



FDA Approval Conference Call

September 30, 2022



photo in memory of Mick, a husband and father, who was a gifted tattoo artist and musician

Amylyx Participants



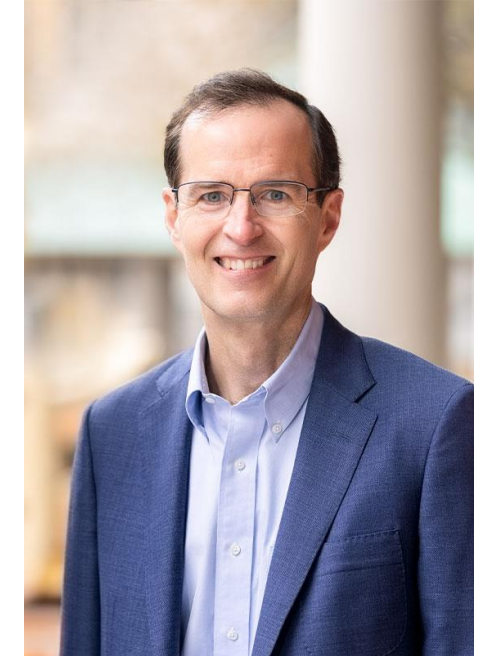
Justin Klee
Co-CEO



Josh Cohen
Co-CEO



Margaret Olinger
Global Head of
Commercial & CCO



James Frates
Chief Financial Officer

Disclaimer

Statements contained in this presentation regarding matters that are not historical facts are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Such statements include, but are not limited to, statements regarding the potential approval of AMX0035 for the treatment of ALS in countries other than Canada and the United States; the potential of AMX0035 as a treatment for ALS and the Company’s plans to explore the use of AMX0035 for other neurodegenerative diseases; the potential market acceptance and market opportunity for RELYVRIO™; the Company’s ability to make RELYVRIO available commercially in the United States, as well as access to and coverage for RELYVRIO; and expectations regarding our longer-term strategy. Any forward-looking statements in this presentation are based on management’s current expectations of future events and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the forward-looking statements include: the success, cost, and timing of Amylyx’ program development activities, Amylyx’ ability to successfully launch RELYVRIO in the United States, Amylyx’ ability to execute on its commercial and regulatory strategy, regulatory developments, expectations regarding the timing of EMA review of AMX0035 for the treatment of ALS, Amylyx’ ability to fund operations, and the impact that the ongoing COVID-19 pandemic will have on Amylyx’ operations, as well as the risks and uncertainties set forth in Amylyx’ United States Securities and Exchange Commission (SEC) filings, including Amylyx’ Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, and subsequent filings with the SEC. All forward-looking statements contained in this presentation speak only as of the date on which they were made. Amylyx undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.



Our mission is to one day end the suffering caused by neurodegenerative diseases.

Every day, we strive for better therapies.



 **relyvrio™**
(sodium phenylbutyrate and
taurursodiol) for oral
suspension 3 g/1 g

is approved in the
United States





ALS is Relentlessly Progressive and Universally Fatal Despite Two FDA-approved Therapies

- Significant unmet need for new treatment options
- ALS leads to deteriorating muscle function, the inability to move and speak, respiratory paralysis, and death^{1,2}

>90%

of people living with ALS have no family history of the disease

~50%

of people with ALS will pass away in about 2 years from diagnosis³

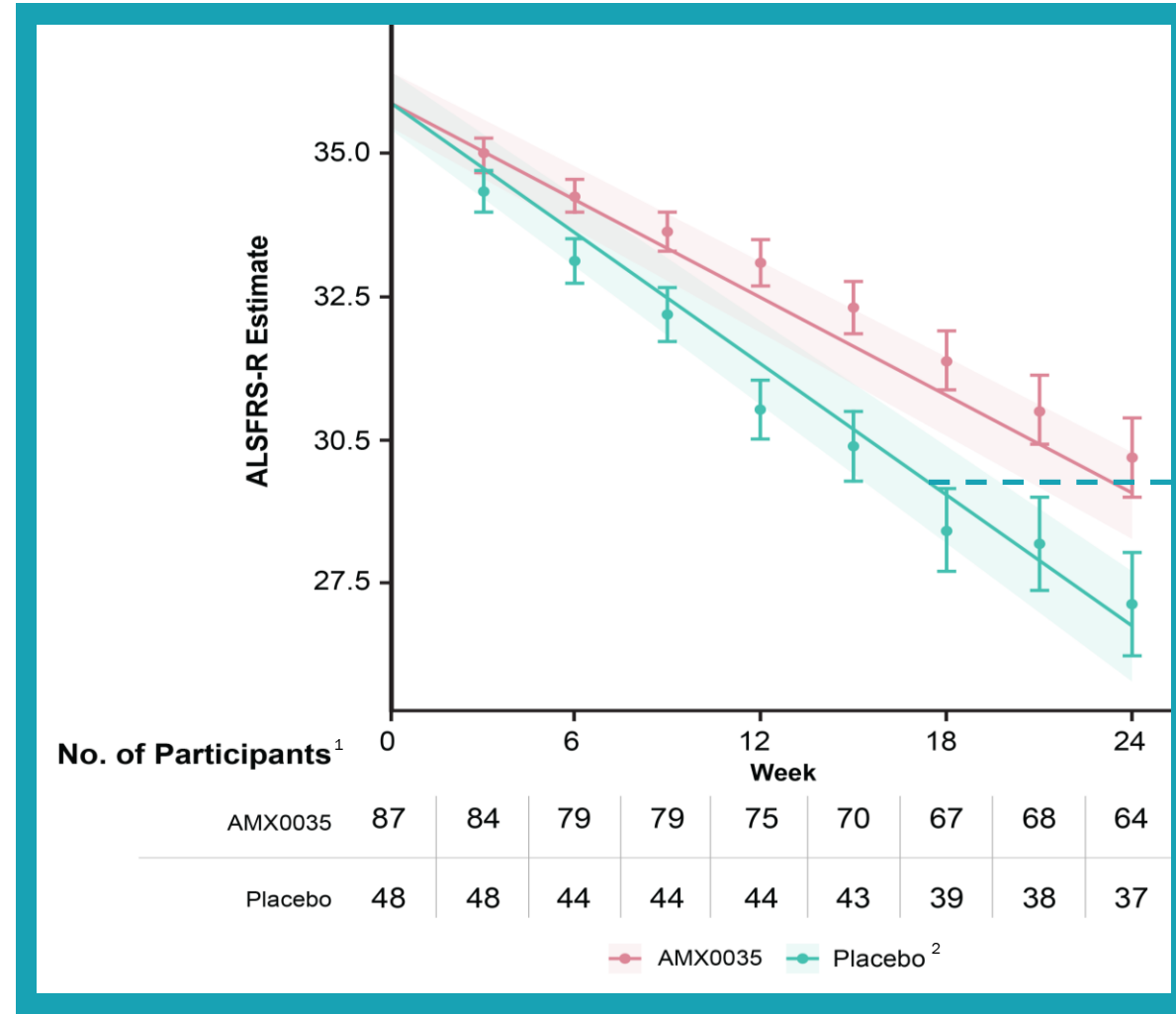
photo in memory of Eric, a husband and father, who was a courageous skydiver and Army veteran

References: 1. Brown RH, Al-Chalabi A. *N Engl J Med.* 2017;377(2):162-172. 2. Al-Chalabi A, et al. *Lancet Neurol.* 2016;15(11):1182-1194. 3. Knibb JA, Keren N, Kulka A, et al. *J Neurol Neurosurg Psychiatry.* 2016;87(12):1361-1367.



CENTAUR Trial Results

Statistically Significant Functional Benefit as Measured by the ALSFRS-R, the Gold Standard Clinical Scale in ALS



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Trial of Sodium Phenylbutyrate–Taurursodiol for Amyotrophic Lateral Sclerosis

S. Paganoni, E.A. Macklin, S. Hendrix, J.D. Berry, M.A. Elliott, S. Maiser, C. Karam, J.B. Caress, M.A. Owegi, A. Quick, J. Wymer, S.A. Goutman, D. Heitzman, T. Heiman-Patterson, C.E. Jackson, C. Quinn, J.D. Rothstein, E.J. Kasarskis, J. Katz, L. Jenkins, S. Ladha, T.M. Miller, S.N. Scelsa, T.H. Vu, C.N. Fournier, J.D. Glass, K.M. Johnson, A. Swenson, N.A. Goyal, G.L. Pattee, P.L. Andres, S. Babu, M. Chase, D. Dagostino, S.P. Dickson, N. Ellison, M. Hall, K. Hendrix, G. Kittle, M. McGovern, J. Ostrow, L. Pothier, R. Randall, J.M. Shefner, A.V. Sherman, E. Tustison, P. Vigneswaran, J. Walker, H. Yu, J. Chan, J. Wittes, J. Cohen, J. Klee, K. Leslie, R.E. Tanzi, W. Gilbert, P.D. Yeramian, D. Schoenfeld, and M.E. Cudkowicz

2.32 point difference, p=0.03

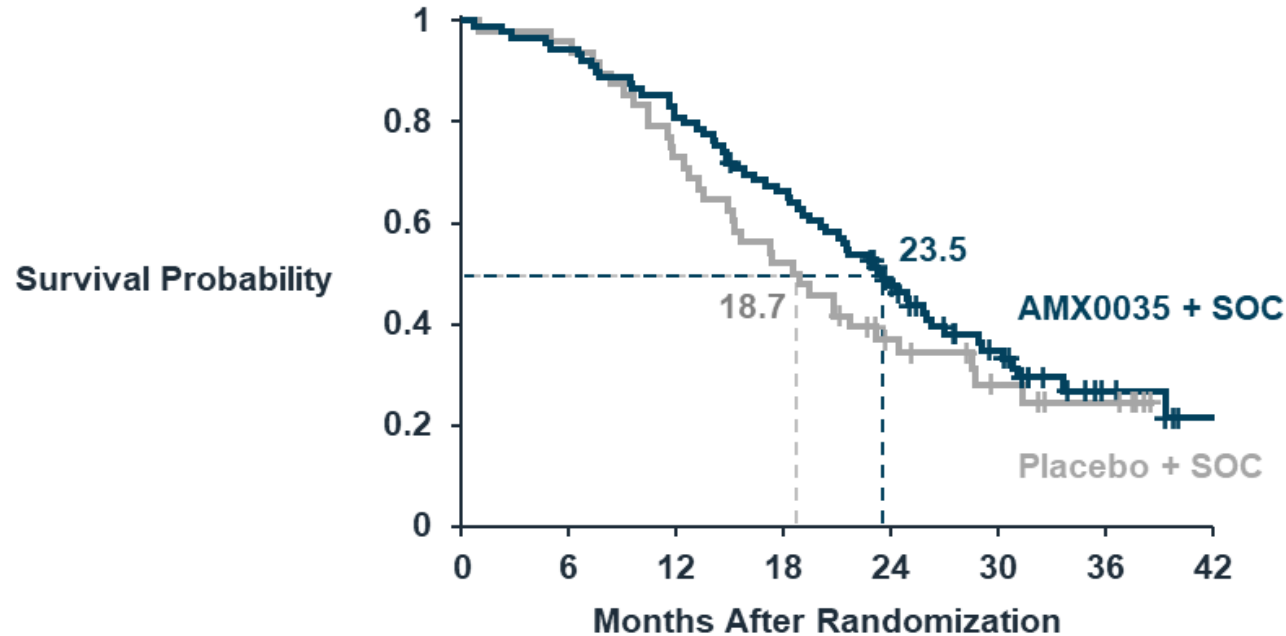
“Each category in the ALSFRS-R seems clinically important, and because each domain includes only five levels that span 0 (cannot do) to 4 (normal), prevention of even 1 unit of worsening in a single domain seems meaningful and desirable for individuals with ALS”.³

References: **1.** Two participants did not have follow-up efficacy assessments and were not included in the efficacy population (modified intention to treat n=135). **2.** 77% of participants were on Riluzole or edaravone at or prior to study entry. **3.** FDA Center for Drug Evaluation and Research, Application Number 209176Orig1s000, Office Director Memo, Ellis F. Unger, MD, May 4, 2017. Paganoni S, et al. New Eng J Med. 2020.



CENTAUR Trial Results

Participants Randomized to RELYVRIO Were Observed to Survive Longer Than Those Randomized to Placebo



In a post hoc, long-term Intention-to-treat (ITT) survival analysis using data from the last participant last visit in the open-label phase (March 2021), median survival duration was 23.5 months in the group originally randomized to RELYVRIO and 18.7 months in the group originally randomized to placebo (4.8-month difference, HR=0.64, 95% CI=0.416-0.995)*

Cox Regression Model	
HR (95% CI)	0.64 (0.416, 0.995)
# of events	94

Note: This is an ITT (all 137 patients) analysis
Survival defined as All Cause Mortality (True Overall Survival)

CI = confidence interval; HR = hazard ratio.

*This exploratory analysis should be interpreted cautiously given the limitations of data collected outside of a controlled study, which may be subject to confounding.

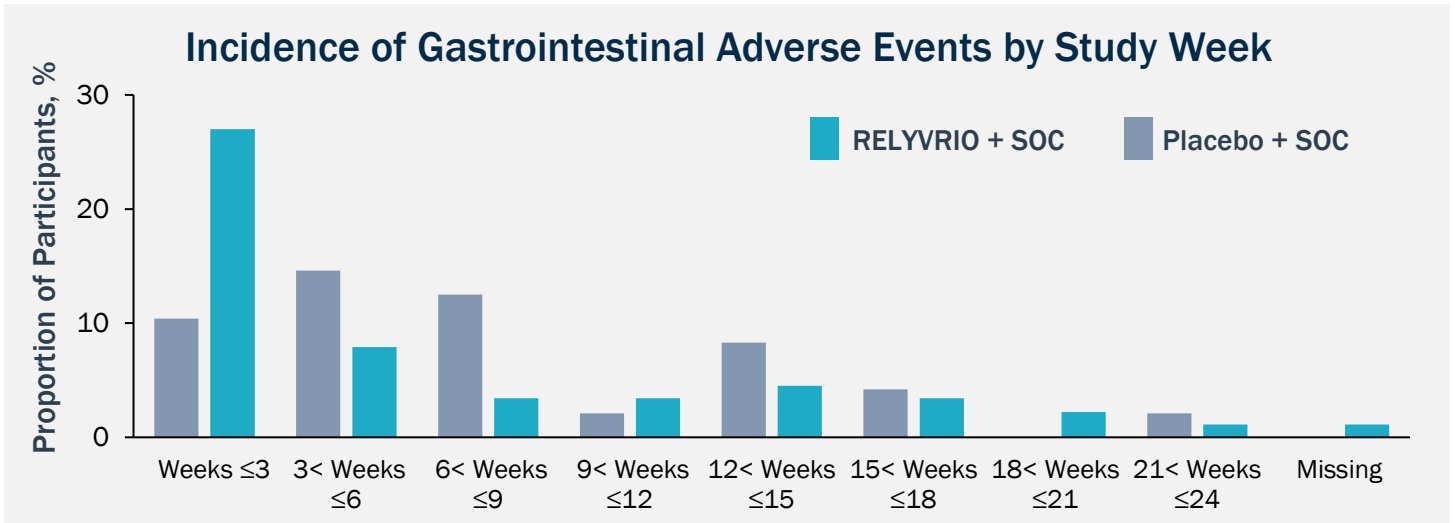


CENTAUR Adverse Events (AEs)

The most common adverse events occurring with RELYVRIO (at least 15% and at least 5% greater than placebo) were diarrhea, abdominal pain, nausea, and upper respiratory tract infection. Gastrointestinal-related adverse reactions occurred throughout the study but were more frequent during the first three weeks of treatment.

Adverse Reactions Reported in More than 5% of RELYVRIO-Treated Patients with ALS and at least 5% Greater than Placebo

Adverse Reaction	RELYVRIO (n=89) %	Placebo (n=48) %
Diarrhea*	25	19
Abdominal pain*	21	13
Nausea	18	13
Upper respiratory tract infection*	18	10
Fatigue*	12	6
Salivary hypersecretion	11	2
Dizziness	10	4



* Adverse reaction is composed of several similar terms. Paganoni S, et al. N Engl J Med. 2020;383:919-930.



relyvrio™

(sodium phenylbutyrate and taurursodiol) for oral suspension 3 g/1 g

Overview of Prescribing Information

Indication Statement

RELYVRIO is indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults.

Dosing and Administration

Administered orally or via a feeding tube. The recommended dosage for the first 3 weeks of treatment is 1 packet daily, increasing to 2 packets daily starting at the beginning of week 4.

Most common adverse events occurring with RELYVRIO

- Diarrhea
- Abdominal pain
- Nausea
- Upper respiratory infection

Please see full Prescribing Information at RELYVRIO.com

Helping People with ALS Gain Access to RELYVRIO

Margaret Olinger

Global Head of Commercial and
Chief Commercial Officer



Significant Unmet Need in the U.S. and Globally



ALS is a global disease that affects at least **200,000 people worldwide**



Affects people globally regardless of ethnic, geographic, or racial background



United States
~29,000 People
living with ALS



Canada
~3,000 People
living with ALS



Europe
>30,000 People
living with ALS
(European Union and
United Kingdom)

Experienced Commercial Team Preparing the Market

Amylyx has activated four core market development priorities pre-launch to ensure success at launch

- 1 Raising awareness of RELYVRIO and Amylyx
- 2 Educating on disease state and RELYVRIO data
- 3 Partnering with key accounts to educate on access and coverage process
- 4 Deepening our understanding of the market

Targeted Approach Covering The Vast Majority of the U.S. Market

186

ALS Association Centers¹

~500

ALS physicians represent
~2/3 of prescriptions²

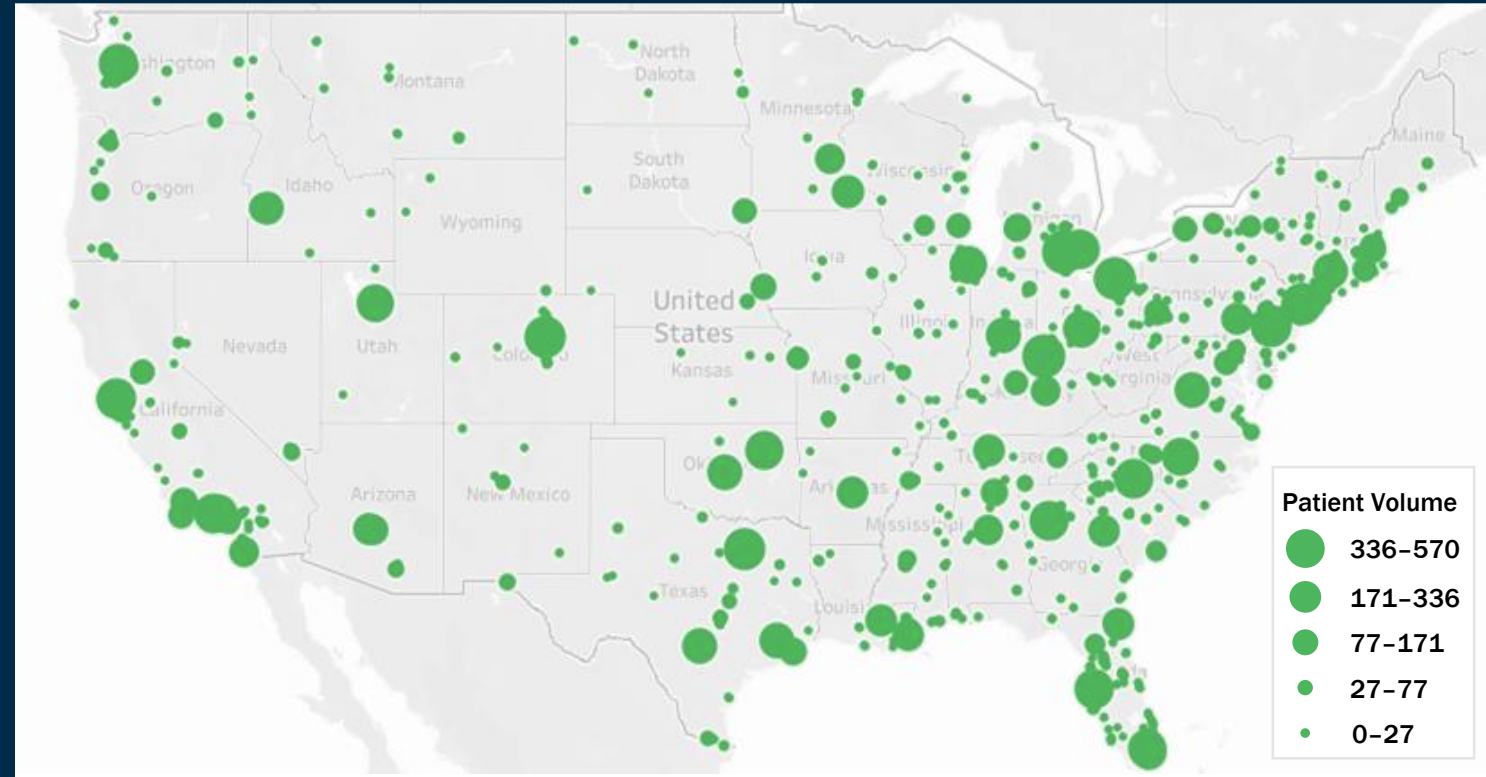
~20 years

on average team launch
experience; many have deep
expertise in rare disease

3

specialty pharmacies used
for distribution

Physicians Treating ALS by Patient Volume²



A wide range of support

Through your dedicated ACT Care Coordinator, you will be connected with the following support and resources.

Reimbursement & Insurance Support

We can help you understand your insurance coverage and benefits for RELYVRIO.

Financial Assistance, if Eligible

We can provide resources for access support through our \$0 Co-Pay Program,* Interim Access Program, and Patient Assistance Program. Talk to your ACT Care Coordinator or visit AmylyxCareTeam.com to learn more.

ALS Education

Our team is here to support you with learning more about ALS and your treatment.

Your doctor is always your best source for treatment information.

Partnership With Specialty Pharmacies

Because RELYVRIO is a specialty medication, it is only available through specialty pharmacies. We'll partner with these facilities to coordinate delivery to your home. To learn more, visit AmylyxCareTeam.com.

Continuous Support

We'll help you get started on RELYVRIO treatment and keep supporting you as you continue on it.

Call ACT Today
866-318-2989
 Monday-Friday, 8 AM to 8 PM ET

*Out-of-pocket costs related to medication, appointments, evaluations, testing, or other related services are not covered by the RELYVRIO Co-Pay Program. The RELYVRIO Co-Pay Program is not available for prescriptions purchased under Medicare, Medicaid, TRICARE, or other federal- and state-funded programs. Amylyx reserves the right to amend or terminate the Program at any time without notice. Co-pay amounts after applying co-pay assistance may depend on the individual's insurance plan and may vary. The RELYVRIO Co-Pay Program is intended to help individuals afford RELYVRIO.

IMPORTANT SAFETY INFORMATION (continued)

Before you receive RELYVRIO, tell your doctor about all of your medical conditions, including if you:

- Have high blood pressure
- Have kidney problems



Compassionate support from a caring team

You'll get to know the ACT™ team as people who are deeply dedicated to your well-being, providing personalized support throughout your treatment journey.

Team of actual Amylyx employees



- Committed to answering your questions by phone before you are enrolled in ACT
- Help you get enrolled in the program



- Will be paired with you throughout your treatment journey
- Available by phone or email, once you are enrolled in ACT
- An experienced, full-time Amylyx employee
- Dedicated to providing the highest levels of customer service



- Registered nurses who can provide additional education about ALS and RELYVRIO™ (sodium phenylbutyrate and taurursodiol)*
- *Your doctor is always your best source for treatment information.



Your ACT Care Coordinator is your primary source for one-on-one support

For more information about RELYVRIO, please see additional Important Safety Information throughout and the full [Prescribing Information](#) and [Medication Guide](#).

Amylyx Care Team (ACT) Support Program

Ready to provide personalized support to adults living with ALS and healthcare professionals

Our Team is Prepared to Answer Questions



Investors and Media

Lindsey Allen
(857) 320-6244
investors@amylyx.com
amylyxmediateam@amylyx.com



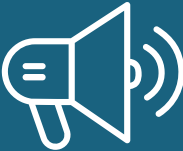
Health Care Professionals

Amylyx Care Team
(866) 318-2989
amylyxcareteam@amylyx.com



People with ALS and their Families

Amylyx Care Team
(866) 318-2989
amylyxcareteam@amylyx.com



Advocacy

Irene Aquino
(857) 320-6251
advocacy@amylyx.com

Focused Priorities

Helping people gain access to RELYVRIO™ in the U.S. and ALBRIOZA™ in Canada, bringing a much-needed new treatment option to people with ALS



ALBRIOZA™ Commercial
Launch in Canada



RELYVRIO™ Commercial
Launch in U.S.



Potential EMA Decision
in 1H'23



Q&A



Thank you.

Our mission is to one day end the suffering caused by neurodegenerative diseases.

Every day, we strive for better therapies.