A Champion in GI
With A One Tract Mind
Focused on Rare and Unmet Needs in Gastroenterology

Short Bowel Syndrome R&D Day
NM-002: Proprietary Long-Acting GLP-1 Agonist
March 23, 2021
Forward Looking Statements

This presentation includes forward-looking statements based upon the Company’s current expectations. Forward-looking statements include, but are not limited to, statements that express our intentions, beliefs, expectations, strategies, predictions or any other statements relating to our future activities or other future events or conditions. These statements are based on current expectations, estimates and projections about our business based, in part, on assumptions made by management. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include, without limitation: (i) uncertainties associated with the clinical development and regulatory approval of product candidates; (ii) risks related to the inability of the Company to obtain sufficient additional capital to continue to advance these product candidates and its preclinical programs; (iii) uncertainties in obtaining successful clinical results for product candidates and unexpected costs and delays that may impact clinical development; (iv) risks related to the failure to realize any value from product candidates and preclinical programs being developed and anticipated to be developed in light of inherent risks and difficulties involved in successfully bringing product candidates to market; (v) the impact of COVID-19 on our operations, clinical trials or future financings and (vi) risks associated with the possible failure to realize certain anticipated benefits of the Company’s 2020 merger and 2020 acquisition of Naia Rare Diseases, Inc., including with respect to future financial and operating results. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements because of these risks and uncertainties. These and other risks and uncertainties are more fully described in periodic filings with the SEC, including the factors described in the section entitled "Risk Factors" in the Company’s Annual Report on Form 10-K for the year ended December 31, 2020 and in other filings that the Company has made and future filings the Company will make with the SEC. You should not place undue reliance on these forward-looking statements, which are made only as of the date hereof or as of the dates indicated in the forward-looking statements. The company expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.
R&D Day Agenda

- **Introduction** - John Temperato, President & CEO
- **Short Bowel Syndrome Overview & Management** – Patrick H. Griffin, MD, CMO
- **Clinical Impact of Chronic Diarrhea in SBS Patients** – Carol Rees Parrish, MS, RDN, University of Virginia Health System
- **Paradigm Shift to GLP-1** – Patrick H. Griffin, MD, CMO
- **Phase 1b/2a Results Update and Recap** – Patrick H. Griffin, MD, CMO
- **Clinical & Regulatory Path Forward** – Patrick H. Griffin, MD, CMO
- **Question & Answer Session**
Introduction
John Temperato, President and CEO
9 Meters in Circuitous Length - But a Straight-Forward Strategy

- Develop capital efficient + regulatory predicates
- Acquire / Partner aligned to focus
- Commercialize efficient US footprint; strategic ROW partnerships
- Rare & unmet needs in GI

GI-Centric, Patient-Focused
- Acquire targeted clinical compounds
- Agnostic within GI tract if needs are unmet
- Rare & unmet needs allows for targeted patient profiling within GI

Focus Provides
- Capital efficient development pathway
- Market protection enhancements
- Capital efficient commercialization
- Payer leverage
# 9 Meters Pipeline in Rare and Unmet Need GI Diseases

<table>
<thead>
<tr>
<th>PROGRAM INDICATION</th>
<th>CLASS</th>
<th>ROUTE</th>
<th>PRE-CLINICAL</th>
<th>PHASE 1</th>
<th>PHASE 2</th>
<th>PHASE 3</th>
<th>UPCOMING MILESTONES</th>
</tr>
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<tbody>
<tr>
<td>Larazotide</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td>Topline readout</td>
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<td></td>
<td>Adult Celiac Disease</td>
<td>Tight Junction Regulator</td>
<td>Oral; Gut Restricted</td>
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<td>Phase 3 → 2022</td>
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<td>NM-002</td>
<td>Short Bowel Syndrome</td>
<td>Long-Acting GLP-1</td>
<td>Injectable</td>
<td></td>
<td></td>
<td></td>
<td>Initiate Phase 2 → 2Q21</td>
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<tr>
<td>NM-003</td>
<td>Orphan Indication TBD</td>
<td>Long-Acting GLP-2</td>
<td>Injectable</td>
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<td>Initiate IND-enabling → 3Q21</td>
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<tr>
<td>NM-102</td>
<td>Orphan Indication TBD</td>
<td>Tight Junction Microbiome Modulator</td>
<td>Oral; Gut Restricted</td>
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<td>Initiate IND-enabling → 3Q21</td>
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<tr>
<td>NM-004</td>
<td>Orphan Indication TBD</td>
<td>Immunomodulator</td>
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<td></td>
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<td>Lead indication selection → 2021</td>
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</table>

**NOTE:** All programs are New Chemical Entities.

**NOTE:** All programs are globally licensed except NM-004, which excludes Asia, except for Japan.
## Multiple Potential Inflection Points Over Next 12-18 Months

<table>
<thead>
<tr>
<th>2Q 2021</th>
<th>3Q 2021</th>
<th>4Q 2021</th>
<th>2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Initiate Phase 2 NM-002 trial</td>
<td>• Initiate IND-enabling pathway for NM-102</td>
<td>• Topline Phase 2 readout of NM-002 trial</td>
<td>• Interim analysis for larazotide Phase 3 for celiac disease</td>
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<tr>
<td>• Obtain USAN name for NM-002</td>
<td>• Initiate IND-enabling pathway for NM-003</td>
<td>• American College of Gastroenterology (ACG) conference abstracts/posters</td>
<td>• Top-line larazotide Phase 3 readout in celiac disease</td>
</tr>
<tr>
<td>• Attendance at Digestive Disease Week (DDW) conference</td>
<td></td>
<td>• Initiate Phase 3 SBS trial for NM-002</td>
<td></td>
</tr>
</tbody>
</table>

Evaluate rest-of-world NM-002 and global larazotide partnerships
Short Bowel Syndrome (SBS) is a Debilitating Orphan Disease

- Orphan disease (orphan designation granted) with an underserved market
- Affects up to 20,000 people in the U.S. with similar prevalence in Europe\textsuperscript{1,2}
- Gattex\textsuperscript{®} (teduglutide) is a GLP-2 analogue approved in US in 2012
  - ~1,400 patients under management WW
  - ~$600M in global sales in 2019/2020
  - 10th most expensive medicine in US in 2020 ($40,000 per month)

\textsuperscript{1}Jeppesen P. Expert Opin Orphan Drugs; 1:515-25; \textsuperscript{2}Transparency Market Research; Short Bowel Syndrome Market, 2019
# NM-002 Target Product Profile

<table>
<thead>
<tr>
<th>NM-002 (proprietary long-acting GLP-1)*</th>
<th>GLP-2 Class</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Profile</strong></td>
<td>– GLP-2 analogue</td>
</tr>
<tr>
<td>✓ Long acting GLP-1 receptor agonist</td>
<td>– Expand intestinal mucosa / villous growth</td>
</tr>
<tr>
<td>✓ Slows gut motility</td>
<td>– Limited effect on gut motility</td>
</tr>
<tr>
<td>✓ Increases time for absorption of key nutrients</td>
<td>– Must be on PS to start class of drug</td>
</tr>
<tr>
<td><strong>Efficacy</strong></td>
<td>– Statistically significant reductions in PS volume</td>
</tr>
<tr>
<td>✓ Improvements in total stool output volume</td>
<td>– Very low rates of patients weaned off</td>
</tr>
<tr>
<td>✓ Improvements in bowel movement frequency</td>
<td>– Weeks to months (2 to 6 months)</td>
</tr>
<tr>
<td>✓ Diarrhea no longer meal-related</td>
<td>– REMS program; safety concerns include:</td>
</tr>
<tr>
<td>✓ Reduction in nocturnal diarrhea</td>
<td>– Acceleration of neoplastic growth</td>
</tr>
<tr>
<td><strong>Onset of Action</strong></td>
<td>– Intestinal obstruction</td>
</tr>
<tr>
<td>✓ Within hours-to-days of dosing</td>
<td>– Biliary and pancreatic disease</td>
</tr>
<tr>
<td><strong>Safety</strong></td>
<td>– QD injections; newer versions once- or twice-weekly</td>
</tr>
<tr>
<td>✓ Known target</td>
<td>– Weight-based dosing for approved GLP-2 drug</td>
</tr>
<tr>
<td>✓ Transient side effects</td>
<td>– Active molecule has over 15 patient years of use</td>
</tr>
<tr>
<td>✓ Active molecule has over 15 patient years of use</td>
<td>– Evaluating weekly to up to monthly</td>
</tr>
<tr>
<td><strong>Dosing</strong></td>
<td>✓ Fixed-dosing</td>
</tr>
<tr>
<td>✓ Evaluating weekly to up to monthly</td>
<td>– Fixed-dosing</td>
</tr>
<tr>
<td>✓ Fixed-dosing</td>
<td>– Weight-based dosing for approved GLP-2 drug</td>
</tr>
</tbody>
</table>

*NM-002 remains investigational and under development*
Patrick H. Griffin MD, FACP – Chief Medical Officer

Dr. Griffin became our chief medical officer in February 2019. Previously, Dr. Griffin served as executive vice president and chief medical officer of Synergy Pharmaceuticals from January 2015 through November 2018, and senior vice president and chief medical officer May 2013 through January 2015. From March 2012 to April 2013, Dr. Griffin served as chief medical officer and senior vice president of development at ImmusanT, Inc. From March 2009 until January 2012, Dr. Griffin served as associate vice president, clinical development and head of external innovation at Sanofi-Aventis (now Sanofi). He is a board-certified physician in both internal medicine and gastroenterology, and is a Fellow of the American College of Physicians. He received his medical degree from Columbia University, completing a residency in internal medicine at Presbyterian Hospital in New York, and a fellowship in gastroenterology at Brigham and Women’s Hospital in Boston. Following his residency and fellowship, Dr. Griffin joined the medical faculty of Columbia College of Physicians and Surgeons, where he held a number of academic, clinical research, teaching and management positions, and a private practice in New York.
Short Bowel Syndrome (SBS) is a Debilitating Orphan Disease

- Severe disease characterized by a near-complete lack of gut motility with significant impact on quality of life
  - Impaired intestinal absorption, diarrhea & metabolic complications
- Limited treatment options with potential life-long dependency on parenteral support (PS)
  - Complex and costly parenteral nutritional support to survive; risk of life-threatening infections & extra-organ impairment
- Typical SBS patient etiology:
  - Irreversible inflammatory bowel disease
  - Motor vehicle accident
  - Atherosclerotic heart disease of mesentery circulation
  - Congenital disease

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SBS Patient Perspective on Chronic Diarrhea Indicative of Significant Impact Over the Last Decade

If you want a one-word description [of living with Short-Bowel Syndrome], it’s ‘hell’. It changes your whole life, it ruins your life. There are ups and downs – mostly downs. It’s very difficult to manage, very difficult.

I’m going so much I have no life. I can’t go anywhere – you go out anywhere you keep going to the bathroom.

The bathroom is probably the most annoying thing... I always have plastic bags with me and because my bag will fill up really fast... I’ve emptied it on the subway... If you do it really fast, people have no idea what’s going on, but it’s still a pain to do.

Patient quotes from NPS market research; Source: SEC 8-k April 2010 NPS Pharmaceuticals Inc.
Treatment Options: Nutrition and Hydration

- Absorption capacity for nutrition, fluid, and electrolytes is proportional to:
  - Length of small bowel
  - Segments of the intact bowel
  - Absorptive quality of remnant bowel
  - Individual capacity for GI mucosal adaptation

- PN/IV support provides the nutrition, fluid, and electrolytes necessary to maintain health and body weight

- IV fluids and electrolytes are required due to fluid loss

- Two years after bowel resection, PN/IV dependence is 49%, decreasing only slightly at 5 years to 45%

Treatment Options: GLP-2 Mechanism of Drug Class
*Trophic gut peptide increases villous height and crypt depth*

Approved therapy:

- GLP-2 class to promote intestinal growth (teduglutide approved in US in 2012, long-acting analogues in development)
- All GLP-2 analogues have the same mechanism likely requiring long-term treatment to achieve significant benefit
- Clinically relevant reduction in PS volume with GLP-2s is delayed
Treatment Options: Supportive Care

• SBS supportive symptom care:
  – Growth hormone and glutamine (approved)
  – Antidiarrheals: loperamide, diphenoxylate/atropine, diluted tincture of opium, codeine
  – Antiemetics for chronic nausea (e.g. 5HT3 antagonists)
  – Acid suppressors: PPI, H2RA
  – Antibiotics: small intestinal bacterial overgrowth
  – Bile acid sequestering agents

• Surgical augmentation and intestinal transplant – for specific cases
Patients With SBS Typically Have No Natural GLP-1

- GLP-1 is naturally produced in a portion of ileum that is removed during surgical resection.
- Natural GLP-1 prevents the GI tract from moving rapidly: known as an “ileal brake”.
- Without this brake, there is a lack of gut motility, causing an SBS patient’s remaining bowels to empty rapidly and frequently:
  - Inability to absorb nutrients and fluids
  - Intractable diarrhea with frequent bowel movements and excessive stool output
- GLP-2 analogues do not appreciably slow down the gut to affect rapid transit time associated with SBS.
- An ideal therapy for SBS patients should:
  - Be safe and tolerable, while providing convenient dosing & administration
  - Rapidly decrease gut motility to improve absorption of nutrients and fluids
  - Rapidly reduce total stool output (TSO) volume & bowel movement frequency
Speaker: Carol Rees Parrish, MS, RDN

Carol Parrish has 30 years of clinical experience, the past 20 of which have been spent specializing in nutrition support and GI disorders at the University of Virginia Health System (UVAHS), Digestive Health Center of Excellence. Carol founded the Medicine Nutrition Support Service in 1991, began the home nutrition support program at the UVAHS Home Health Company, developed the GI Nutrition Clinic, originated our Celiac Support Group, and is the co-founder of both nutrition support traineeship programs. She has been the nutrition series editor for the popular Practical Gastroenterology Journal’s Nutrition Series since 2003.

Previously, she was a clinical nutritionist at Fairfax Hospital from 1981-1990 and a nutrition counselor at multiple practices from 1984-1990. Ms. Parrish received her Bachelor of Science from the University of California, Davis, and a Master of Science from Rosalind Franklin University of Medicine and Science. She completed her general internship at Milwaukee County Medical Complex. In addition to being a member of many professional affiliations, Ms. Parrish has written multiple abstracts, chapters, and publications.
The Clinical Impact of Chronic Diarrhea Importance in SBS Patients

Carol Rees Parrish, MS, RDN
University of Virginia
A PATIENT’S GUIDE TO
Managing a Short Bowel

4th Edition

by
Carol Rees Parrish, MS, RD

Available at no cost to patients & clinicians @
www.shortbowelsyndrome.com under “sign up at top”

NOTE: New 2021 version will be available this summer
Paradigm Shift to GLP-1
NM-002: Proprietary Long-Acting GLP-1 Agonist

Patrick H. Griffin, MD, FACP, CMO
Why is a paradigm shift needed?

- Chronic diarrhea due to malabsorption in SBS has not been fully addressed with current treatments.
- Relief from incessant diarrhea continues to be a high unmet need and requires a solution for all SBS patients, independent of parenteral requirements.
- NM-002 is a proprietary long-acting GLP-1 agonist which may address the root cause of this unmet need.
In a shortened bowel, motility is increased, reducing nutrient uptake and causing quicker movement of food through the bowel.

Typical Short Bowel Syndrome

GLP-1 travels through the blood, which affects gut motility elsewhere in the body.

NM-002 rapidly replaces physiological effects of missing GLP-1 to normalize GI transit with potentially twice or once-monthly dosing.

Motility is slowed, allowing more time for nutrient uptake.

NM-002 Replaces GLP-1 and Restores the “Ileal Brake”
NM-002 is XTENylated™ Creating Ultra-Long Half-Life

XTENylation Key Benefits:

- Increases exenatide half-life from 2 to ~170 h in PK modelling
- Not PEGylation conjugation
- Fully recombinant process
- Increased drug stability
- Reduced immunogenicity
- Fully biodegradable
- Defined chemical structure
- Purifiable drug product
- Manufacturing known and scalable
- Clinically validated: Human PoC using exenatide-XTEN completed; multiple other targets also completed clinical studies in > 200 patients

Source: Amunix Pharmaceuticals, Inc. Mountain View, CA; ORI – origin of replication; KAN® – Kanamycin resistance gene
NM-002 Pharmacokinetics Supports Target Product Profile

<table>
<thead>
<tr>
<th>Day</th>
<th>Parameter</th>
<th>50 mg Cohort (n=3)</th>
<th>100 mg Cohort (n=4)</th>
<th>150 mg Cohort (n=2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Mean AUC\text{0-1} (h*ng/mL)</td>
<td>1481465.77</td>
<td>2849924.89</td>
<td>2651203.79</td>
</tr>
<tr>
<td></td>
<td>Mean C\text{max} (ng/mL)</td>
<td>13893.92</td>
<td>24894.00</td>
<td>24347.01</td>
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<tr>
<td></td>
<td>Mean T\text{max} (h)</td>
<td>144</td>
<td>150</td>
<td>168</td>
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<tr>
<td>15</td>
<td>Mean AUC\text{0-1} (h*ng/mL)</td>
<td>5151279.93</td>
<td>11558003.89</td>
<td>15518762.38</td>
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<tr>
<td></td>
<td>Mean C\text{max} (ng/mL)</td>
<td>19067.26</td>
<td>46097.44</td>
<td>58973.28</td>
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<tr>
<td></td>
<td>Mean T\text{max} (h)</td>
<td>84.0</td>
<td>108</td>
<td>84.0</td>
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</table>

All parameters are mean values.

1. One 50 mg dose patient did not receive a 2nd dose

Source: Pharmacokinetic data from NM-002 Phase 1b/2a trial in short bowel syndrome
Short Bowel Syndrome
NM-002 Phase 1b/2a Results
Patrick H. Griffin, MD, FACP, CMO
Phase 1b/2a Study: SBS Clinical Trial Design

Open label, two-dose, dose escalation study of NM-002 in adult patients with SBS

NM-002 given twice, at 3 different dose levels, in 3 cohorts

Doses were administered on Days 1 and 15 by subcutaneous injection.

Main outcomes:
Safety & tolerability

Key secondary outcomes:
Total stool output (TSO); bowel movement frequency; urine output*; parenteral support; PK

Patients followed for 6 weeks after the second dose.

Overall demographics in trial: 5m/4f (8 Caucasian); avg.age = 51.8 y; avg.height = 175.1 cm; avg.weight = 68.0 kg; avg.BMI = 22.1 kg.m⁻²

*The study protocol called for an analysis of urine output, however, it proved difficult to measure in an ambulatory setting.
**Phase 1b/2a Trial: Treatment Emergent Adverse Events**

<table>
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<tr>
<th>System Organ Class Preferred Term</th>
<th>50 mg Cohort (n=3)</th>
<th>100 mg Cohort (n=4)</th>
<th>150 mg Cohort (n=2)</th>
<th>Any exposure to NM-002 (n=9)</th>
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</thead>
<tbody>
<tr>
<td># of subjects n (%)</td>
<td># of events n</td>
<td># of subjects n (%)</td>
<td># of events n</td>
<td># of subjects n (%)</td>
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<tr>
<td>TEAEs</td>
<td>3 (100.0)</td>
<td>7</td>
<td>3 (75.0)</td>
<td>6</td>
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<tr>
<td>Gastrointestinal disorders</td>
<td>2 (66.7)</td>
<td>6</td>
<td>2 (50.0)</td>
<td>5</td>
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<tr>
<td>- Nausea</td>
<td>2 (66.7)</td>
<td>3</td>
<td>2 (50.0)</td>
<td>3</td>
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<tr>
<td>- Vomiting</td>
<td>2 (66.7)</td>
<td>3</td>
<td>1 (25.0)</td>
<td>2</td>
</tr>
<tr>
<td>General disorders and administrative site conditions</td>
<td>1 (33.3)</td>
<td>1</td>
<td>0 (0.0)</td>
<td>0</td>
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<tr>
<td>- Oedema</td>
<td>1 (33.3)</td>
<td>1</td>
<td>0 (0.0)</td>
<td>0</td>
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<tr>
<td>Nervous system disorders</td>
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<td>0</td>
<td>0 (0.0)</td>
<td>0</td>
</tr>
<tr>
<td>- Dizziness</td>
<td>0 (0.0)</td>
<td>0</td>
<td>0 (0.0)</td>
<td>0</td>
</tr>
<tr>
<td>Skin and subcutaneous tissue disorders</td>
<td>0</td>
<td>0</td>
<td>1 (25.0)</td>
<td>1</td>
</tr>
<tr>
<td>- Rash</td>
<td>0</td>
<td>0</td>
<td>1 (25.0)</td>
<td>1</td>
</tr>
</tbody>
</table>

NM-002 was generally safe and well tolerated: 17 treatment-emergent adverse events (TEAEs) were observed in 9 patients, 15 of which were mild, transient and self-limited without further intervention. The majority of TEAEs were GI-related (nausea and vomiting).
## Phase 1b/2a Efficacy: Total Stool Output (TSO)

<table>
<thead>
<tr>
<th>Patient</th>
<th>NM-002 Dose (mg)</th>
<th>Baseline (mL)</th>
<th>First 48 Hours Post Dose 1 (mL)</th>
<th>Change from Baseline (mL)</th>
<th>First 48 Hours Post Dose 2 (mL)</th>
<th>Change from Baseline (mL)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>50</td>
<td>22508</td>
<td>12550</td>
<td>-9958</td>
<td>13950</td>
<td>-8558</td>
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<tr>
<td>2</td>
<td>50</td>
<td>1900</td>
<td>200</td>
<td>-1700</td>
<td>300</td>
<td>-1600</td>
</tr>
<tr>
<td>6¹</td>
<td>50</td>
<td>1175</td>
<td>350</td>
<td>-825</td>
<td>-</td>
<td>-</td>
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<tr>
<td>3</td>
<td>100</td>
<td>720</td>
<td>615</td>
<td>-105</td>
<td>325</td>
<td>-395</td>
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<tr>
<td>4</td>
<td>100</td>
<td>1285</td>
<td>420</td>
<td>-865</td>
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<td>1165</td>
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<td>5</td>
<td>100</td>
<td>2280</td>
<td>2000</td>
<td>-280</td>
<td>1940</td>
<td>-340</td>
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<td>7</td>
<td>100</td>
<td>5390</td>
<td>3010</td>
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<tr>
<td>8</td>
<td>150</td>
<td>2570</td>
<td>2150</td>
<td>-420</td>
<td>1480</td>
<td>-1090</td>
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<tr>
<td>9</td>
<td>150</td>
<td>4850</td>
<td>3900</td>
<td>-950</td>
<td>3000</td>
<td>-1850</td>
</tr>
</tbody>
</table>

1. Patient 06 did not receive a 2nd dose.  
2. The baseline prior to the second dose in this patient was substantially higher than the original baseline volume due to rapid increase in oral intake.

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**Lasting effect seen in patients, confirming single ascending dose T2DM study data (Cleland, et. al.)**
Phase 1b/2a Efficacy: Bowel Movement Frequency

<table>
<thead>
<tr>
<th>Patient</th>
<th>NM-002 Dose (mg)</th>
<th>Baseline (#)</th>
<th>First 48 Hours Post Dose 1 (#)</th>
<th>Change from Baseline (#)</th>
<th>First 48 Hours Post Dose 2 (#)</th>
<th>Change from Baseline (#)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>50</td>
<td>22</td>
<td>1</td>
<td>-21</td>
<td>4</td>
<td>-18</td>
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<tr>
<td>6¹</td>
<td>50</td>
<td>5</td>
<td>8</td>
<td>3</td>
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<tr>
<td>8</td>
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<td>12</td>
<td>9</td>
<td>-3</td>
<td>9</td>
<td>-3</td>
</tr>
<tr>
<td>9</td>
<td>150</td>
<td>13</td>
<td>9</td>
<td>-4</td>
<td>8</td>
<td>-5</td>
</tr>
</tbody>
</table>

Patients 1 & 3 have an ostomy, therefore missing from the bowel frequency table; total stool output (previous slide) more relevant in these patients

1. Patient 06 did not receive a 2nd dose
Urine Output Unreliable In This Ambulatory Setting Trial

To date, urine output has not been an efficacy endpoint for any SBS development program and there are currently no plans to use this as an end measure in our go-forward clinical and regulatory path.
Parenteral Support: Data from 2/5* Patients on NM-002 After Only Two Doses

*5 of 9 total patients in the trial were on PS; the remaining 3 patients (not shown) had no worsening of PS values and were stable on baseline PS
Results of the SF-36 Quality of Life instrument show directional improvement in multiple elements of health status over the course of this study.
Summary of Study Results

- Study met its primary objective: NM-002 demonstrated an excellent safety and tolerability profile.

- NM-002 demonstrated a clinically relevant improvement in total stool output (TSO) volume, supporting a clear “GO” decision for next phase of development.

- Data support twice monthly fixed dosing regimen (or better).

- Rapid improvement in clinically relevant efficacy outcomes:
  - All 9 patients showed meaningful reduction in total stool output volume within 48 hours of first dose.
    - Average TSO reduction of **42% from baseline** in all 9 patients at 48 hours post dose 1.
  - Efficacy seen with 1st dose carried through to 2nd dose at Day 15.
    - Average TSO reduction of **46% from baseline** in 7/8 patients within 48 hours post dose 2.
  - Bowel movement frequency: 4/7 after receiving 1 dose and 5/6 after receiving 2 doses had reductions.
  - Parenteral support: 2 of 5 patients on PS in this trial had reduction after each dose.
  - Quality of life: SF-36 data suggests overall improvements in general well-being in this trial.

---

1. Given the size of the study population, note that the trial was not powered for efficacy analyses.
2. Excludes 1 patient that did not receive a 2nd dose, and another patient that had substantial increase in oral intake prior to 2nd dose.
Clinical and Regulatory Path Forward

Patrick H. Griffin, MD, FACP, CMO
FDA Response on Planned Phase 2 Program

**FDA Type C meeting communication supports plan to initiate Phase 2 study with NM-002 for SBS using Total Stool Output (TSO) as the primary efficacy outcome measure**

**Multi-center, double-blind, double-dummy, randomized placebo-controlled trial; FDA has provided global anchor questions and specific guidance for performance of exit interviews to support clinical meaningfulness of observed efficacy**

**Secondary endpoints will include parenteral requirements, diarrhea impact, meal-related stool output, nocturnal stool output, sleep quality and quality of life**
Goals of Phase 2 Trial

• Remote trial execution in Covid-19 environment (Telehealth, remote outcome assessments, e.g., oral intake & TSO)

• Remote outcome measurements
  – stool output volume
  – oral intake volume
  – body weight
  – vital signs, etc.

• Identify most efficacious, safe dose compared to placebo

• Confirm target patient population (parenteral support not a requirement)
## Proposed NM-002 Study Design & Timeline

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>Treatment Day</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>0</td>
</tr>
<tr>
<td>1</td>
<td>6</td>
<td>50 mg</td>
</tr>
<tr>
<td>2</td>
<td>6</td>
<td>100 mg</td>
</tr>
<tr>
<td>3</td>
<td>6</td>
<td>50 mg</td>
</tr>
<tr>
<td>4</td>
<td>4</td>
<td>PBO</td>
</tr>
</tbody>
</table>

- Study population: all comers (regardless of phenotype and/or PS requirement)
- Site selection finalized: 5 (primary) + 1 (backup)
- Timeline: study initiation on target for 2Q 2021
Managing the Phase 2 Program During Covid-19

- Data collection considerations
- Training, communication and management of the trial team
- Patient recruitment
- Patient retention during the trial
- Managing investigational drug product & matching placebo
- Patient study sample management
- Monitoring & audit of study
- Study close-out, completion & data analysis
## Informing the NM-002 Phase 3 SBS Clinical Program

<table>
<thead>
<tr>
<th></th>
<th>teduglutide (approved)</th>
<th>glepaglutide (Phase 3 investigational agent)</th>
<th>apraglutide (phase 3 investigational agent)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase 3 patient number</td>
<td>173</td>
<td>129</td>
<td>144</td>
</tr>
<tr>
<td>Duration of double-blind treatment</td>
<td>24 weeks</td>
<td>24 weeks</td>
<td>48 weeks (efficacy at 24 weeks)</td>
</tr>
<tr>
<td>No. of groups</td>
<td>2 (1 drug/1 pbo)</td>
<td>3 (2 drug/1 pbo)</td>
<td>2 (1 drug/1 pbo)</td>
</tr>
<tr>
<td>Duration of safety extension</td>
<td>30 months</td>
<td>2 Years*</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Based on current data we project a double-blind treatment period of 12 weeks enrolling 80-100 patients followed by adequate long-term safety timeline to be determined.

Source: Gattex® Prescribing Information; *Clinicaltrials.gov accessed March 18, 2021
NM-002 Near Term Inflection Points

- **Early December**: Topline Phase 1b/2a results
- **April**: Pending USAN Name
- **4Q21**: Topline Phase 2 results

- **2020**
  - March 23: 9 Meters SBS R & D Day - Full data set review

- **2021**
  - 2Q21: Phase 2 initiation - 22 patient trial starts
  - 4Q21: Phase 3 SBS study initiation
Thank You

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