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): **January 11, 2021**

AMICUS THERAPEUTICS, INC.
(Exact Name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction of
Incorporation)

Delaware	001-33497	71-0869350
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

1 Cedar Brook Drive, Cranbury, NJ 08512
(Address of Principal Executive Offices, and Zip Code)

609-662-2000
Registrant's Telephone Number, Including Area Code

(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:

☐ 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 $0.01	FOLD	NASDAQ

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 2.02 – Results of Operations and Financial Condition

On January 11, 2021, Amicus Therapeutics, Inc. (the "Company") issued a press release announcing preliminary 2020 revenue and its 2021 strategic outlook, along with various business updates. A copy of the press release is filed as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information furnished pursuant to this Item 2.02, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, and shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 8.01 – Other Events

On January 11, 2021, the Company also published presentation materials which senior management will be using in its meetings with investors and analysts at the 39th Annual J.P. Morgan Healthcare Conference. A copy of these materials is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference

Item 9.01 Financial Statements and Exhibits

(d) Exhibits:

Exhibit No.	Description
99.1	Press Release dated January 11, 2021
99.2	Presentation Materials – 39th Annual J.P. Morgan Healthcare Conference
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Signature Page

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: January 11, 2021

AMICUS THERAPEUTICS, INC.
By: /s/ Ellen S. Rosenberg
Name: Ellen S. Rosenberg
Title: Chief Legal Officer and Corporate Secretary

Amicus Therapeutics Reports Preliminary 2020 Revenue and Provides 2021 Outlook

Full-Year 2020 Galafold® Revenue of ~$261M Exceeds Guidance

Strengthened Galafold IP Portfolio Now Includes 24 Issued Patents Including 13 Patents through 2038

Pompe Phase 3 PROPEL Study Last Patient, Last Visit Complete with Data Expected in 1Q2021

AT-GAA Pompe Clinical and CMC Milestones On-Track to Support 2021 BLA and MAA

Multiple Data and Manufacturing Updates and Advancements Planned Across Industry-Leading Rare Disease Gene Therapy Portfolio

Cash Position Sufficient to Achieve Self-Sustainability

CRANBURY, NJ, January 11, 2021 – Amicus Therapeutics (Nasdaq: FOLD), a patient-dedicated global biotechnology company focused on discovering, developing and delivering novel medicines for rare diseases, today provided preliminary, unaudited Galafold revenue for the full-year 2020 and introduced its full-year 2021 strategic outlook and financial guidance.

Over the previous year, Amicus substantially met or exceeded its strategic priorities, highlighted by:

- $261 million of global product revenue for Galafold driven by strong adoption and patient adherence
- Completed last patient, last visit of the AT-GAA Phase 3 PROPEL clinical study, advanced manufacturing activities, and initiated the rolling Biologics License Application (BLA) with the U.S. Food and Drug Administration (FDA)
- Advanced clinical development and manufacturing for CLN6 and CLN3 Batten programs
- Progressed Pompe gene therapy and disclosed Fabry as the next gene therapy IND candidate
- Maintained strong financial position

John F. Crowley, Chairman and Chief Executive Officer of Amicus Therapeutics, Inc., stated, “During 2020, Amicus remained steadfast on our journey to becoming a leading global rare disease biotechnology company. Despite the extraordinary challenges of COVID, Amicus emerged from 2020 a better and stronger company organizationally, strategically, scientifically and financially. Following continued momentum and strong adoption across the globe for our Fabry precision medicine Galafold, we have again for 2020 exceeded our annual revenue guidance. We are eagerly looking ahead to our Phase 3 readout of AT-GAA in Pompe disease this quarter with high expectations that this novel medicine has the potential to become the new standard of care in Pompe disease treatment. And finally, our world leading gene therapy pipeline gives us tremendous promise in the ability to develop next-generation gene therapies to treat many devastating rare diseases. Amicus is in a stronger position than ever and remains focused on transforming the lives of people living with these rare, life-threatening conditions and creating significant value for our shareholders.”

Amicus is focused on the following five key strategic priorities in 2021:

- Achieve continued double-digit growth and Galafold revenue of at least $300 million+[1]
- Report data from the AT-GAA Phase 3 PROPEL study and complete BLA and MAA filings for regulatory approvals
- Advance clinical studies, regulatory discussions and scientific data across industry leading gene therapy pipeline
- Further manufacturing capabilities and capacity to build world-class technical operations to support all gene therapy programs
- Maintain strong financial position

[1]Guidance range to be provided on full-year earnings call.

Mr. Crowley will discuss Amicus' corporate objectives and key milestones in a presentation at the 39th Annual J.P. Morgan Healthcare Conference on Tuesday, January 12, 2021, at 8:20 a.m. ET. A live webcast of the presentation can be accessed through the Investors section of the Amicus Therapeutics corporate web site at http://ir.amicusrx.com/events.cfm, and will be archived for 90 days.

Full-Year 2020 Galafold Summary and 2021 Guidance

Global revenue for Galafold in full-year 2020 was approximately $261 million, preliminary and unaudited, representing a year-over-year increase of 43% from total revenue of $182 million in 2019, and exceeded the Company's 2020 guidance of $250 million to $260 million despite worsening of the COVID-19 pandemic towards the end of the year. Full-year revenue benefited from a positive currency impact of approximately $2 million. Fourth quarter Galafold revenue was approximately $70 million, preliminary and unaudited. While we observed increased lag times between patient identification and Galafold initiation due to the resurgence of COVID in the fourth quarter, demand for Galafold for Fabry patients with amenable variants worldwide remained strong with queues of potential new Galafold patients in multiple geographies. We also continue to see 90%+ compliance rates among already treated Galafold patients.

For the full-year 2021, the Company anticipates total Galafold revenue at least $300 million+. Double-digit revenue growth in 2021 is expected to be driven by continued operational growth and commercial execution across all major markets, including the U.S., EU, U.K. and Japan. Non-GAAP operating expense guidance in 2021 is expected to remain flat at $410 million to $420 million, driven by continued investment in the global Galafold launch, AT-GAA clinical studies and advancing the gene therapy pipeline. The current cash position is sufficient to achieve self-sustainability without the need for future dilutive financing.

Updates and Anticipated 2021 Milestones by Program

Galafold (migalastat) Oral Precision Medicine for People Living with Fabry Disease and have an Amenable Variant

- Continued revenue growth in 2021 of at least $300 million. Guidance range to be provided on full-year earnings call.
- Following the issuance of 11 new patents covering a range of treatment methods, Galafold has 24 issued patents, 13 of which extend IP protection into 2038
- Plans to expand EU label to cover adolescent population
- Continued geographic expansion
- Registry and other Phase 4 studies

AT-GAA For Pompe Disease

- Report data from the AT-GAA Phase 3 PROPEL study in 1Q2021
- Complete the BLA submission in 1H2021 and the EU MAA submission to be completed in 2H2021
- Ongoing supportive studies, including an open-label study in 12- to <18-year-olds living with Pompe and plans to initiate additional pediatric studies in 2021

Gene Therapy Pipeline

- As part of the J.P. Morgan Conference virtual presentation, Amicus will highlight initial preclinical proof of concept data in CLN1 Batten disease and its plans on initiating an early-stage gene therapy program in Angelman Syndrome
- Advance manufacturing and regulatory discussions to finalize clinical and regulatory path for the CLN6 Batten disease gene therapy program and begin dosing additional patients with GMP grade material
- Report initial data from the CLN3 Batten disease Phase 1/2 study, advance manufacturing and regulatory discussions to finalize clinical and regulatory path, and submit IND for next clinical study
- Continue IND-enabling work in both Pompe and Fabry
- Additional preclinical data and potential IND candidate declarations across multiple preclinical programs
- Manufacturing advancements and updates across the portfolio

About Galafold

Galafold® (migalastat) 123 mg capsules is an oral pharmacological chaperone of alpha-Galactosidase A (alpha-Gal A) for the treatment of Fabry disease in adults who have amenable *GLA* variants. In these patients, Galafold works by stabilizing the body's own dysfunctional enzyme so that it can clear the accumulation of disease substrate. Globally, Amicus Therapeutics estimates that approximately 35 to 50 percent of Fabry patients may have amenable *GLA* variants, though amenability rates within this range vary by geography. Galafold is approved in over 40 countries around the world, including the U.S., EU, U.K., Japan and others.

U. S. INDICATIONS AND USAGE

Galafold is indicated for the treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene (*GLA*) variant based on *in vitro* assay data.

This indication is approved under accelerated approval based on reduction in kidney interstitial capillary cell globotriaosylceramide (KIC GL-3) substrate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

U.S. IMPORTANT SAFETY INFORMATION

ADVERSE REACTIONS

The most common adverse reactions reported with Galafold (≥10%) were headache, nasopharyngitis, urinary tract infection, nausea and pyrexia.

USE IN SPECIFIC POPULATIONS

There is insufficient clinical data on Galafold use in pregnant women to inform a drug-associated risk for major birth defects and miscarriage. Advise women of the potential risk to a fetus.

It is not known if Galafold is present in human milk. Therefore, the developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for Galafold and any potential adverse effects on the breastfed child from Galafold or from the underlying maternal condition.

Galafold is not recommended for use in patients with severe renal impairment or end-stage renal disease requiring dialysis.

The safety and effectiveness of Galafold have not been established in pediatric patients.

To report Suspected Adverse Reactions, contact Amicus Therapeutics at 1-877-4AMICUS or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For additional information about Galafold, including the full U.S. Prescribing Information, please visit https://www.amicusrx.com/pi/Galafold.pdf.

EU Important Safety Information

Treatment with Galafold should be initiated and supervised by specialists experienced in the diagnosis and treatment of Fabry disease. Galafold is not recommended for use in patients with a nonamenable mutation.

- Galafold is not intended for concomitant use with enzyme replacement therapy.
- Galafold is not recommended for use in patients with Fabry disease who have severe renal impairment (<30 mL/min/1.73 m^2). The safety and efficacy of Galafold in children 0–15 years of age have not yet been established.
- No dosage adjustments are required in patients with hepatic impairment or in the elderly population.
- There is very limited experience with the use of this medicine in pregnant women. If you are pregnant, think you may be pregnant, or are planning to have a baby, do not take this medicine until you have checked with your doctor, pharmacist, or nurse.
- While taking Galafold, effective birth control should be used. It is not known whether Galafold is excreted in human milk.
- Contraindications to Galafold include hypersensitivity to the active substance or to any of the excipients listed in the PRESCRIBING INFORMATION.
- It is advised to periodically monitor renal function, echocardiographic parameters and biochemical markers (every 6 months) in patients initiated on Galafold or switched to Galafold.
- OVERDOSE: General medical care is recommended in the case of Galafold overdose.
- The most common adverse reaction reported was headache, which was experienced by approximately 10% of patients who received Galafold. For a complete list of adverse reactions, please review the SUMMARY OF PRODUCT CHARACTERISTICS.
- Call your doctor for medical advice about side effects.

For further important safety information for Galafold, including posology and method of administration, special warnings, drug interactions and adverse drug reactions, please see the European SmPC for Galafold available from the EMA website at www.ema.europa.eu.

About Fabry Disease

Fabry disease is an inherited lysosomal disorder caused by deficiency of an enzyme called alpha-galactosidase A (alpha-Gal A), which results from mutations in the GLA gene. The primary biological function of alpha-Gal A is to degrade specific lipids in lysosomes, including globotriaosylceramide (referred to here as GL-3 and also known as Gb3). Lipids that can be degraded by the action of alpha-Gal A are called "substrates" of the enzyme. Reduced or absent levels of alpha-Gal A activity lead to the accumulation of GL-3 in the affected tissues, including heart, kidneys, and skin. Accumulation of GL-3 and progressive deterioration of organ function is believed to lead to the morbidity and mortality of Fabry disease. The symptoms can be severe, differ from person to person, and begin at an early age.

About Amicus Therapeutics

Amicus Therapeutics (Nasdaq: FOLD) is a global, patient-dedicated biotechnology company focused on discovering, developing and delivering novel high-quality medicines for people living with rare metabolic diseases. With extraordinary patient focus, Amicus Therapeutics is committed to advancing and expanding a robust pipeline of cutting-edge, first- or best-in-class medicines for rare metabolic diseases. For more information please visit the company's website at www.amicusrx.com, and follow us on Twitter and LinkedIn.

Forward Looking Statement

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 relating to preclinical and clinical development of our product candidates, the timing and reporting of results from preclinical studies and clinical trials, the prospects and timing of the potential regulatory approval of our product candidates, commercialization plans, manufacturing and supply plans, financing plans, and the projected revenues and cash position for the Company. The inclusion of forward-looking statements should not be regarded as a representation by us that any of our plans will be achieved. Any or all of the forward-looking statements in this press release may turn out to be wrong and can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. For example, with respect to statements regarding the goals, progress, timing, and outcomes of discussions with regulatory authorities, and in particular the potential goals, progress, timing, and results of preclinical studies and clinical trials, including as they are impacted by COVID-19 related disruption, are based on current information. The potential impact on operations from the COVID-19 pandemic is inherently unknown and cannot be predicted with confidence and may cause actual results and performance to differ materially from the statements in this release, including without limitation, because of the impact on general political and economic conditions, including as a result of efforts by governmental authorities to mitigate COVID-19, such as travel bans, shelter in place orders and third-party business closures and resource allocations, manufacturing and supply chain disruptions and limitations on patient access to commercial or clinical product. In addition to the impact of the COVID-19 pandemic, actual results may differ materially from those set forth in this release due to the risks and uncertainties inherent in our business, including, without limitation: the potential that results of clinical or preclinical studies indicate that the product candidates are unsafe or ineffective; the potential that it may be difficult to enroll patients in our clinical trials; the potential that regulatory authorities, including the FDA, EMA, and PMDA, may not grant or may delay approval for our product candidates; the potential that we may not be successful in commercializing Galafold in Europe, Japan, the US and other geographies or our other product candidates if and when approved; the potential that preclinical and clinical studies could be delayed because we identify serious side effects or other safety issues; the potential that we may not be able to manufacture or supply sufficient clinical or commercial products; and the potential that we will need additional funding to complete all of our studies and manufacturing. Further, the results of earlier preclinical studies and/or clinical trials may not be predictive of future results. Statements regarding corporate financial guidance and financial goals and the attainment of such goals. With respect to statements regarding projections of the Company's revenue and cash position, actual results may differ based on market factors and the Company's ability to execute its operational and budget plans. In addition, all forward-looking statements are subject to other risks detailed in our Annual Report on Form 10-K for the year ended December 31, 2019 and the Quarterly Report filed on Form 10-Q for the quarter ended September 30, 2020. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, and we undertake no obligation to revise or update this news release to reflect events or circumstances after the date hereof.

Non-GAAP Financial Measures

In addition to financial information prepared in accordance with U.S. GAAP, this presentation also contains adjusted financial measures that we believe provide investors and management with supplemental information relating to operating performance and trends that facilitate comparisons between periods and with respect to projected information. These adjusted financial measures are non-GAAP measures and should be considered in addition to, but not as a substitute for, the information prepared in accordance with U.S. GAAP. We typically exclude certain GAAP items that management does not believe affect our basic operations and that do not meet the GAAP definition of unusual or non-recurring items. Other companies may define these measures in different ways. When we provide our expectation for non-GAAP operating expenses on a forward-looking basis, a reconciliation of the differences between the non-GAAP expectation and the corresponding GAAP measure generally is not available without unreasonable effort due to potentially high variability, complexity and low visibility as to the items that would be excluded from the GAAP measure in the relevant future period, such as unusual gains or losses. The variability of the excluded items may have a significant, and potentially unpredictable, impact on our future GAAP results.

CONTACT:

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Amicus Therapeutics
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FOLD–G

Exhibit 99.2

Amicus Therapeutics®

39th Annual J.P. Morgan Healthcare Conference

John F. Crowley, Chairman and Chief Executive Officer
January 12, 2021

Forward-Looking Statements

This presentation contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 relating to preclinical and clinical development of our product candidates, the timing and reporting of results from preclinical studies and clinical trials, the prospects and timing of the potential regulatory approval of our product candidates, commercialization plans, manufacturing and supply plans, financing plans, and the projected revenues and cash position for the Company. The inclusion of forward-looking statements should not be regarded as a representation by us that any of our plans will be achieved. Any or all of the forward-looking statements in this press release may turn out to be wrong and can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. For example, with respect to statements regarding the goals, progress, timing, and outcomes of discussions with regulatory authorities, and in particular the potential goals, progress, timing, and results of preclinical studies and clinical trials, including as they are impacted by COVID-19 related disruption, are based on current information. The potential impact on operations from the COVID-19 pandemic is inherently unknown and cannot be predicted with confidence and may cause actual results and performance to differ materially from the statements in this release, including without limitation, because of the impact on general political and economic conditions, including as a result of efforts by governmental authorities to mitigate COVID-19, such as travel bans, shelter in place orders and third-party business closures and resource allocations, manufacturing and supply chain disruptions and limitations on patient access to commercial or clinical product. In addition to the impact of the COVID-19 pandemic, actual results may differ materially from those set forth in this release due to the risks and uncertainties inherent in our business, including, without limitation: the potential that results of clinical or preclinical studies indicate that the product candidates are unsafe or ineffective; the potential that it may be difficult to enroll patients in our clinical trials; the potential that regulatory authorities, including the FDA, EMA, and PMDA, may not grant or may delay approval for our product candidates; the potential that we may not be successful in commercializing Galafold in Europe, Japan, the US and other geographies or our other product candidates if and when approved; the potential that preclinical and clinical studies could be delayed because we identify serious side effects or other safety issues; the potential that we may not be able to manufacture or supply sufficient clinical or commercial products; and the potential that we will need additional funding to complete all of our studies and manufacturing. Further, the results of earlier preclinical studies and/or clinical trials may not be predictive of future results. Statements regarding corporate financial guidance and financial goals and the attainment of such goals. With respect to statements regarding projections of the Company's revenue and cash position, actual results may differ based on market factors and the Company's ability to execute its operational and budget plans. In addition, all forward-looking statements are subject to other risks detailed in our Annual Report on Form 10-K for the year ended December 31, 2019 and the Quarterly Report filed on Form 10-Q for the quarter ended September 30, 2020. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, and we undertake no obligation to revise or update this news release to reflect events or circumstances after the date hereof.

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A RARE COMPANY

A leading fully integrated, global rare disease biotechnology company

Galafold® (migalastat)
First Oral Precision Medicine for Fabry Disease

Gene Therapy PLATFORM
Protein Engineering & Glycobiology

World Class BIOLOGICS Capabilities

EMPLOYEES in 27 Countries

AT-GAA
Phase 3 in Pompe Disease

Robust R&D Engine
Nearly 50+ Lysosomal Disorders and More Prevalent Rare Diseases

Cash Sufficient to Achieve Self-Sustainability

Two Clinical-Stage Gene Therapies

GLOBAL COMMERCIAL ORGANIZATION

Making A Difference – People and Culture

A commitment to Diversity, Equity and Inclusion

BEGINNING 2021

Strengthen our culture of inclusivity by delivering on our diversity, equity and inclusion programs

- 50% of all hiring slates will include diverse* candidates
- 50% of all Director and above hires should be diverse
- 33% of all other hires should be diverse

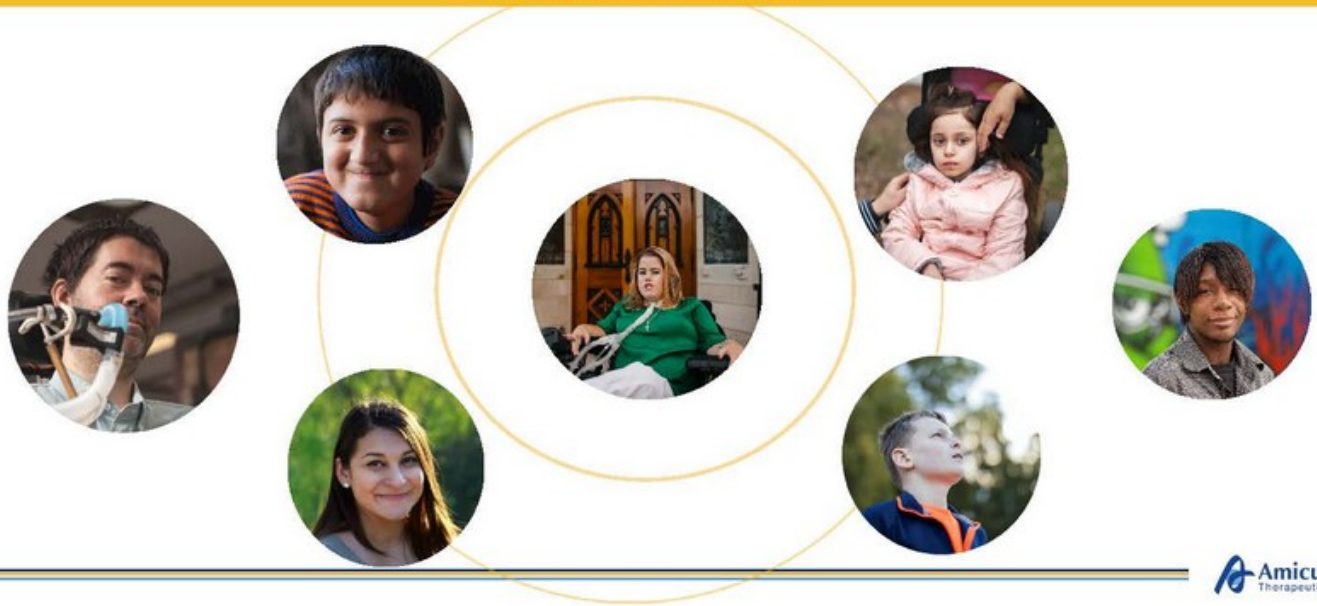
2023 AND BEYOND

- Maintain global gender diversity of 50% or greater
- Increase U.S. diversity* to 40%
- Maintain pay parity

*Diversity includes maintaining/increasing gender diversity and increasing representation of all underrepresented races, veterans, disabled, and LGBTQ employees

2021: Our Passion for Making a Difference Unites Us

Per Ardua Ad Astra



Amicus Therapeutics

Positioned for Significant Value Growth

Strong Revenue Drivers

- Exceptional Galafold launch continues with $1B+ opportunity
- Anticipate further growth driven by potential AT-GAA launch (2022) - a $1B-$2B+ opportunity

Diverse Gene Therapy Portfolio

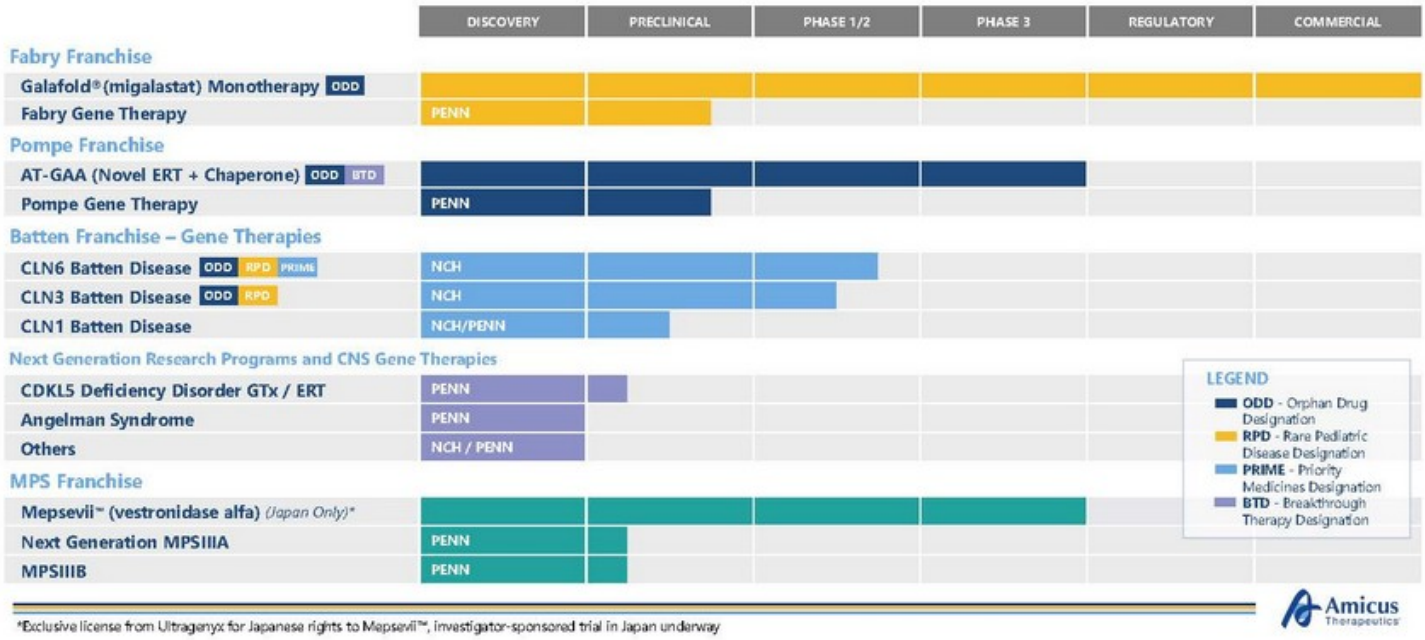
- Broad clinical and preclinical pipeline
- Established clinical proof of concept in CLN6 Batten disease
- Gene therapy platform with rights to 50+ lysosomal disorders and 12 additional rare diseases; together a $1B+ opportunity

Financial Strength

- Cash position sufficient to achieve self-sustainability without the need for future dilutive financing
- Non-GAAP Operating Expense to remain flat YoY driven by strong financial discipline

Amicus Therapeutics

A RARE PORTFOLIO



*Exclusive license from Ultragenyx for Japanese rights to Mepsevii™, investigator-sponsored trial in Japan underway

Amicus Therapeutics

2020 Key Strategic Priorities

1. Achieve global product revenue for Galafold of $250M-$260M ✓
2. Complete Pompe Phase 3 PROPEL study, enroll pediatric studies and advance manufacturing to support 2021 BLA and MAA ✓
3. Advance clinical development, manufacturing and regulatory discussions for CLN6 and CLN3 Batten programs ✓
4. Progress Pompe gene therapy towards IND and disclose up to two additional IND candidates ✓
5. Maintain strong financial position ✓

2021 Key Strategic Priorities

1. Achieve double-digit Galafold growth and revenue of at least $300M+
2. Report data from the AT-GAA Phase 3 PROPEL study and complete BLA and MAA filings for regulatory approvals
3. Advance clinical studies, regulatory discussions and scientific data across industry leading gene therapy pipeline
4. Further manufacturing capabilities and capacity to build world-class technical operations to support all gene therapy programs
5. Maintain strong financial position

Galafold® (migalastat) Global Launch…

…taking a leadership role in the treatment of Fabry disease

"We push ideas as far and as fast as possible"
- Amicus Belief Statement

Galafold Snapshot (as of December 31, 2020)

Galafold is an orally delivered small molecule precision medicine with a unique mechanism of action for Fabry patients with amenable variants that replaces the need for intravenously delivered ERT

One of the Most Successful Rare Disease Launches

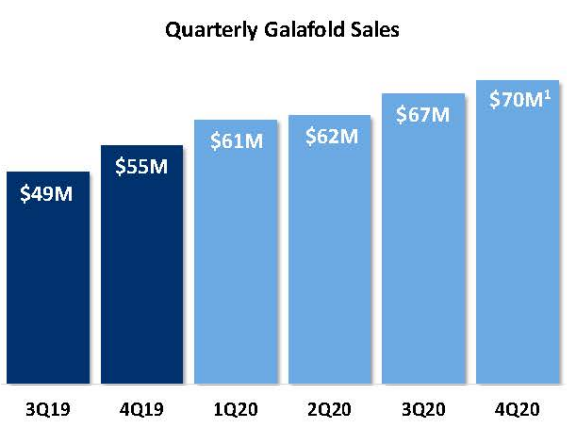
- ~$261M 2020 Galafold Revenue*
- $300M+ FY21 Global Galafold Revenue
- 348 Amenable Variants in U.S. Label
- 40+ Countries with Regulatory Approvals
- Continued Expansion in 2021
- 1,384 Amenable Mutations Included in the EU Label

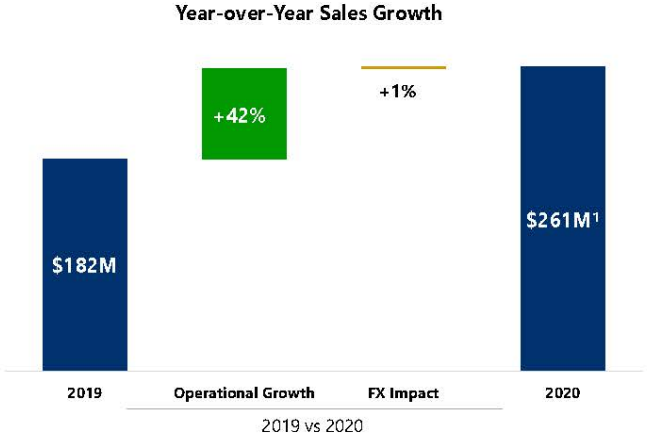
*Preliminary and unaudited

Amicus Therapeutics

2020 Galafold Success

Growth remains strong with Q4 revenue of $70M and FY 2020 revenue of $261M[1]





[1]Preliminary and unaudited

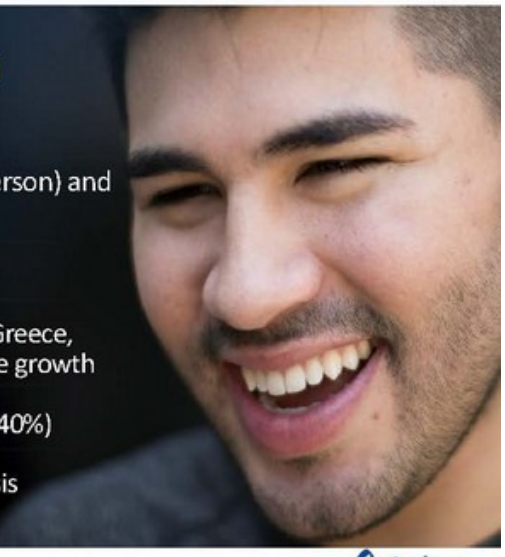
Amicus Therapeutics

Galafold Global Commercial Momentum (as of December 31, 2020)

2020 exceeded revenue goals even with COVID related disruptions to healthcare systems

FY20 Strength Reflects Continued Strength with 1,400+ Treated Patients

- Fundamentally transformed global business to a hybrid model (virtual/in-person) and achieved majority of pre-COVID call volume
- Achieved estimated 49%+ global market share of treated amenable patients*
- Multiple regulatory and reimbursement approvals including Poland, Hungary, Greece, Luxembourg, Argentina and Iceland continue to lay strong foundation for future growth
- Demographics: Global mix of switch (60%) and previously untreated patients (40%)
- Continue to support diagnostic initiatives to drive a shorter pathway to diagnosis



*Market share based on reported global Fabry sales for the calendar year ending 3Q20 and assumes a 35% amenability rate

Amicus Therapeutics

Adapting to a New Way of Delivery

Amicus was able to fully transform its commercial model to adapt to a new environment and achieve a substantial majority of pre-COVID touchpoints

Conducted HCP research to understand their needs and best channels to utilize

Retrained team members on Fabry disease to ensure that virtual calls were impactful

Global work to bring external programs and initiatives under one digital umbrella

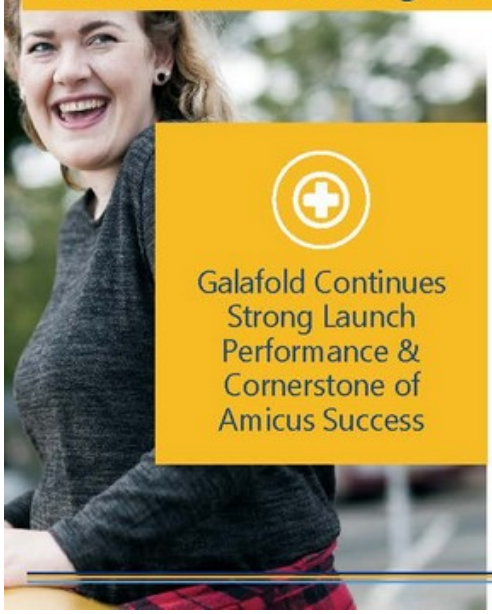
All affiliates are trained and fully utilizing digital channels for external communication

Well positioned for continued success in 2021

Amicus Therapeutics

Outlook for 2021

Continued double-digit Galafold revenue growth to at least $300 million in 2021



- 2020 execution lays a solid foundation and global demand remains strong with continued growth anticipated in 2021 and beyond
- New Galafold patient additions slowed in Q4 due to COVID reemergence and resulting in increased lag time between patient identification and treatment initiation
- In 2021, project double-digit revenue growth with new patient starts to be at least consistent with 2020
- Expect higher patient adds and revenue growth in the second half of 2021 as COVID impact eases
- Continue to see greater than 90% compliance and adherence rates globally

Amicus Therapeutics

Galafold Opportunity

With inherent Fabry market growth and our work to improve screening and diagnosis, Galafold has the potential to drive $1B+ annual revenue at peak

*Preliminary and unaudited

Amicus Therapeutics

Galafold Long-Term Opportunity

With inherent Fabry market growth and our work to improve diagnosis and screening of this underdiagnosed and misdiagnosed disorder, Galafold has the potential to drive $1B+ annual revenue at peak

~15,000+
Total Diagnosed Fabry Patients[1]

~9,000+
Total Treated Fabry Patients

~3,000+ **Treated Amenable Patients**
Patients on a Fabry therapy with a genetic mutation that is amenable to Galafold treatment

~6,000+ **Diagnosed Untreated Patients[2]**
Patients with a Fabry diagnosis who are not currently on any treatment

~1,400+ **Galafold Patients on Therapy**
Patients who are currently on Galafold as a treatment for their Fabry disease

Diagnostic Initiatives

1. Management estimates excluding China, India and other non-commercial countries. 2. Company estimates 35% up to 50% of diagnosed untreated patients have an amenable variant

Amicus Therapeutics

AT-GAA: Next Potential Standard of Care for Pompe Disease

"We encourage and embrace constant innovation"
- Amicus Belief Statement

Pompe Disease Overview

Pompe disease is a severe and fatal neuromuscular disease and one of the most prevalent lysosomal disorders with very high unmet medical need

- 5,000 – 10,000+ patients diagnosed WW[1]; newborn screening suggests underdiagnosis
- Age of onset ranges from infancy to adulthood
- Patients on current standard of care decline after ~2 years
- Respiratory and cardiac failure are leading causes of morbidity and mortality
- Deficiency of GAA leading to glycogen accumulation and cellular dysfunction
- Symptoms include muscle weakness, respiratory failure and cardiomyopathy
- ~$1B+ global Pompe ERT sales[2]

1. National Institute of Neurological Disorders and Stroke (NIH). 2. Based on calendar year ending September 30, 2019. Exchange rate as of 1/6/19. Source: Sanofi Press Releases

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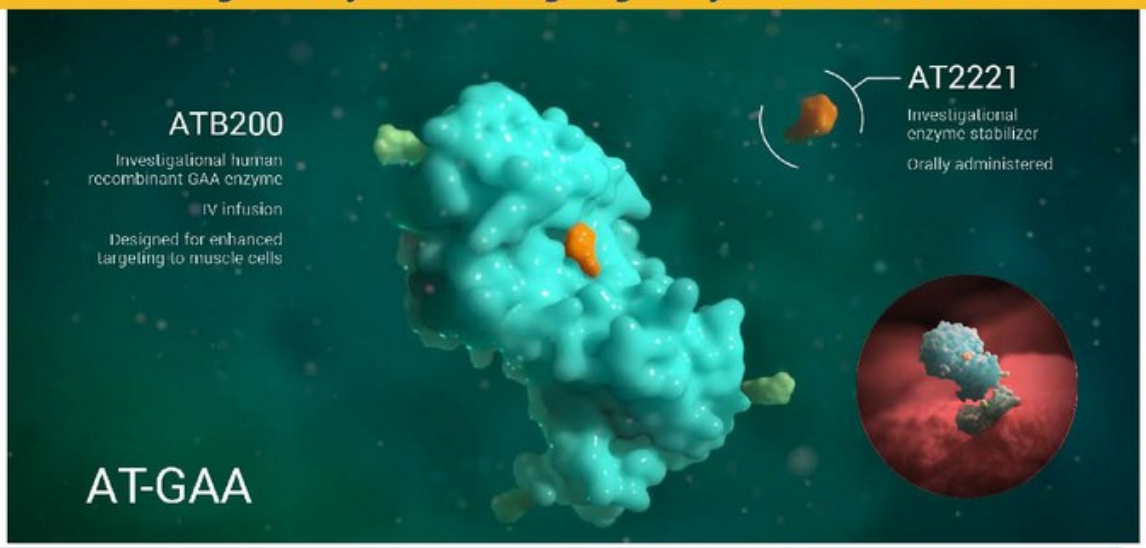
AT-GAA: Foundation in Protein Engineering

Amicus scientists created a uniquely glycosylated and highly phosphorylated ERT (AT-GAA) that significantly enhances targeting to key muscles affected



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Pompe Patient Experience in Phase 1/2 Clinical Study (ATB200-02)

Highly differentiated mechanism of action demonstrated compelling Phase 1/2 results showing strong and durable effects in patients out to two years

6-Min Walk Test (m)

Cohort	Baseline (n=10)	Change at Month 6 (n=10[1]) Mean (SD)	Change at Month 12 (n=10[1]) Mean (SD)	Change at Month 24 (n=9[1,2]) Mean (SD)
Cohort 1 ERT-Switch Ambulatory	397.2 (96.8)	+23.9 (52.2)	+42.2 (46.5)	+36.4 (60.5)
Cohort	**Baseline (n=5)**	**Change at Month 6 (n=5) Mean (SD)**	**Change at Month 12 (n=5) Mean (SD)**	**Change at Month 24 (n=5) Mean (SD)**
Cohort 3 ERT-Naïve	399.5 (83.5)	+41.8 (29.4)	+63.1 (29.1)	+60.7 (36.5)

FVC (% Predicted)

Cohort	Baseline (n=9[3])	Change at Month 6 (n=9[3]) Mean (SD)	Change at Month 12 (n=93) Mean (SD)	Change at Month 24 (n=8[2,3]) Mean (SD)
Cohort 1 ERT-Switch Ambulatory*	52.6 (14.7)	-1.2 (4.0)	-3.0 (6.0)	+0.9 (4.9)
Cohort	**Baseline (n=5)**	**Change at Month 6 (n=5) Mean (SD)**	**Change at Month 12 (n=5) Mean (SD)**	**Change at Month 24 (n=5) Mean (SD)**
Cohort 3 ERT-Naïve	53.4 (20.3)	+4.4 (5.6)	+4.6 (8.8)	+6.8 (6.8)

Data from interim analysis 3

[1]One patient in Cohort 1 discontinued after 18 weeks due to burden of travel; baseline value is not shown for this patient. [2]One patient in Cohort 1 discontinued from study before Month 24. [3]Baseline FVC not available for 1 patient in Cohort 1

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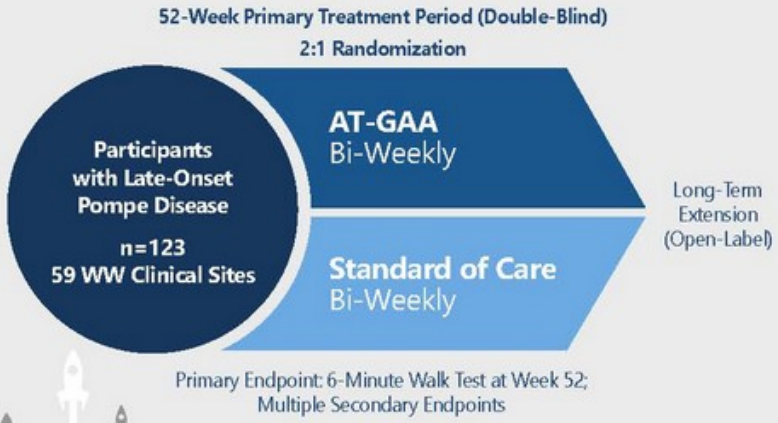
PROPEL (ATB200-03) Study Design

PROPEL

Phase 3 exceeded enrollment and last patient, last visit complete with data expected in 1Q2021 – Highly powered for success and supports a broad label



- PROPEL pivotal study over-enrolled with data expected in 1Q2021
- Study includes ERT-switch and ERT-naïve patients
- FDA and EMA agreed upon primary endpoint of 6MWD, an integrated measure of disease progression that evaluates both cardiopulmonary and musculoskeletal systems

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AT-GAA: Key Takeaways

- PROPEL study last patient, last visit complete with data expected 1Q2021
- Breakthrough Therapy Designation and Promising Innovative Medicine designation highlight unmet need in Pompe disease
- Rolling BLA submission initiated with the U.S. FDA and on track for submission in 1H2021; EU MAA filing expected 2H2021
- Expanded Access Program for infantile-onset Pompe patients underway
- Process performance qualification (PPQ) runs with our partners at WuXi have been successfully completed for the drug substance and drug product
- Peak revenue potential of $1B-$2B, with exclusivity well into 2030s

Amicus Therapeutics

Amicus Gene Therapy Pipeline

"We have a duty to obsolete our own technologies"
- Amicus Belief Statement

A World Leading Gene Therapy Company

1

Gene Therapy Center of Excellence

Discovering, developing and applying Amicus protein engineering experience to next-generation gene therapies

3

Industry Leading Collaborations

With key experts in the field at University of Pennsylvania, Nationwide Children's Hospital and Sanford Research

9

Active Clinical and Preclinical Programs

Across devastating neurologic and lysosomal disorders, including human proof of concept data in CLN6 Batten

50+

Rare Disease Indications

Rights to most lysosomal disorders and 12 larger rare diseases

70+

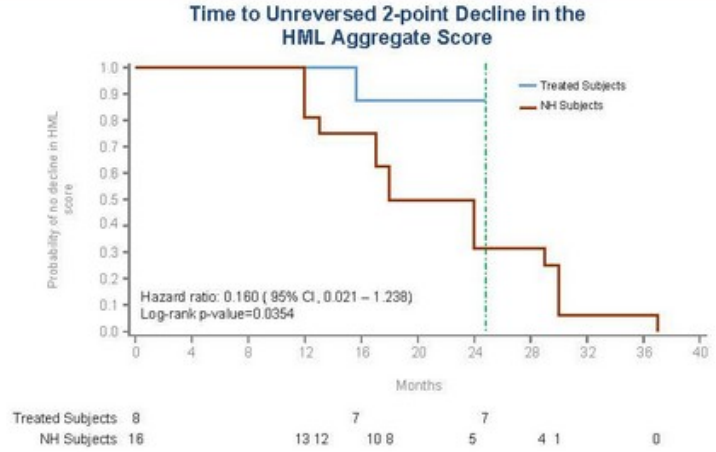
Dedicated Scientists

Driving innovative science

Amicus Therapeutics

CLN6 Batten Disease Gene Therapy

Encouraging interim data show a meaningful effect in slowing disease progression at 24 months in devastating early childhood disease that is 100% fatal



M+L, motor and language. NH, natural history.
[a]The efficacy analysis included all patients with 24-month HML data (8 of 13 treated patients in the study). [b]24-month HML data are available for 16 of 17 patients in the natural history cohort derived from a retrospective CLN6 natural history study conducted by Emily de los Reyes, MD (ClinicalTrials.gov Identifier: NCT03285425). Data cutoff March 13, 2020.

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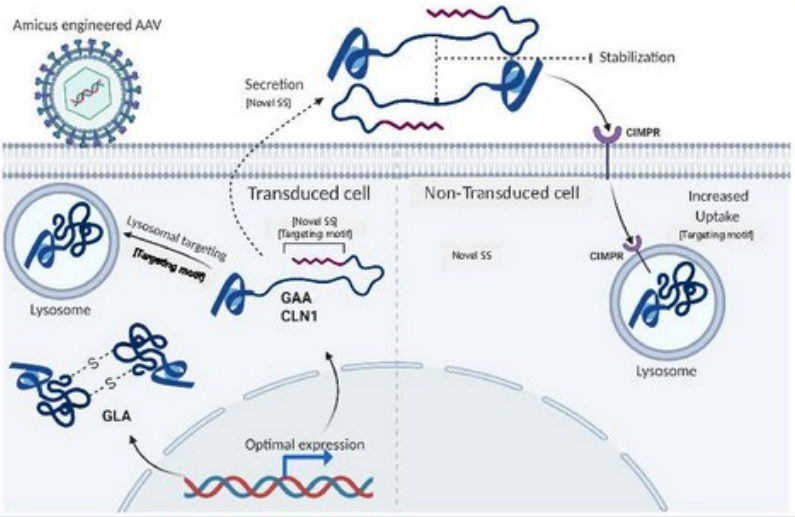
Amicus Protein Engineering Technologies for Lysosomal Targeting

Preclinical POC established for multiple engineered lysosomal targets for optimal expression, secretion, stability and/or cell targeting



- Proof of concept established for Pompe (GAA), Fabry (GLA), CLN1 (PPT1)
- Enhances targeting of therapeutic proteins to lysosome and uptake/cross-correction of neighboring non-transduced cells

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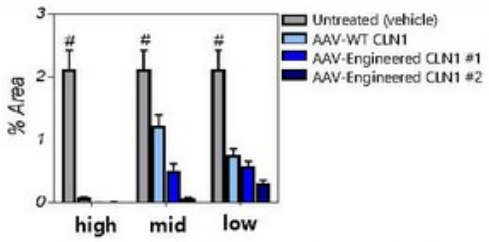
Gene Therapy Pipeline Update: CLN1 Batten Disease

Initial preclinical proof of concept data demonstrate that Amicus-engineered constructs prevent accumulation of substrate material at lower doses versus wild type

CLN1 Batten Disease Overview

- Infantile-onset form of Batten with high unmet need
- Disease onset between 1-3 years of age with rapid loss of motor function, language and vision with mortality before age 10
- Estimated prevalence of 1,000-2,000 children in addressable commercial markets
- Strong strategic fit with Amicus Batten franchise

CLN1 KO Mouse: Thalamus Accumulated Substrate Material (ASM)



- Provides preclinical proof of concept for improved potency with Amicus-engineered transgene
- Additional proof of concept studies planned for 2021 to support IND candidate selection

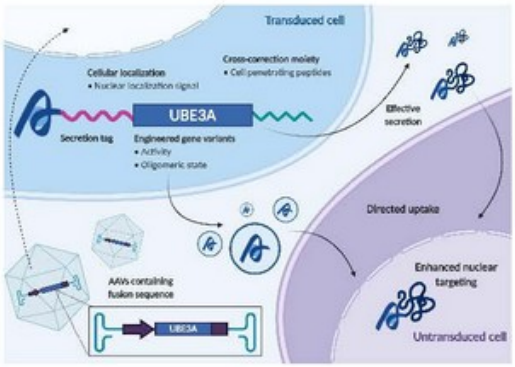
Gene Therapy Pipeline Update: Angelman Syndrome

Amicus plans to initiate a program to leverage our protein engineering to construct an optimized AAV gene therapy approach in Angelman Syndrome

Angelman Syndrome Overview

- Severe neurodevelopmental disorder resulting in severe cognitive, motor and language impairment and seizures
- Caused by mutations in ubiquitin-protein ligase E3A (UBE3A) in neurons
- Disease onset in childhood with survival into late adulthood
- Estimated 30,000+ patients in addressable commercial markets
- No current disease modifying treatment
- Significant opportunity for a one-time AAV gene therapy to restore UbE3A activity leveraging Amicus protein engineering

Amicus Engineering Approach: Angelman



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Gene Therapy Manufacturing

Amicus will build, staff and operate its own Gene Therapy Manufacturing Center of Excellence to become one of the leading, global gene therapy manufacturers

- Manufacturing and process science capabilities and capacity in gene therapy will be crucial for Amicus success
- Work underway towards Amicus first clinical manufacturing and process development facility
- Experience in complex biologics manufacturing and quality control provide critical expertise

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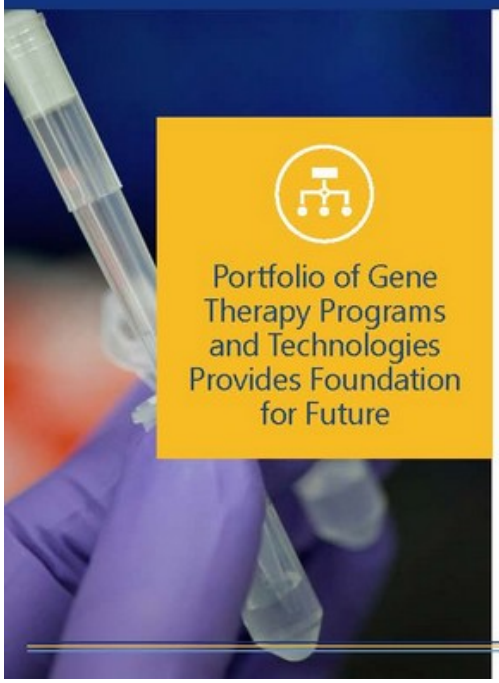
Gene Therapy: Updates & Key Takeaways



- CLN6 Phase 1/2 interim data have shown positive impact with potential to become first approved gene therapy for fatal brain disease in children
- Initial data from the CLN3 Batten disease Phase 1/2 study in 1Q21
- Manufacturing on track to initiate next clinical studies in CLN6 and CLN3 using material from planned commercial process
- Preclinical POC in CLN1 demonstrates ability to continue leveraging protein engineering capabilities towards new targets
- Progressing manufacturing and IND-enabling work for Fabry and Pompe gene therapy programs
- Additional data and potential IND candidate disclosed across multiple preclinical programs this year
- Continued foundational gene therapy discovery and research activities across 50+ diseases

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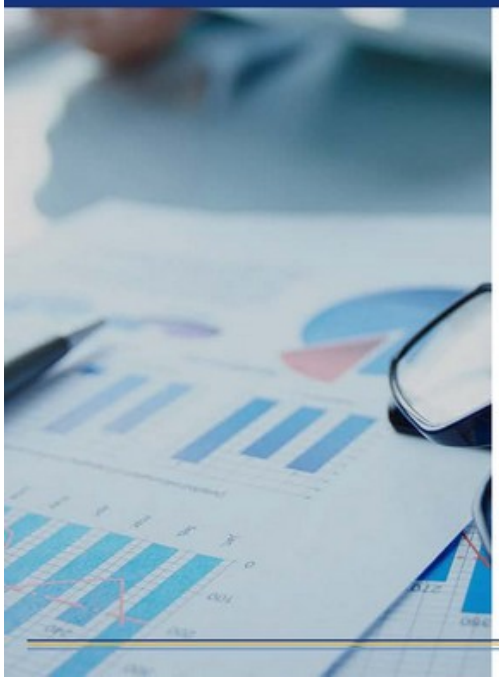
Financial Summary

"We are business led and science driven"
- Amicus Belief Statement

Financial Outlook: Key Takeaways



- Galafold revenue in 2020 was ~$261 million, exceeding the Company's guidance
- Non-GAAP operating expense guidance for 2021 is expected to remain flat at $410 million to $420 million
  - Driven by disciplined expense management and continued investment in the global Galafold launch, AT-GAA clinical studies and advancing our gene therapy pipeline
- Current cash position is sufficient to achieve self-sustainability without the need for future dilutive financing

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Key Takeaways

Recent successes across our science, clinical, regulatory and commercial efforts position us for the future

- Galafold Continues Strong Launch Performance and Cornerstone of Amicus Success
- AT-GAA for Pompe Advances Toward Approval as "Crown Jewel" of Amicus Portfolio
- Portfolio of Gene Therapy Programs and Technologies Provides Foundation for Future
- Cash Position Sufficient to Achieve Self-Sustainability without the Need for Future Dilutive Financing

Thank You

Amicus Therapeutics