# progenity® Prepare for life.

SECOND QUARTER 2021 – FINANCIAL RESULTS

August 2021

## FORWARD-LOOKING STATEMENTS

This presentation contains "forward-looking statements" within the meaning of the federal securities laws, which statements are subject to substantial risks and uncertainties and are based on estimates and assumptions. All statements, other than statements of historical facts included in this presentation, including statements concerning our plans, objectives, goals, strategies, future events, future revenues or performance, financing needs, plans or intentions relating to product candidates, estimates of market size, estimates of market growth, business trends, expected testing supply and demand, the anticipated timing, design and conduct of our planned clinical trials, the development of our product candidates, including the timing and likelihood of regulatory filings and approvals for our product candidates, our ability to commercialize our product candidates, if approved, the pricing and reimbursement of our product candidates, if approved, the potential to develop future product candidates, the potential benefits of strategic collaborations and our intent to enter into any strategic arrangements, the timing and likelihood of success, plans and objectives of management for future operations and future results of anticipated product development efforts, are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "might," "will," "objective," "intend," "should," "could," "could," "expect," "believe," "design," "estimate," "predict," "potential," "plan" or the negative of these terms, and similar expressions intended to identify forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors that could cause our actual results to differ materially from the forward-looking statements expressed or implied in this presentation, including those described in "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our Annual Report on Form 10-Q, filed with the U.S

We cannot assure you that we will realize the results, benefits or developments that we expect or anticipate or, even if substantially realized, that they will result in the consequences or affect us or our business in the way expected. Forward-looking statements are not historical facts and reflect our current views with respect to future events. Given the significant uncertainties, you should evaluate all forward-looking statements made in this presentation in the context of these risks and uncertainties and not place undue reliance on these forward-looking statements as predictions of future events. All forward-looking statements in this presentation apply only as of the date made and are expressly qualified in their entirety by the cautionary statements included in this presentation. We disclaim any intent to publicly update or revise any forward-looking statements to reflect subsequent events or circumstances, except as required by law.

Industry and Market Data: We obtained the industry, market, and competitive position data used throughout this presentation from our own internal estimates and research, as well as from industry and general publications, and research, surveys, and studies conducted by third parties. Internal estimates are derived from publicly available information released by industry analysts and third-party sources, our internal research and our industry experience, and are based on assumptions made by us based on such data and our knowledge of the industry and market, which we believe to be reasonable. In addition, while we believe the industry, market, and competitive position data included in this prospectus is reliable and based on reasonable assumptions, we have not independently verified any third-party information, and all such data involve risks and uncertainties and are subject to change based on various factors. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.



## RECENT HIGHLIGHTS

#### **WOMEN'S HEALTH**

- Successful completion of the validation study for the Preecludia<sup>™</sup> rule-out test for preeclampsia
- Achieved the primary endpoint of the study protocol
- Demonstrated strong performance and a high NPV in line with target in a broad use population
- Proceeding toward publication in peer-reviewed journal

#### STRATEGIC TRANSFORMATION

- Completed closure of Ann Arbor laboratory; refocused resources toward innovation pipeline
- Opex reduction plan on track to achieve target
- Already achieved \$97 reduction in annual operating expenses annual run rate
- Maintaining Avero Diagnostics while pursuing divestiture

#### **ORAL BIOTHERAPEUTICS**

- Initiated preclinical studies of PGN-OB1 (adalumimab) and PGN-OB2 (GLP 1 agonist)
- Goal is to demonstrate bioavailability of drug candidates in comparison to parenteral administration
- Initial data is promising with average bioavailability of approximately 15% and reaching up to 44%<sup>1</sup>
- Existing Pharma partnerships advancing as expected

#### **GASTROINTESTINAL HEALTH**

- Ongoing clinical study in ulcerative colitis patients using adalimumab delivered by enema as proxy for PGN-001 (adalumimab)
- Designing first clinical study for PGN-600 (tofacitinib)
- Established IBD Clinical Advisory Board
- DDS article published in Crohn's & Colitis 360

Animals where significant drug was detected



**INNOVATION PIPELINE UPDATE** 

# PREECLUDIA™ RULE-OUT TEST FOR PREECLAMPSIA

Test developed with >3,700 patient samples, targeting NPV >95%

# PREECLAMPSIA IS THE #2 CAUSE

of maternal mortality<sup>1</sup>

#### **CURRENT METHODS CANNOT DIFFERENTIATE**

preeclampsia from other hypertensive disorders

>700,000 PATIENTS present with symptoms each year<sup>2,3,4</sup>

#### **UP TO \$3 BILLION**

estimated market opportunity in the United States

#### **CLINICAL VALIDATION: PRO-104**

- Achieved primary endpoint of validation study protocol (hazard ratio)
- Demonstrated strong performance and a high NPV level
  - In line with target
  - At high prevalence rate and in a broad use population
- Proceeding toward publication of results in peer reviewed journal





- Prospective, cohort study producing blinded samples from 400 patients
- Results support a rule-out window up to 14 days in the target population

SENSITIVITY	SPECIFICITY	NPV
88.0%	73.3%	98.2%*
(78.2% – 94.4%)	(68.1% – 78.0%)	(95.5% – 99.3%)

<sup>\*</sup>NPV calculated at a 10% prevalence representing the expected prevalence



- N = 356 enrolled subjects\*\*
- Demonstrated commercial laboratory systems readiness
- Performance consistent with verification study
- NPV >97%, sensitivity >87%, with prevalence =11% within 14 day rule-out window; specificity >65%





### CLINICAL DEVELOPMENT **STRATEGY**

- Market education and development
- Initiate trials with partner to evaluate clinical utility
- Develop health economics data
- Targeted publication of key data

<sup>1.</sup> Henderson JT, et al. Preeclampsia Screening: Evidence Report and Systematic Review for the US Preventive Services Task Force.

<sup>2.</sup> Ananth CV, et al. Pre-eclampsia rates in the United States, 1980-2010: age-period-cohort analysis. BMJ. 2013 Nov 7;347:f6564

<sup>3.</sup> https://www.sciencedirect.com/topics/medicine-and-dentistry/gestational-hypertension

<sup>4.</sup> Center for Disease Control and Prevention. Births: Final Data for 2018 (In press). https://www.cdc.gov/nchs/nvss/births.htm

## **DRUG PROGRAMS**

# Drug/Device Combination Products and Drug Delivery Systems

#### **ORAL BIOTHERAPEUTICS**

#### **ODBS**

Oral biotherapeutics delivery system



#### Ionis Pharmaceuticals

Antisense therapy + OBDS

#### Large Pharma Co

Drug + OBDS

# **BIOTHERAPEUTICS**

**ORAL SYSTEMIC DELIVERY OF** 

- PGN-0B1: adalimumab + OBDS
  - ► GMP drug substance batch produced
- PGN-OB2: GLP-1 agonist + OBDS

- Recently achieved preclinical avg. bioavailability levels of approx. 15% and maximum levels up to 44% of IV for adaluminab following a single dose<sup>1</sup>
- Progress continues under current pharma partnerships

#### TARGETED THERAPEUTICS

#### DDS

Drug delivery system



#### **PGN-600**

Tofacitinib + DDS

#### **PGN-001**

Adalimumab + DDS

#### LOCALIZED DRUG DELIVERY FOR GI DISORDERS

- PGN-600: tofacitinib + DDS
- PGN-001: adalimumab + DDS

- Announced first clinical data supporting device auto-location and payload delivery in colon
- Announced positive pre-clinical safety/PK & PD data for PGN-600 (tofacitinib + DDS)
- Ongoing clinical PK study for adalimumab with local drug delivery for ulcerative colitis

1. Animals where significant drug was detected

# **GASTROINTESTINAL HEALTH - DIAGNOSTICS**

# *Ingestible GI diagnostic platforms*

#### RECOVERABLE SAMPLING SYSTEM

#### **RSS**

sampling + preservation technology



• LOCALIZE

**SAMPLE** 

**PRESERVE** 

RECOVER

• ANALYZE

# DISCOVERY AND DIAGNOSTICS IN MULTIPLE GI DISEASES

Recover and preserve:

- Microbial and cellular samples
- Multi-omics opportunities
- ▶ Device development
  - Second-generation design to achieve:
    - Improved manufacturability
    - Reduced cost

#### PIL Dx: INGESTIBLE LAB-IN-A-CAPSULE

#### PIL Dx

ingestible fluorescent technology



·····• LOCALIZE

**SAMPLE** 

**ANALYZE IN SITU** 

... TRANSMIT RESULTS

# LEAD INDICATION = SIBO: >100 MILLION PATIENT VISITS/YEAR

- ► No capsule recovery required
- Multiple fluorescent-based assays and diseases to explore
- ► ACG Abstract Award/Oral Presentation:
  - Clinical study demonstrating assay accuracy compared to invasive standard of care protocol
- Device development
  - Second-generation design
  - Improved manufacturability
  - Reduced cost

## SINGLE-MOLECULE DETECTION PLATFORM

Novel, single-molecule counting assay, initially for NIPT

Potentially applicable to known genomic, epigenomic, and proteomic targets



#### **QUALITY RESULTS**

Maintain premium clinical value and reliability



#### **FASTER RESULTS**

Enables 3-day laboratory turnaround time



#### **COST EFFECTIVENESS**

Chemistry greatly reduces assay cost vs. NGS



#### Q3 2020

 Achieved development milestone demonstrating potential to "quantify" fetal fraction



#### Q4 2020

 Made critical advancement by finalizing probe pool design and testing



#### Q4 2021

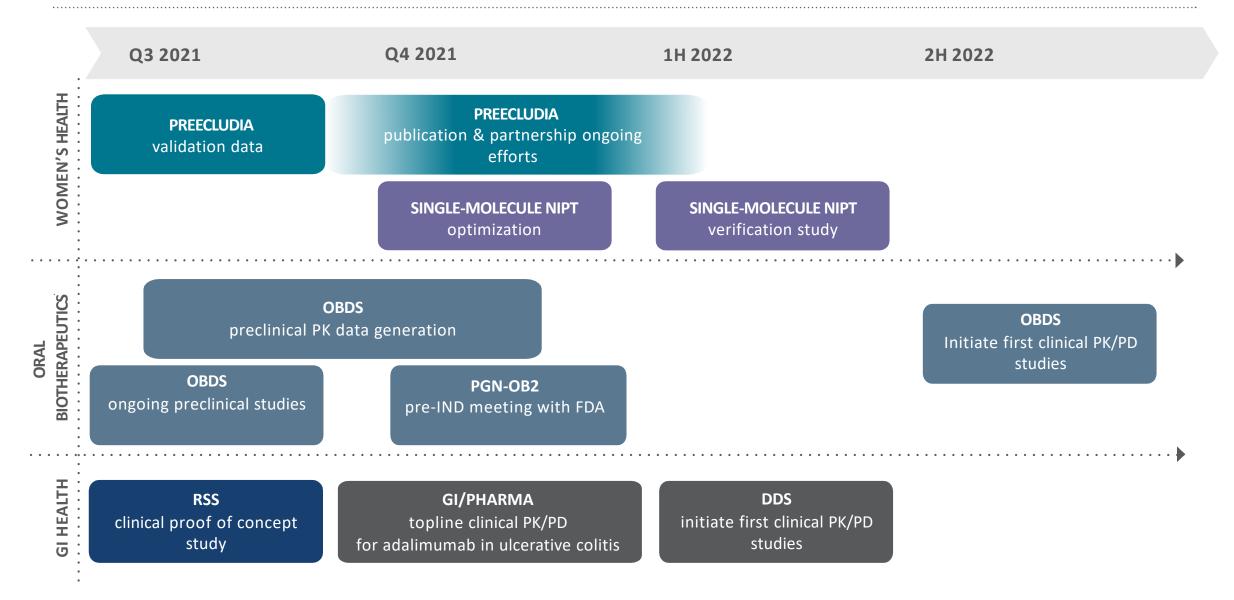
• Anticipated optimization exit



#### 1H 2022

Anticipated validation exit

# **NEAR-TERM POTENTIAL CATALYSTS**





**OPERATING EXPENSES** 

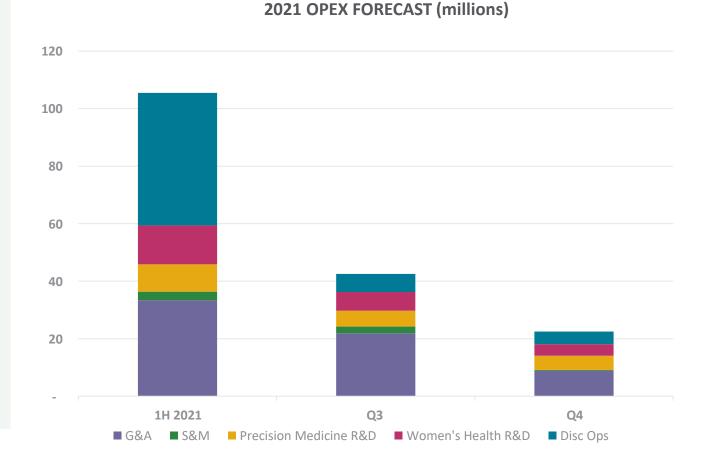
# **OPEX REDUCTIONS**

Secured \$97 million in OPEX<sup>1</sup> annual run rate reductions (66% of target)<sup>2</sup> to be realized in the second half of 2021

Expecting additional \$50 million in OPEX annual run rate reduction by end of Q4 2021<sup>2</sup>

Monthly expense run rate reducing from \$15 million in 1H'21 to <\$7 million by end of 2021

Focusing stage-gated capital allocation on innovation pipeline





<sup>&</sup>lt;sup>1</sup> Operating expenses before stock-based compensation accruals

<sup>&</sup>lt;sup>2</sup> Assumes Avero sale by end of 2021

# Orogenity® Prepare for life.