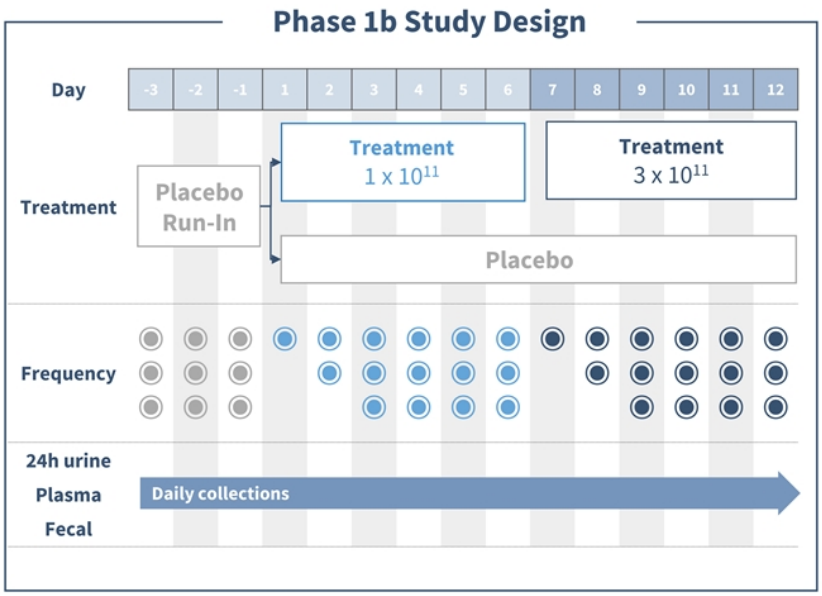
Randomized, placebo-controlled parallel arm, in-patient study

Primary endpoint: safety and tolerability

Controlled diet: Standardized dietary oxalate intake[1]

Patient population: prior Roux-en-Y gastric bypass, with abnormal GI physiology typical of EH

Disposition: 11 patients, 7 received SYNB8802 and 4 received placebo, 1 patient discontinued during placebo treatment

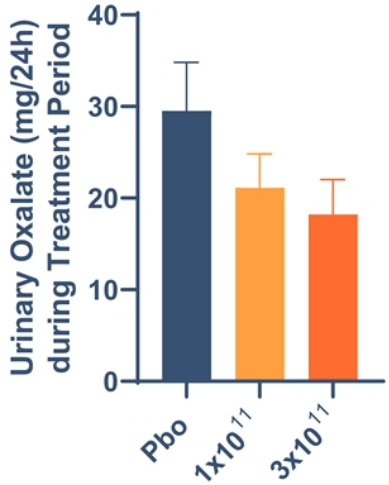


[1] Meals contained an average level of oxalate and low calcium, divided over 3 meals a day during in patient stay

Urinary Oxalate Levels Show Dose-Related Change with SYNB8802

Urinary Oxalate Values During Dosing Period*

Phase 1b SYNB8802-CP-002 Study



- Urinary oxalate levels at screening were consistent with diet and patient population (at ~30), and generally remained consistent with baseline values during the treatment period for placebo patients
- For both treatment periods, at both dose levels, dose-related reduction in urinary oxalate levels in response to SYNB8802 were observed

* Per pharmacometrics analysis including data from 7 patients receiving SYNB8802 at both the $1x10^{11}$ and $3x10^{11}$ dose levels and 4 patients receiving placebo

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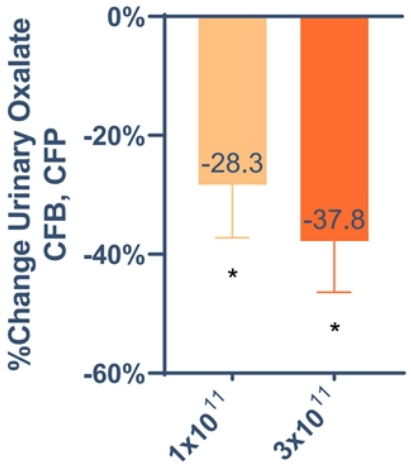
POC Achieved by Lowering of Urinary Oxalate

SYNB8802 Urinary Oxalate Lowering vs. Baseline Compared to Placebo*

Phase 1b SYNB8802-CP-002 Study



- Findings demonstrate that by consuming oxalate in the GI tract to prevent its absorption, SYNB8802 resulted in changes in urinary oxalate in gastric bypass patients
- Data analyzed using a pharmacometric model that enabled use of data from all patients on all study days

* Per pharmacometrics analysis including data from 7 patients receiving SYNB8802 at both the $1x10^{11}$ and $3x10^{11}$ dose levels and 4 patients receiving placebo
CFB=change from baseline, CFP=change from placebo

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Safety and Tolerability Findings

SYNB8802 – Proof of Concept from 002 Study Top-Line Results

- SYNB8802 was well tolerated, with **no serious adverse events**
- The most common adverse events were **GI-related, mild, and transient**
- The GI-related AEs occurred at a **similar frequency in active and placebo** groups
- One patient in the placebo group discontinued during dosing due to the need for antibiotics

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SYNB8802: Proof of Concept Achieved, Focused Path Forward

- **EH: Well-recognized burden** of recurrent stones, with no FDA approved specific medical treatment options

- **SYNB8802:** POC data shows potential for a **powerfully differentiated** treatment
  - Dose related lowering of UOx established in patients with gastric bypass
  - Validated mechanism of metabolizing oxalate in GI tract to prevent its absorption
  - Both $1x10^{11}$ and $3x10^{11}$ doses exceeded -20% threshold for clinically meaningful reduction in recurrent stone risk, with urinary oxalate lowering of -38% vs. placebo at the $3x10^{11}$ dose TID

- **Enriched, concentrated target patient population: EH with highly recurrent stones**
  - Profoundly affected by pain, interventions of recurrent stones
  - Connected to specialists (e.g. stone clinics)

- **Path forward: plan to advance towards registrational trial, likely clinical endpoint of stone disease progression**

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Cross-Platform Implications

Dave Hava, PhD
Chief Scientific Officer

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SYNB8802 POC: A Milestone for Synthetic Biotic Platform

- ✓ **3rd positive data readout in 4Q 2022,** following proof of concept in PKU, and proof of mechanism in HCU
- ✓ **2nd disease state with POC achieved**
- ✓ **Platform experience accelerates learnings,** for dosing, tolerability

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Concluding Remarks

Dr. Aoife Brennan
President & CEO

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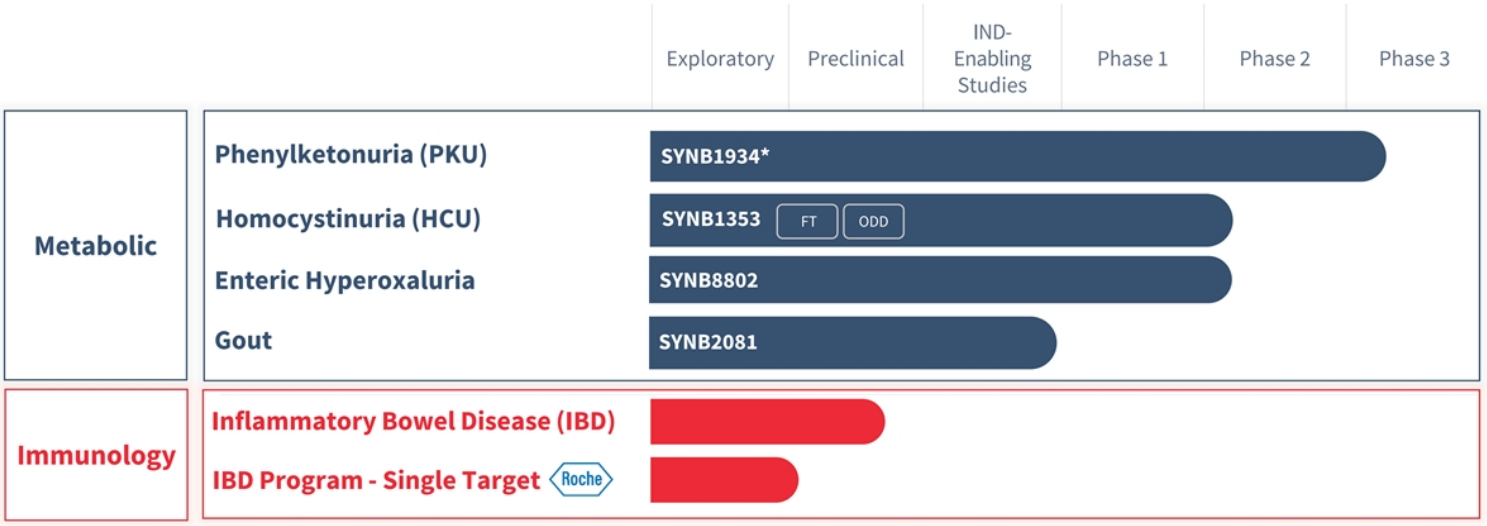
Advancing a New Class of Biotherapeutics



FT = Fast Track granted by FDA

ODD = Orphan Drug Designation granted by FDA

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*First generation SYNB1618 for PKU received both ODD and FT designations by the FDA and orphan medicinal product designation by the EMA.

Available For Questions

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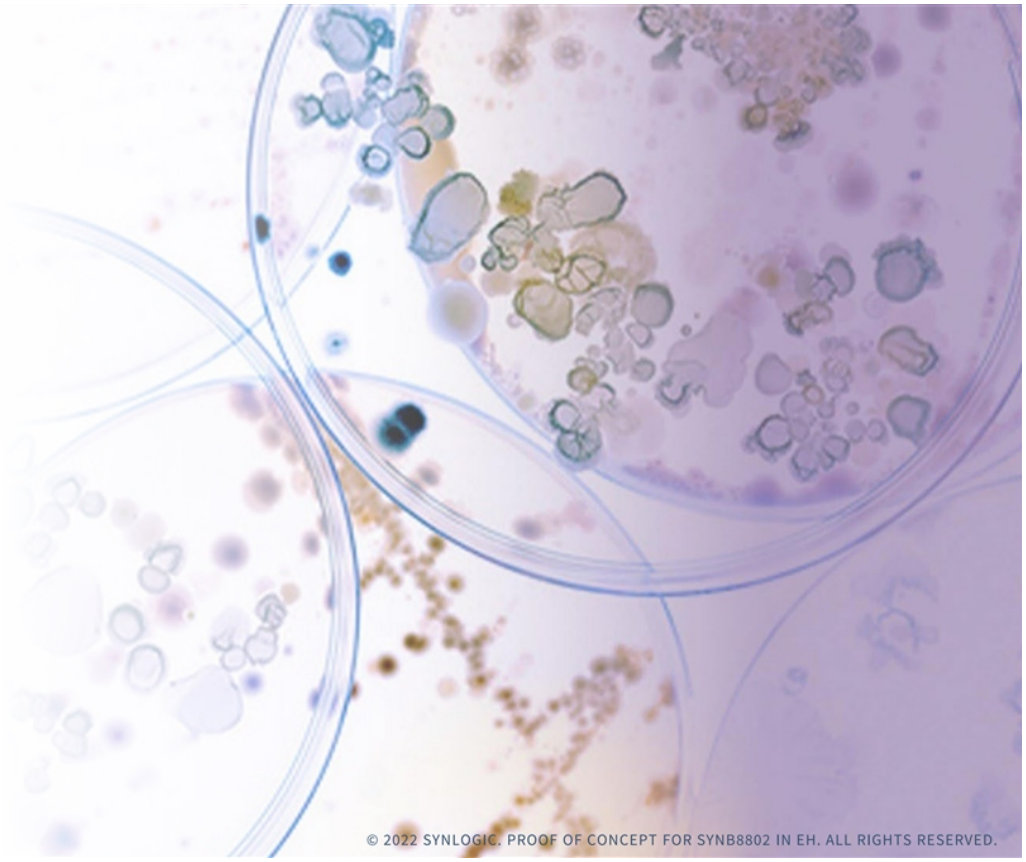
Thank You



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