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): **November 11, 2019**

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 November 11, 2019, Amicus Therapeutics, Inc. (the "Company") issued a press release announcing its financial results for the fiscal quarter ended September 30, 2019. A copy of this press release is attached hereto as Exhibit 99.1. The Company also hosted a conference call and webcast on November 11, 2019, a recording of which is currently available on its website, to discuss its third quarter results of operations. A copy of the conference call presentation materials and transcript of the call are attached hereto as Exhibit 99.2 and Exhibit 99.3, respectively. Exhibits 99.1, 99.2 and 99.3 are incorporated herein by reference.

In accordance with General Instruction B.2. of Form 8-K, the information in this Current Report on Form 8-K and the Exhibits 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 liability of that section, nor shall it be deemed 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 9.01 Financial Statements and Exhibits

(d) Exhibits:

Exhibit No.	Description
99.1	Press Release dated November 11, 2019
99.2	Presentation Materials - November 11, 2019
99.3	Conference Call Transcript - November 11, 2019

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.

AMICUS THERAPEUTICS, INC.

Date: November 14, 2019

By: /s/ Ellen S. Rosenberg

Name: Ellen S. Rosenberg

Title: Chief Legal Officer and Corporate Secretary

Amicus Therapeutics Announces Third Quarter 2019 Financial Results and Corporate Updates

3Q19 Galafold® (migalastat) Revenue of $48.8M
and 1,000+ Patients on Therapy Reflects Continued Strong Global Uptake

Reiterating Upwardly Revised FY19 Revenue Guidance of $170M-$180M

Complete Enrollment of 120+ Patients in AT-GAA Pompe Pivotal Study on Track by YE19

Continued Progress Across Industry Leading Rare Disease Gene Therapy Portfolio

Strong Balance Sheet with $514M+ Cash Provides Cash Runway Well into 1H22

Conference Call and Webcast Today at 8:30 a.m. ET

CRANBURY, NJ, November 11, 2019 – Amicus Therapeutics (Nasdaq: FOLD), a global biotechnology company focused on discovering, developing and delivering novel medicines for rare metabolic diseases, today announced financial results for the third quarter ended September 30, 2019. The Company also summarized recent program updates and reiterated its full-year 2019 guidance.

John F. Crowley, Chairman and Chief Executive Officer of Amicus Therapeutics, Inc. stated, "The third quarter represented another consecutive period of significant growth and adoption for Galafold across all geographies, as well as continued momentum in our Pompe pivotal study and our gene therapy pipeline. We are on track to meet or exceed each of our key strategic priorities for the year as we lay the foundation for our long-term success. Importantly, we have significantly strengthened our financial outlook with careful management of our expenses and investments. With confidence in our base business and overall financial outlook, we are well capitalized to continue to grow our revenues, advance our pipeline, and move toward self-sustainability and profitability as we continue to build Amicus into a leading global rare disease biotechnology company delivering on our mission for patients and shareholders."

Corporate Highlights for 3Q19 and Early 4Q19

- **Global revenue for Fabry precision medicine Galafold in the third quarter of 2019 was $48.8 million and continues to track toward the upwardly revised full-year 2019 revenue guidance of $170 million to $180 million.** Third quarter revenue represented a year-over-year increase of 137% from total revenue of $20.6 million in the third quarter of 2018, and a quarter over-quarter increase of 11% from total revenue of $44.1 million in the second quarter of 2019**.** As of September 30, 2019, Galafold represented an estimated 30% of global market share of treated amenable patients. Global compliance and adherence rates continue to exceed 90%.
- **Financial outlook strengthened with current cash runway now revised to well into 1H 2022 through major portfolio milestones and global growth.**
- **Positive Phase 2 clinical data for AT-GAA in Pompe disease**. Amicus presented initial six-month data in additional ERT-switch patients (Cohort 4) and full 24-month data from the first three cohorts in Phase 1/2 ATB200-02 clinical study at World Muscle Society.
- **Pompe Pivotal PROPEL study is expected to over-enroll (~120 Patients) by YE 2019.** Given the strong global interest among the Pompe patient and physician community for AT-GAA, which has U.S. Breakthrough Therapy designation, this global study is now expected to enroll ~120 patients by year-end 2019. Pompe manufacturing also continues to advance with PPQ runs now initiated at WuXi.
- **Positive interim Phase 1/2 clinical data for gene therapy in CLN6 Batten disease.** Initial results as well as additional supportive data at Child Neurology Society showed AAV-CLN6 gene therapy has the potential to halt the progression of a devastating disease that causes loss of brain function and is fatal in childhood.
- **Pompe gene therapy clinical candidate declared to move into IND-enabling studies**. Dose-ranging preclinical studies are currently underway to build off the initial preclinical results showing robust uptake and glycogen reduction in multiple tissues, including brain and spinal cord.
- **Robust portfolio of gene therapy programs and technologies provides foundation for future, including two clinical-stage programs (CLN6 and CLN3), and eight preclinical gene therapies.**

3Q19 Financial Results

- Total revenue in the third quarter 2019 was $48.8 million, a year-over-year increase of 137% from total revenue of $20.6 million in the third quarter of 2018, and a quarter over-quarter increase of 11% from total revenue of $44.1 million in the second quarter of 2019**.** On a constant currency basis, third quarter 2019 total revenue was $50.3 million, representing operational revenue growth measured at constant currency exchange rates of 143%, which was offset by a negative currency impact of $1.3 million, or 6%.
- Cash, cash equivalents, and marketable securities totaled $514.2 million at September 30, 2019, compared to $504.2 million at December 31, 2018.
- Total GAAP operating expenses of $100.5 million for the third quarter of 2019 decreased as compared to $172.5 million in the third quarter of 2018. The decrease is primarily due to an upfront payment of $100 million for the Celenex asset acquisition in 2018 partially offset by continued investments in the Galafold launch, Pompe clinical study program, and our gene therapy pipeline.
- Total non-GAAP operating expenses of $89.7 million for the third quarter of 2019 increased as compared to $63.0 million in the third quarter of 2018, reflecting continued investments in the Galafold launch, Pompe clinical study program, and our gene therapy pipeline. Full reconciliation of GAAP results to the Company's non-GAAP adjusted measures for all reporting periods appear in the tables to this press release.
- Net loss was $61.8 million, or $0.24 per share, compared to a net loss of $159.2 million, or $0.84 per share, for the third quarter 2018.

2019 Financial Guidance

Following the success in the first three quarters of the year, in addition to the strength in global Galafold launch metrics across all major geographies, Amicus raised the lower end of the full-year 2019 Galafold revenue guidance from $160 to $180 million to $170 to $180 million. The Company anticipates full-year 2019 non-GAAP operating expense of $410 million to $420 million. A reconciliation of the differences between the non-GAAP expectation and the corresponding GAAP measure is not available without unreasonable effort due to high variability, complexity and low visibility as to the items that would be excluded from the GAAP measure.

Cash, cash equivalents, and marketable securities totaled $514.2 million at September 30, 2019. Following a diligent review of current and outer year operating and capital expense projections, and robust outlook for Galafold revenue, Amicus now expects to end 2019 with more than $420 million in cash on hand and has extended the cash runway projection from 2021 to well into the first half of 2022.

2019 Key Strategic Priorities

- Nearly double annual worldwide revenue for Galafold with over 1,000 Fabry patients on Galafold by year end.
- Complete enrollment in pivotal Phase 3 PROPEL clinical study in Pompe disease and report additional Phase 2 data.
- Report additional two-year results from Phase 1/2 clinical study in CLN6 Batten disease and complete enrollment in ongoing CLN3 Batten disease Phase 1/2 study.
- Establish preclinical proof of concept for Fabry and Pompe gene therapies.
- Maintain a strong financial position.

Conference Call and Webcast

Amicus Therapeutics will host a conference call and audio webcast today, November 11, 2019 at 8:30 a.m. ET to discuss the third quarter 2019 financial results and corporate updates. Interested participants and investors may access the conference call by dialing 877-303-5859 (U.S./Canada) or 678-224-7784 (international), conference ID: 8654236.

A live audio webcast can also be accessed via the Investors section of the Amicus Therapeutics corporate website at http://ir.amicusrx.com/, and will be archived for 30 days. Web participants are encouraged to register on the website 15 minutes prior to the start of the call. A replay of the call will be available for seven days beginning at 11:30 a.m. ET on November 11, 2019. Access numbers for this replay are 855-859-2056 (U.S./Canada) and 404-537-3406 (international); conference ID: 8654236.

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 Argentina, Australia, Canada, European Union, Israel, Japan, South Korea, Switzerland and the U.S.

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 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 on Twitter and LinkedIn.

Non-GAAP Financial Measures

In addition to financial information prepared in accordance with U.S. GAAP, this press release 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. Full reconciliations of GAAP results to the comparable non-GAAP measures for the reported periods appear in the financial tables section of this press release. 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.

Forward-Looking Statements

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, 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. 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, 2018. 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.

CONTACTS:

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TABLE 1

Amicus Therapeutics, Inc.
Consolidated Statements of Operations
(Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Revenue:				
Net product sales	$ 48,768	$ 20,596	$ 126,944	$ 58,601
Cost of goods sold	5,596	4,310	15,018	10,060
Gross profit	43,172	16,286	111,926	48,541
Operating expenses:				
Research and development	58,892	138,227	194,466	213,685
Selling, general, and administrative	39,680	31,867	126,561	88,435
Changes in fair value of contingent consideration payable	789	1,300	2,652	2,700
Depreciation and amortization	1,116	1,073	3,261	3,015
Total operating expenses	100,477	172,467	326,940	307,835
Loss from operations	(57,305)	(156,181)	(215,014)	(259,294)
Other income (expense):				
Interest income	2,752	2,721	7,990	7,371
Interest expense	(4,026)	(4,715)	(15,105)	(13,763)
Loss on exchange of convertible notes	—	—	(40,624)	—
Change in fair value of derivatives	—	—	—	(2,739)
Other expense	(3,481)	(1,039)	(3,272)	(3,593)

Loss before income tax	(62,060)	(159,214)	(266,025)	(272,018)
Income tax benefit (expense)	251	51	(634)	1,104
Net loss attributable to common stockholders	$ (61,809)	$ (159,163)	$ (266,659)	$ (270,914)
Net loss attributable to common stockholders per common share — basic and diluted	$ (0.24)	$ (0.84)	$ (1.13)	$ (1.47)
Weighted-average common shares outstanding — basic and diluted	254,674,422	189,162,841	235,527,540	184,606,790

TABLE 2

Amicus Therapeutics, Inc.
Consolidated Balance Sheets
(Unaudited)
(in thousands, except share and per share amounts)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 166,319	$ 79,749
Investments in marketable securities	347,875	424,403
Accounts receivable	33,731	21,962
Inventories	9,154	8,390
Prepaid expenses and other current assets	19,578	16,592
Total current assets	576,657	551,096
Operating lease right-of-use assets, less accumulated amortization of $2,420 and $0 at September 30, 2019 and December 31, 2018, respectively	35,814	—
Property and equipment, less accumulated depreciation of $17,907 and $15,671 at September 30, 2019 and December 31, 2018, respectively	34,673	11,375
In-process research & development	23,000	23,000
Goodwill	197,797	197,797
Other non-current assets	14,351	6,683
Total Assets	$ 882,292	$ 789,951
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable, accrued expenses, and other current liabilities	$ 81,475	$ 80,625
Deferred reimbursements	5,250	5,500
Operating lease liabilities	6,356	—
Total current liabilities	93,081	86,125
Deferred reimbursements	8,906	10,156
Convertible notes	2,096	175,006
Senior secured term loan	147,164	146,734
Contingent consideration payable	22,036	19,700
Deferred income taxes	6,465	6,465
Operating lease liabilities	49,686	—
Other non-current liabilities	4,591	2,853
Total liabilities	334,025	447,039
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.01 par value, 500,000,000 shares authorized, 254,772,163 and 189,383,924 shares issued and outstanding at September 30, 2019 and December 31, 2018, respectively	2,591	1,942
Additional paid-in capital	2,210,890	1,740,061
Accumulated other comprehensive loss:		
Foreign currency translation adjustment	1,156	495
Unrealized gain (loss) on available-for-sale securities	124	(427)
Warrants	12,387	13,063
Accumulated deficit	(1,678,881)	(1,412,222)
Total stockholders' equity	548,267	342,912
Total Liabilities and Stockholders' Equity	$ 882,292	$ 789,951

TABLE 3

Amicus Therapeutics, Inc.
Reconciliation of Non-GAAP Financial Measures
(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Total operating expenses - as reported GAAP	**$ 100,477**	**$ 172,467**	**$326,940**	**$ 307,835**
Research and development:				
Share-based compensation	3,106	2,905	12,090	8,603
Research and development asset acquisition expense	-	100,000	-	100,000
Selling, general and administrative:				
Share-based compensation	5,737	4,149	19,432	12,270
Changes in fair value of contingent consideration payable	789	1,300	2,652	2,700
Depreciation and amortization	1,116	1,073	3,261	3,015
Total operating expense adjustments to reported GAAP	10,748	109,427	37,435	126,588
Total operating expenses - as adjusted Non-GAAP	$ 89,729	$ 63,040	$289,505	$ 181,247

Amicus Therapeutics®

3Q19 Financial Results Conference Call & Webcast

November 11, 2019

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 ou 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 c commercialization plans, manufacturing and supply plans, financing plans, and the projected revenues and cash position for the Company. The inclusion of forward-looking statements s 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 presentation may turn out to be wrong and can be a 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 ou discussions with regulatory authorities, and in particular the potential goals, progress, timing, and results of preclinical studies and clinical trials, actual results may differ materially from 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 th 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 PM 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 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 potentia 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 manu Further, the results of earlier preclinical studies and/or clinical trials may not be predictive of future results. In addition to financial information prepared in accordance with U.S. GAAP, release also contains adjusted financial measures that we believe provide investors and management with supplemental information relating to operating performance and trends tha 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 substitute for, the information prepared in accordance with U.S. GAAP. With respect to statements regarding projections of the Company's revenue and cash position, actual results m 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 Annu on Form 10-K for the year ended December 31, 2018. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All 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 afte hereof.

In addition to financial information prepared in accordance with U.S. GAAP, this press release also contains adjusted financial measures that we believe provide investors and manage supplemental information relating to operating performance and trends that facilitate comparisons between periods and with respect to projected information. These adjusted financial 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 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 ways. Full reconciliations of GAAP results to the comparable non-GAAP measures for the reported periods appear in the financial tables section of this press release. When we pr 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 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 relev 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.

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 BIOLOGIC Capabilities

Global Footprint in 27 Countries

AT-GAA

Phase 3 in Pompe Disease

Robust R&D Engine

Nearly 50+ Lysosomal Disorders and More Prevalent Rare Disease

$514M+ Cash as of 9/30/19

Two Clinical-Stage Gene Therapies

GLOBAL COMMERCIAL ORGANIZATION

Key Takeaways for 3Q19 Results

**Today's Conference Call and Recent Analyst Day Highlight our Success and Outlo
Across our Science, Clinical, Regulatory and Commercial Efforts**

Galafold Continues Strong Launch Performance & Cornerstone of Amicus Success

Amicus Financial Outlook Strengthened with Current Cash Revised Now Well into 1H2022

AT-GAA for Pompe Advances Toward Approval as "Crown Jewel" of Amicus Portfolio

Portfolio of Ge
Therapy Progra
and Technologi
Provides Founda
for Future

Financial Summary

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

3Q19 Select Financial Results

3Q19 Revenue of $48.8M Primarily from Global Galafold Sales

(in thousands, except per share data)	Sept. 30, 2019	Sept. 30, 2018
Product Revenue	48,768	20,596
Cost of Goods Sold	5,596	4,310
R&D Expense[1]	58,892	138,227
SG&A Expense	39,680	31,867
Changes in Fair Value of Contingent Consideration	789	1,300
Depreciation and Amortization	1,116	1,073
Loss from Operations	(57,305)	(156,181)
Income Tax Benefit	251	51
Net Loss	(61,089)	(159,214)
Net Loss Per Share	(0.24)	(0.84)

[1]Inclusive of the 2018 upfront payment of $100 million for the Celenex asst acquisition.

Cash Runway Now Well into 1H2022 (2.5+ years)

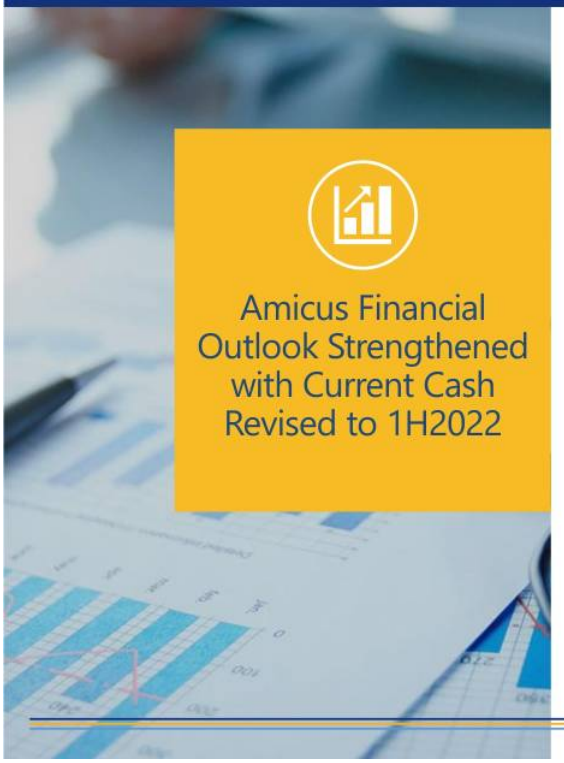
Financial Summary & Guidance

Strong Balance Sheet with $514M+ Cash at 9/30/19 – Cash Runway Well into 1H2

FINANCIAL POSITION	
Cash	$514M
Cash Runway[1]	Well Into 1H2022
Debt[2]	$152.8M
CAPITALIZATION	
Shares Outstanding	254,772,163
FINANCIAL GUIDANCE	
FY19 Galafold Revenue Guidance	$170M-$180M
FY19 Non-GAAP OpEx Guidance	$410M-$420M
YE19 Cash Balance	$420M+

[1]Based on existing operating plan [2]Includes $2.8 million of convertible debt and $150 million of straight debt

Financial Outlook: Key Takeaways



Amicus Financial Outlook Strengthened with Current Cash Revised to 1H2022

- Company now fully funded through major milestones in portfolio and continued global growth
- Cumulative Galafold projected revenues of $1B+ in 2020-202 offset significant majority of company spend/investments
- Achieved through OpEx savings, CapEx phasing, program prioritization and increased Galafold revenue projections
- Under current operating plan, 2019 is peak year for non-GAA operating expense on path to profitability
- No material business development planned or needed in nex several years
- Only modest additional capital required to extend runway int profitability with multiple non-equity sources available as/wh needed

Galafold® (migalastat) Global Launch…

…taking a leadership role in the treatment of Fabry disease

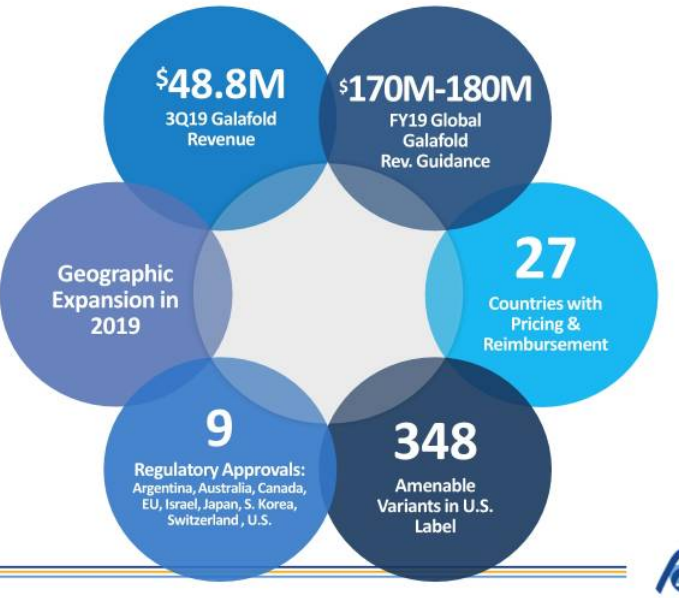
"We push ideas as far and as fast as possible

- Amicus Belief Statemer

Galafold Snapshot (as of September 30, 2019)

Galafold is the Cornerstone of Amicus' Success. It is an Orally Delivered Small Molecule Precision Medicine with a U Mechanism of Action for Fabry Patients with Amenable Variants that Replaces the Need for Intravenously Delive Enzyme Replacement Therapy.

One of the Most Successful Rare Disease Launches

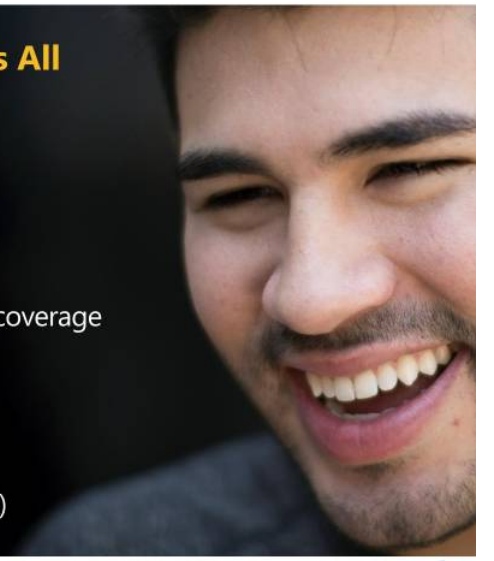


Galafold is indicated for adults with a confirmed diagnosis of Fabry Disease and an amenable mutation/variant. The most common adverse reactions reported with Galafold (≥10%) were headache, nasopharyngitis, urinary tract infection, nausea and pyrexia. For additional information about Galafold, including the full U.S. Prescribing Information, please visit https://www.amicusrx.com/pi/Galafold.pdf. 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.

Galafold Global Launch Momentum (as of September 30, 2019)

Global Commercial Metrics Continue to be Very Strong with >90% Compliance and Adherence, Global Market Share of Treated Amenable Patients and Continued Broad Market Access

3Q19 Strength Continues to Reflect Positive Momentum Across All Key Global Commercial Metrics and 1,000+ Treated Patients

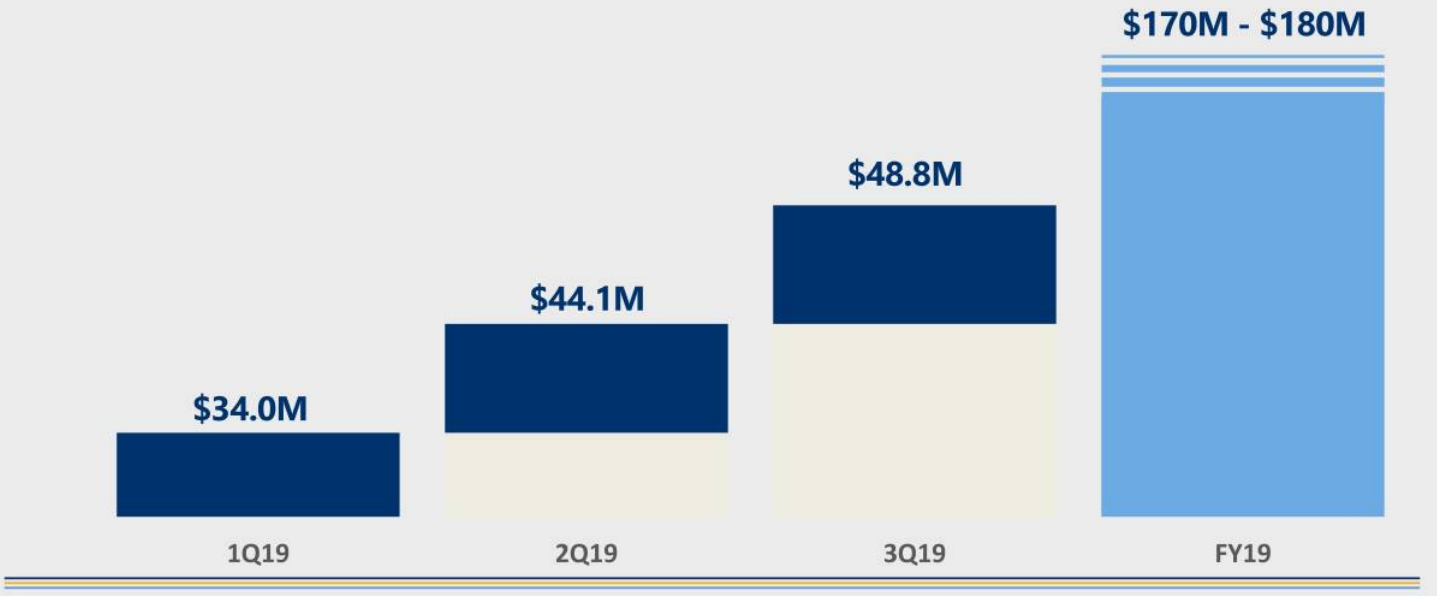


- **Global**: 30%+ estimated global market share of treated amenable patients*
- **U.S.**: Steady growth in adoption from 100+ prescribers and broad reimbursement coverage
- **International**: Growing contribution from previously untreated patients
- **Japan**: On track to deliver full year objectives
- **Demographics**: Global mix of switch (66%) and previously untreated patients (34%)

*Market share based on reported global Fabry sales for the calendar year ending 3Q19 and assumes a 35% amenability rate.

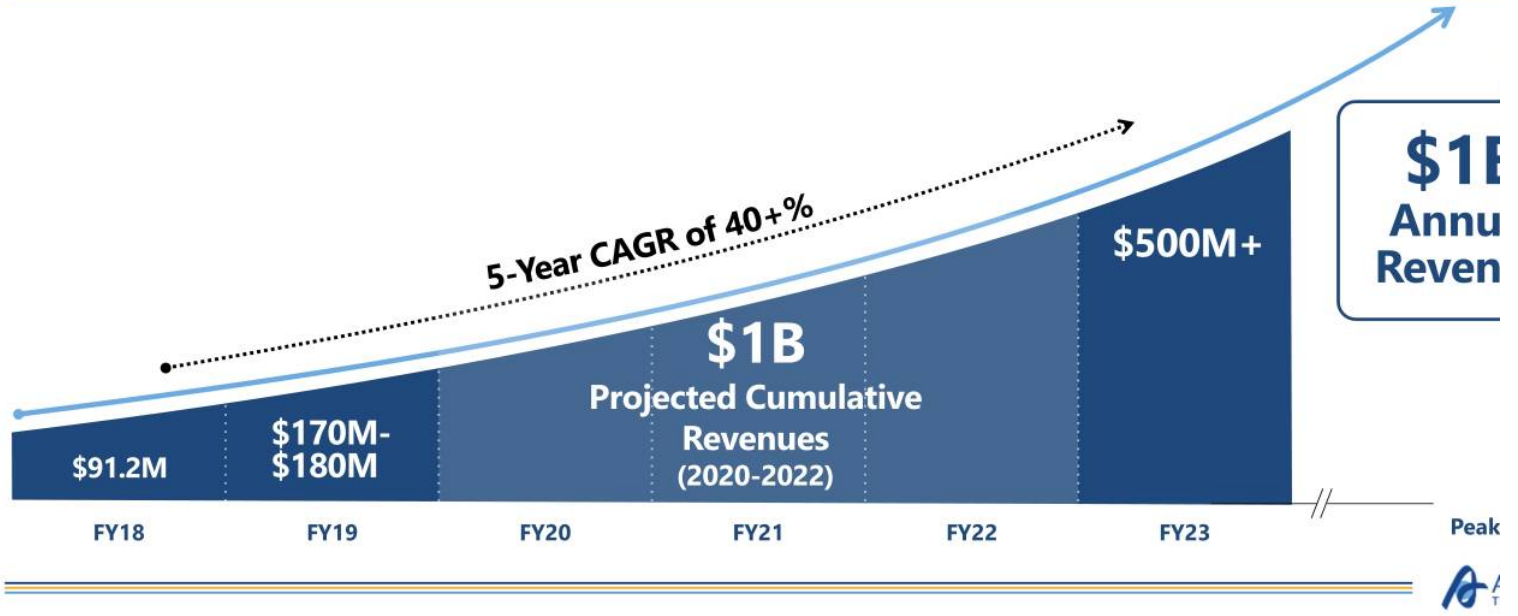
Galafold Success and FY19 Galafold Revenue Guidance

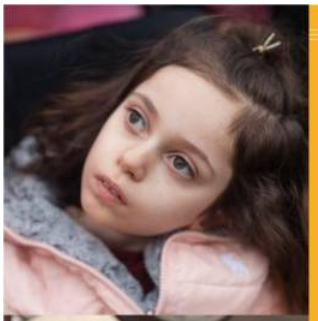
Strong Q3 Performance of $48.8M Gives Confidence in Upwardly Revised Guidance of $170M - $180M. We Expect to Fall in the Midpoint of this Revised Guidance, Inclusive of FX

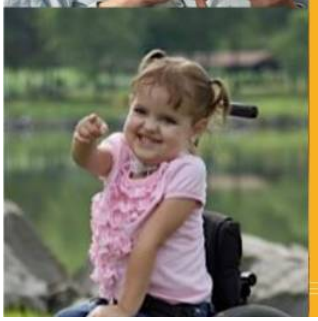


Galafold Growth Trajectory

Galafold is on Track to Generate $1B+ in Projected Cumulative Revenues from 2020-2022 and i an Anticipated Path to $500M+ in Annual Sales in 2023 and $1B+ Annual Sales at Peak





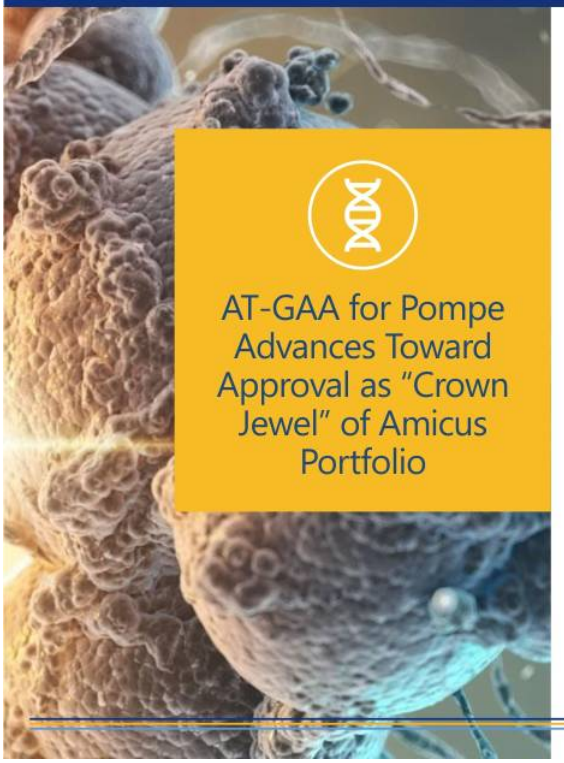


Program Updates

"We have a duty to obsolete our own technologies

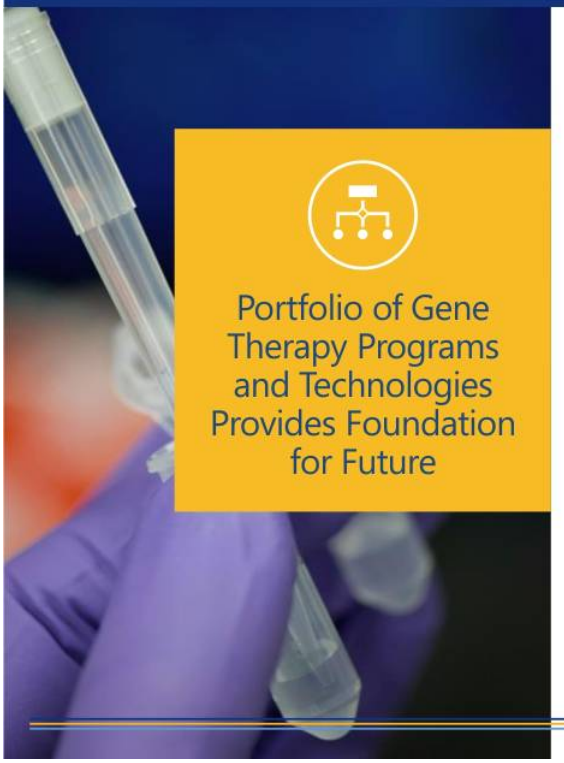
- Amicus Belief Statemer

AT-GAA: Updates & Key Takeaways



- PROPEL pivotal study expected to over-enroll (~120 Patients) by YE2019
- Pediatric study underway
- Amicus natural history data (POM-002) generally consistent with declines in 6MWT in published literature
- Manufacturing PPQ runs at WuXi biologics initiated
- Phase 2 data and natural history published literatur comparison continue to support potential to become Pompe standard of care
- Peak revenue potential of $1B-$2B, with exclusivity well into 2030s

Gene Therapy: Updates & Key Takeaways



- CLN6 Phase 2 interim data shows profound impact with pote to become first ever approved gene therapy for fatal brain disease in children
- Additional patients to be dosed in Phase 2 study of CLN3 (la cause of childhood neurodegeneration, 5,000+ children)
- Orphan drug designations granted in U.S. and EU for intrath AAV gene therapies for CLN6 and CLN3 Batten disease.
- Pompe gene therapy clinical candidate declared to move int IND-enabling studies
- Penn Collaboration is R&D engine, with rights to 50+ diseas
- 8 preclinical gene therapies in development

Closing Remarks

"We are business led and science driven

- Amicus Belief Statemer

2019 Key Strategic Priorities

1. Nearly double annual revenue for Galafold® (guidance $170M-$180M)
2. Complete enrollment in AT-GAA Pivotal Study (PROPEL) and report additional Phase 1/2 data
3. Report additional 2-year clinical results in CLN6-Batten disease and complete enrollment in ongoing CLN3-Batten disease Phase 1/2 study
4. Establish preclinical proof of concept for Fabry and Pompe gene therapies
5. Maintain strong financial position

Our Passion for Making a Difference Unites Us

Amicus is Now at a Major Inflection Point and Positioned to Create Significant Shareholder Value Ahead while Advancing our Mission for Patients







Thank You

"Our passion for making a difference unites us"

-Amicus Belief Statement

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Appendix

Reconciliation

Amicus Therapeutics, Inc.
Reconciliation of Non-GAAP Financial Measures
(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Total operating expenses - as reported GAAP	**$ 100,477**	**$ 172,467**	**$ 326,940**	**$ 307,835**
Research and development:				
Share-based compensation	3,106	2,905	12,090	8,603
Research and development asset acquisition expense	-	100,000	-	100,000
Selling, general and administrative:				
Share-based compensation	5,737	4,149	19,432	12,270
Changes in fair value of contingent consideration payable	789	1,300	2,652	2,700
Depreciation and amortization	1,116	1,073	3,261	3,015
Total operating expense adjustments to reported GAAP	10,748	109,427	37,435	126,588
Total operating expenses - as adjusted	$ 89,729	$ 63,040	$ 289,505	$ 181,247

AMICUS THERAPEUTICS, INC. (FOLD)

Q3 2019 EARNINGS CALL – TRANSCRIPT

(November 11, 2019 – 8:30AM EST)

OPENING

Operator:	Good morning, ladies and gentlemen, and welcome to the Amicus Third Quarter 2019 Results Conference Call Webcast. (Operator Instructions) As a reminder, this call is being recorded. I would now like to turn the conference over to your host, Ms. Sara Pellegrino, Vice President of Investor Relations. You may begin.
Sara Pellegrino: Amicus Therapeutics, Inc., Vice President of Investor Relations and Corporate Communications	Good morning. Thank you for joining our conference call to discuss Amicus Therapeutics Third quarter 2019 Financial Results and Corporate Highlights. Speaking on today's call, we have John Crowley, Chairman and Chief Executive Officer; Bradley Campbell, President and Chief Operating Officer; and Daphne Quimi, Chief Financial Officer. Also joining for Q&A are Dr. Jay Barth, Chief Medical Officer; Dr. Hung Do, Chief Science Officer; and Dr. Jeff Castelli, Chief Portfolio Officer and Head of Gene Therapy. As referenced on Slide 2, we may make forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 relating to our business as well as our plans and prospects. Our forward-looking statements should not be regarded as representation by us that any of our plans will be achieved. Any or all of the forward-looking statements made on this call may turn out to be wrong and can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. You are cautioned not to place undue reliance on any forward-looking statements, which speak only to 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 presentation and conference call to reflect events or circumstances after the date hereof. For a full discussion of such forward-looking statements and the risks and uncertainties that may impact them, we refer you to forward-looking statements and risk factors section of our annual report on Form 10-K for the year ended December 31, 2018, filed with the

Securities and Exchange Commission. The third quarter press release and materials from today's call, which will be available on our corporate website, and the quarterly report on 10-Q for the quarter ended September 30, 2019, to be filed following today's SEC holiday tomorrow.

At this time, it is my pleasure to turn the call over to John Crowley, Chairman and Chief Executive Officer of Amicus. John?

John F. Crowley:

Amicus Therapeutics, Inc., Chairman & CEO

Great. Thanks, Sara, and welcome, everyone, to our third quarter 2019 results conference call. I'm pleased to host today's conference call to highlight the tremendous effort and progress that we've made at Amicus during the third quarter and now into the early fourth quarter beginning on Slide 3.

A month ago, at our Analyst Day in New York, we grounded everyone in the vision for what we are building. The next great global biotechnology company, poised to impact many thousands of people around the world living with rare diseases. To achieve this vision, we are continuing to grow our very successful Galafold base business, which Brad will detail in a moment. We are also investing in the advancement of our leading rare disease pipeline, including our Phase III Pompe biologic, AT-GAA as well as our robust gene therapy pipeline and portfolio. We are also maintaining a very strong balance sheet and financial discipline to keep us fully funded well into the first half of 2022 through all major upcoming milestones, with a clear sight of -- line of sight to profitability and self-sustainability.

So let me move now to Slide #4. Again, as highlighted at the Amicus Analyst Day in October and again today, despite the volatility of the financial markets during the third quarter, our Amicus team focused intensely on the execution of our plans and the achievement of extraordinary results. For Amicus, the third quarter was another significant period of growth and execution across all of our science, clinical, regulatory and commercial efforts. Here are the four key takeaways.

First, Galafold continues to be one of the most successful launches for a rare disease medicine ever, and it remains the cornerstone of our success, with $48.8 million in third quarter revenue. We're also now treating more than 1,000 patients at a 90%-plus compliance and adherence rates, and we have upwardly revised full year 2019 guidance of now $170 million

to $180 million. All of the global launch metrics that we track are on target or exceeding target, including new patient starts, compliance and adherence to therapy, reimbursement and access, new country approvals and a broadening prescriber base, among others.

Secondly, following the completion of our strategic business review, our financial outlook is now significantly strengthened, with current cash of $514 million and runway revised now well into the first half of 2022, getting us on a path to profitability and self-sustainability. Much of our investment in research and development and the infrastructure that we have built around the world to deliver Galafold and to scale up and prepare for approval of AT-GAA, will also be offset significantly by growing revenues from Galafold and will also be highly leverageable.

Third is AT-GAA. That is our next-generation enzyme replacement therapy for Pompe disease and the crown jewel of our portfolio. This continues its significant momentum toward approval and to becoming what we believe will be the new standard of care for people living with Pompe disease. Today, we are announcing that 100 patients are now enrolled in the pivotal PROPEL study, which remains on track to now fully enroll about 120 patients by the end of this year.

On today's call, we're also reporting that the PPQ runs have been successfully initiated with our key partner, WuXi Biologics. And fourth, finally, our portfolio of gene therapy programs and technologies provides our foundation for the future and it continues to advance. Advances here in the third quarter include positive interim data in CLN6 Batten disease, a clinical-stage CLN3 gene -- 3 program as well.

We also announced at Analyst Day last month that we have selected a highly differentiated Pompe gene therapy candidate, a gene therapy candidate that is now moving forward into IND-enabling talk studies. And as I emphasized at the beginning of the call, we have a very strong balance sheet, financial discipline and financial path ahead. The completion of our strategic business review has further strengthened our financial position, which Daphne will highlight in just a moment, this includes savings to operating expenses already realized in the third quarter. We achieved that by taking actions with our spending and investments in a number of categories, including operating expenses to include SG&A and R&D; capital

expenses, including the phasing of capital expenditures; program prioritization; and also increased outlook for Galafold and the reported projection there, all of which will be highlighted today. So with that as setup, let me go ahead and turn the call over now to Daphne to review the Amicus' financial results, guidance and outlook. Daphne?

Daphne Quimi:

Amicus Therapeutics, Inc., Chief Financial Officer

Thank you, John, and good morning, everyone. Our financial overview begins on Slide 6 with our income statement for the 3-month period ending September 30, 2019. For the third quarter of 2019, we achieved Galafold revenue of $48.8 million, which is an increase of 137% over the third quarter of 2018. This includes year-over-year operational revenue growth measured at constant currency exchange rates of 143%, offset by a negative currency impact of $1.3 million or 6%. Cost of goods sold includes manufacturing costs as well as royalties associated with the sale of our product. Cost of goods sold as a percentage of net sales was 11.5% in the third quarter of 2019 as compared to 20.9% for the prior year period. Cost of goods sold as a percent of revenue was favorable as Galafold's revenue continues to grow in the United States where we do not own royalties as well as other countries where we are subject to lower royalties. We continue to make significant investments in R&D and manufacturing, with the ongoing pivotal study and commercial scale-up in our Pompe program as well as the expansion of our gene therapy portfolio and capabilities.

During the third quarter of 2019, we reported $58.9 million in R&D expense as compared to $138.2 million for the prior year period. The decrease is primarily due to an upfront payment of $100 million for the Celenex asset acquisition in 2018, partially offset by continued investments in the Pompe clinical study program and our gene therapy pipeline.

Total selling, general and administrative expense for the third quarter of 2019 was $39.7 million as compared to $31.9 million for the prior year period. The increase represents the expanded geographic scope of the ongoing Galafold commercial launch, including launch activities in Japan and the United States.

Net loss for the third quarter of 2019 was $61.8 million or $0.24 per share as compared to a net loss of $159.2 million or $0.84 per share for the prior year period. As of September 30, 2019, we had approximately 254.8 million shares outstanding.

Turning now to Slide 7. As John mentioned, we are now fully funded well into the first half of 2022 through the upcoming milestones in our portfolio and continued global growth. As part of our normal course of business, and considering all the new programs that we have integrated into our organization, we completed a strategic business review, where we identified our top priorities and areas of investment to drive efficiencies and cost savings while advancing all our key programs. As a result, we are taking the following actions that extend our cash runway. We will continue to support Galafold's revenue growth and have increased confidence around a higher-growth trajectory than we had previously forecast, as Bradley will highlight later. Through our internal teams and contract manufacturing partners, we have identified and are implementing synergies and efficiencies within gene therapy development and manufacturing. We also expect to take a phased approach to build out Amicus facilities, internal manufacturing and other capital expenditures.

We plan to continue our prudent gene therapy portfolio management process to support 1 to 2 INDs starting in 2021 and beyond. And as we grow, we are leveraging internal resources and external collaborators for measured internal headcount growth through 2022. We have recently begun to implement these measures and have already seen some positive impact in the third quarter. Going forward, again, to emphasize, we expect total operating expenses in 2020 to 2022 to remain flat as we, firstly, leverage the commercial global infrastructure that is already in place for the AT-GAA launch and other products in our pipeline; and secondly, transition the costs associated with the development of AT-GAA to multiple gene therapy programs in our pipeline.

Moving on to Slide 8. A few comments about our current cash position and 2019 financial guidance. Cash, cash equivalents and marketable securities totaled $514 million at September 30, 2019, compared to $504 million at December 31, 2018. The current cash position and total shares outstanding are inclusive of the June 2019 equity offering.

Looking at the remainder of 2019, we are reaffirming our upwardly revised full year Galafold revenue guidance of $170 million to $180 million, in addition to our non-GAAP operating expense guidance of $410 million to $420 million.

We define non-GAAP operating expense as research and development and SG&A expenses, excluding share-based compensation expense, changes in fair value of contingent consideration and depreciation. Total operating expense decreased year-over-year, and we're slightly down quarter-over-quarter. Some of these reductions reflected initiatives to moderate our rate of growth and cost control measures that we have taken. We do expect total operating expenses in the fourth quarter to be higher to reflect the initiation of the PPQ runs at WuXi for AT-GAA and the ramp-up of gene therapy manufacturing at our CMO partners. We expect to end the year within the previously stated full year non-GAAP operating expense range of $410 million to $420 million. And again, we expect that annual range to remain constant in the years ahead.

Considering our anticipated operating expenses and net cash generated from Galafold revenue, we expect to have approximately $420 million in cash at the end of 2019, which provides a runway well into the first half of 2022.

On Slide 9, I'll summarize the key takeaways for our financial outlook, as I highlighted during our Analyst Day. As mentioned, we are fully funded through upcoming major milestones. We have no financing planned or needed for the remainder of 2019 or the foreseeable future. We have made significant investments in R&D and G&A to move AT-GAA through manufacturing and towards the end of its development as well as build our global commercial infrastructure. These investments will be largely behind us by the end of 2019, and we believe that this is our peak year for non-GAAP operating expense.

As I mentioned earlier, we will leverage the support organization we have built to maximize value of future program advancements and products with only a modest additional investment required for the AT-GAA commercial effort.

Our total annual non-GAAP operating expense is expected to remain relatively flat within this $410 million to $420 million range in 2020 to 2022.

We expect operating expenses to be significantly offset by the projected $1 billion in cumulative global Galafold revenue over the same 3-year period, which Bradley will highlight in a moment. And as we execute what we believe to be the right set of tools, partnerships and technologies, we are not planning for

any significant business development activities in the foreseeable future.

I'm happy to address any questions during the Q&A but, for now, I'll turn it to Bradley to highlight the Galafold launch.

Bradley L. Campbell:

Amicus Therapeutics, Inc., President, COO & Director

Great. Thank you, Daphne, and good morning, everyone. Let me provide more color on the continued growth for Galafold in the third quarter and on our achievement of 1,000 patients on therapy at the end of Q3. Our mission at Amicus is to get our medicines to as many patients as quickly as possible. And with this key milestone, we are increasingly confident in the potential to drive Galafold adoption in thousands of additional patients along the path to $500 million in global sales in 2023 and $1 billion peak revenue opportunity.

Let's begin with a global snapshot on Slide 11. Total third quarter revenue, as has been mentioned, was $48.8 million, again, a year-over-year increase of 137%, driven by exceptionally strong momentum in new countries, including the U.S. and Japan as well as steady growth in our earlier-launch countries. Specifically, this reflects a $33.4 million or 68% of revenue generated outside of the United States and the remaining $15.4 million or 32% coming from within the United States. We have pricing and reimbursement now secured in 27 countries around the world, including 3 new additions this quarter, with South Korea, Greece and Argentina.

We already have the commercial team to support these global approvals, and we will continue to pursue opportunities to get Galafold approved and delivered to patients in more countries around the world going forward. This ongoing geographic expansion will continue to be an important growth driver, along with continuing to switch patients from enzyme replacement therapy and increasing uptake in the diagnosed untreated market, which I'll highlight more in a moment.

Turning now to Slide 12. Let me comment on the positive momentum across all key global commercial metrics that we're focusing on this quarter. First, at the global level, we estimate Galafold now has approximately 30% global market share of treated amenable patients, which is up from 24% in the second quarter, as we continue to add new switch patients as well as previously untreated patients to Galafold. Next, as John mentioned, compliance and adherence to this oral precision medicine continued to exceed 90% globally, reflecting what we

think is the strength of the experience that physicians and patients are having with Galafold. New patient starts continue to be very strong as well, and we continue to see strong performance across the metrics highlighted on this slide, in each of our regions, including the U.S., Japan, Europe and our smaller and midsized markets throughout the world.

Globally, we're also very encouraged by the increasing contribution from previously untreated patients. And as of September 30, on a global basis, 66% of patients on Galafold had switched from enzyme replacement therapy, while 34% were previously not treated. This is an important point, about 340 of our 1,000-plus patients have taken Galafold as their very first treatment for Fabry. So we've actually grown the overall Fabry market in 3 short years by about 5%, as Galafold is increasingly becoming a first-line standard of care treatment for Fabry patients with amenable mutations. In the medium term, we see that mix approaching 50-50 between switched and previously untreated patients. And in the longer term, we think a majority of Galafold patients may actually have been treatment-naive prior to the launch of Galafold.

Turning now to Slide 13. Let me recap the quarterly performance year-to-date that supports our upwardly revised guidance of $170 million to $180 million in global sales. In the third quarter, specifically, the increasing contributions of the U.S. and Japan and the continued growth in Europe helped to offset some of the uneven ordering patterns that we've seen in the third quarter in previous years. Given the trajectory we're on year-to-date, we think we'll do $50-plus million in GAAP revenue for Q4, which would put us in the middle of that $170 million to $180 million revenue guidance range. And remember, that's inclusive of about $4 million to $5 million of expected negative cumulative FX impact for the year, which we expect will be about $1 million to $1.25 million in foreign exchange impact each quarter, as Daphne highlighted upon briefly before. So again, great performance so far in the base business, with strong tailwinds coming into the end of the year.

Turning now to Slide 14. With these 3 years of performance behind us, including the first year of launch now in the U.S. and Japan, we can confidently say we are on a path to that $500 million sales opportunities in 2023. And as I outlined at Analyst Day, we're expecting about a 40% year-on-year growth rate to get to that $500 million. And we expect to generate $1 billion in cumulative revenue between 2020 and 2022 alone, and that

goes a long way towards funding the R&D and OpEx that Daphne just described.

We also have even further confidence in the $1 billion-plus revenue opportunity at peak. And just to put that in context, the global Fabry market was about $1.4 billion in 2018 as the overall Fabry population continues to grow, particularly through the increase of newborn and targeted screening and other diagnostic initiatives, which we're also beginning to invest in.

And finally, as a reminder, we have orphan exclusivity in U.S. and Europe, which alone takes us to the end of the 2020s, in addition to our Orange Book-listed patents that give us IP coverage into the late 2030s.

So with that, let me turn the call back to John to discuss our program updates for AT-GAA and Pompe as well as our gene therapy portfolio. John?

John F. Crowley: Great. Thanks, Bradley. So as many of you know, we just completed a detailed review of our entire portfolio during our October Analyst Day. So for today's call, I will highlight a few new pieces of information and briefly review the key takeaways. Many of the details that we covered at the Analyst Day can be reviewed on the event webcast and transcript, which of course, is available on our website.

So I'll begin here on Slide 16 with our crown jewel AT-GAA for Pompe disease. To remind everybody, again, this is the first-ever second-generation breakthrough therapy designation for any lysosomal storage disease therapy product as well as the first and only BTD for Pompe disease ever. We've seen tremendous momentum from, what we believe, maybe the next standard of care, again, for a broad population of people living with Pompe disease, and for a product representing, what we believe, could be a potential $2 billion-plus opportunity.

There are 3 new important updates with respect to AT-GAA on today's call.

First, we are reporting on the call today that the PPQ runs have now begun at WuXi Biologics. These will serve as the foundation for our CMC module for a BLA submission, which we continue to anticipate will be for full approval based on the results from the pivotal PROPEL study. Second, we continue to

make great strides in the PROPEL study enrollment, and we have now enrolled the target 100 patients in this study. This is a great achievement. As mentioned at Analyst Day, we are now targeting approximately 120 patients for this study in order to meet the extraordinary demand among physicians and patients across global participating sites. And we remain on track to complete that enrollment by year-end. We also continue our supported studies, including our important pediatric study to support a broad potential label for AT-GAA. And third, we have completed a high-level assessment of the data from our Amicus Natural History study, known as POM-002. This is a retrospective natural history study of 100 patients treated with standard of care enzyme replacement therapy, who are matched to the patients treated with AT-GAA in our Phase II Pompe study. We plan to present the details at an upcoming medical meeting in the first half of 2020, and we plan that this will also support our BLA submission for full approval.

Importantly, you should expect that the data in POM-002 to be consistent with the natural history on standard of care enzyme replacement therapy in the published literature. Some of this was highlighted during the Analyst Amicus Day in October. As a reminder, our base case remains as a pivotal PROPEL study, together with additional data that we've collected in the Phase I/II study to support the full approval of AT-GAA. And while we engage with regulators frequently on this program, I'll remind everybody that we will not be providing any color or expectations on any pending or future regulatory interactions until after they have occurred and only if they materially impact our assumptions from this base case.

We continue to be extremely excited and optimistic about AT-GAA as well as our preclinical Pompe gene therapy program to build what we believe could be the largest and most valuable franchise in the industry with the potential to offer solutions to all patients living with Pompe disease globally.

Moving on now to Slide 17. I'll highlight here, our industry-leading portfolio of gene therapies for rare diseases. First, in CLN6. We've seen positive interim data in our clinical study, which demonstrates meaningful impact of our AAV gene therapy in this devastating form of Batten disease. The positive interim data now includes our initial primary analysis of the combined Hamburg Motor & Language Scores, of Motor & Language Function, in addition to the individual component scores on motor, language, seizure and vision that continue to

support the potential for this gene therapy to halt the progression of this devastating fatal neurologic disease. The CLN6 results provide important read through also for our clinical study in CLN3 Batten disease. Again, CLN3 Batten is the most common form of childhood neurodegeneration. And in this program, we have safely dosed the initial cohort in addition to the patients in our higher dose cohort. Also, we have now received EU and U.S. orphan drug designations for both CLN6 and CLN3 Batten disease, which together with our CLN1 and CLN8 programs provide a robust Batten disease franchise that combined may represent $1 billion in peak recurring revenue and of course, the opportunity to help thousands of children. As we mentioned at Analyst Day, we have also now declared a Pompe gene therapy clinical candidate to move now into IND-enabling toxicology studies and this program has the potential to enter the clinic in 2021. Here in this program, we are focused on protein engineering and other work with our colleagues at UPenn to ensure that we can optimize expression, secretion and targeting so that we may have a wider effective therapeutic window. And finally, our collaboration with Penn. In this collaboration, we have an R&D engine, we believe, to fuel our future growth with rights to 50-plus diseases, including 8 preclinical programs.

So now on Slide 18. Following these program updates, I'd like to conclude the call with a reminder of our 5 key strategic priorities, all of which we are on track to meet or exceed. First, the success we've had with Galafold, as Brad went into detail with, our confidence in 2019 guidance and the trajectory that it puts us on toward that $500 million in Galafold sales by 2023. And again, with what we believe is a $1 billion peak potential for Galafold.

Second, again, AT-GAA, which remains our crown jewel of our portfolio. We have a high degree of confidence in the data that we've seen, the PROPEL study that we've enrolled, and again, now with a very sharp focus on manufacturing, we continue to make sure that we have enabled the CMC section of the BLA. Also too, we've seen tremendous progress across our Batten franchise and in clinic, as well as our preclinical gene therapy programs in collaboration with UPenn. And very importantly too, I'll highlight here, our financial strength and financial discipline and now the extension of our cash runway now well into the first part of 2022. Again, we are fully funded now through all major milestones while continuing to grow the company with no need to raise capital in 2019 or anytime soon.

As we need -- and as we need additional capital, we think that it's in the outer years and we also believe that, that capital could come from multiple non-equity sources and non-equity-linked sources to close, what we think is, a very small gap on the path to profitability and self-sustainability.

So on Slide 19 here, just to conclude, finally, before we turn the call over to Q&A, I'd just like to focus again on the people living with rare diseases. We are fighting to bring new hope and to alleviate an enormous amount of suffering for many thousands of people and their families. And we're here to deliver on a mission to these patients and to create significant value for our shareholders.

So with that, operator, we're happy to take questions.

QUESTIONS & ANSWERS

Operator:	(Operator Instructions) Our first question comes from Anupam Rama of JPMorgan.
Tessa Thomas Romero: JP Morgan Chase & Co., Research Division – Associate	This is Tessa on this morning for Anupam. A few from us on the Batten's program, specifically. First, can you remind us of latest thinking about next steps for the CLN6 program, specifically with an eye towards regulatory strategy here? And then secondly, for the CLN3 program, with dosing complete, as noted in prior remarks, how should we be thinking about next program updates for CLN3?
John F. Crowley:	Sure. Thank you, Tessa. So for the questions for CLN6 and CLN3, jay, I'll let you comment on what we see as next steps there.
Jay Barth: Amicus Therapeutics, Inc., Chief Medical Officer	Sure. We, of course, have dosed the initial cohort of patients and have also say the additional patients to be dosed in the CLN6 study, with the aim of then engaging the regulators with the data that we have to discuss steps forward. And that's something that we'll be able to disclose after we have had those interactions. But we plan to move ahead with the clinical study that we have now and expand actually the cohort in that study to include additional patients. That's for CLN6. For CLN3, we -- as John stated before, we have built the initial cohort of patients for the low dose, moving towards dosing additional patients in the higher dose cohort, with the anticipation when

	additional material is available to dose additional patients presumably at the higher dose, that shows the same safety as we've seen in low dose. And once again, with the body of data that we get in the Phase I/II study, engage regulators with that and discuss what the regulatory path forward would be for CLN3 as well, and this is something that will happen over the next year.
John F. Crowley:	So Tessa, just one thing to add to that, in addition to all the clinical work and regulatory discussions that Jay has highlighted. I'll also highlight that significant amount of the effort in both of these programs now involve the technology transfer, which is well underway for both of these programs to Brammer and Paragon, respectively, and a lot of the work, again, will focus on all of the CMC requirements that would be necessary to support any BLA filings here.
Operator:	And our next question comes from Ritu Baral of Cowen.
Ritu Subhalaksmi Baral: Cowen and Company, LLC, Research Division - MD & Senior Biotechnology Analyst	This is [] on for Ritu. Just 2 quick ones from me. One on the Battens program. I'm just wondering, how are things going in terms of building out natural history? Is that really being done by Nationwide's? Or are you guys also considering on cohort? And then the second thing is, I know you're initiating the PPQ runs with WuXi, would there be potentially a possibility for submitting a rolling BLA starting next year? Just wondering how you guys are thinking about that?
John F. Crowley:	Sure. Jeff -- I'll ask Jeff Castelli, our Head of Gene Therapy to talk about the national history, which we think is going to be very important as the basis of approval for these Battens programs. So Jeff, where are we with both of those?
Jeffrey P. Castelli: Amicus Therapeutics, Inc., Chief Portfolio Officer & Head of Gene Therapy	Sure. So I think as you've seen at Analyst Day, we've already provided some of the initial natural history data, that has all come from nationwide. They have an ongoing study, continue to compile data in that trial. We also have identified several other sources of natural history data. So collectively, we are very optimistic we can get in the ballpark of 50 patients or so for a natural history data set, which we think will be very robust for doing any kind of natural match comparisons.
John F. Crowley:	Sure. And just to your question, again, with the PPQ runs initiated and a heavy focus on the CMC section for AT-GAA. We think particularly with the breakthrough therapy

	designation with this program that there is a potential for a BLA -- a rolling-BLA submission to begin. But again, we're not going to comment on ongoing discussions with regulators once we have clarity on the potential there, we'll be able to provide an update as well.
Operator:	And our next question comes from Joseph Schwartz of SVB Leerink.
Dae Gon Ha: SVB Leerink LLC, Research Division - Associate	Congrats on all the progress. So two questions for me. This is Dae Gon, dialing in for Joe. Maybe for Jay or Jeff. If we can maybe first touch upon Batten's disease? So when we saw the latest update of the Child Neurology Society Presentation, like you mentioned in the prepared remarks, we saw some subscores. Particularly, I was wondering about what your thoughts were with regards to the visual acuity that we saw in 3 out of the 6. I think it's older patients that seem to progress. So any thoughts on intravitreal administration of the CLN6 gene therapy? And then on the second part, with regards to the Pompe gene therapy, can you remind us, is this the same candidate you presented the preclinical data for at ASGCT? And I understand that there is increasing competitive forces sort of coalescing in this area. But any additional data that we can expect to emerge before you enter into the clinic? Or any specifics you can provide on this candidate?
John F. Crowley:	Yes. Jay, I'll let you take the first part with what the additional data for Batten that we showed in -- at the Child Neurology event.
Jay Barth:	Yes, to bring everyone up to speed a bit on what was presented at Child Neurology Society a couple of weeks ago that you're referring to, it was both more granular data on the Hamburg Motor & Language subscores, which -- both combined and separately, which showed stabilization, both in the combined Motor & Language, plus each component individually Motor and Language. They're very consistent with one another, showing that the effect of the gene therapy on the patients, most profoundly in the younger patients, but in almost all of the patients as well when compared to natural history, match comparison in terms of slowing the progression of the disease or frankly, stabilizing it. That was in the Motor & Language. The additional new data were on the Vision scale within the Hamburg and the seizure scale within the Hamburg. Both showed general stabilization or a -- slowing the progression of the disease. A caveat and I think we said at the time for the

visual scores and the Hamburg is that is just one, the first data that we have on the Vision available, but there will be more data related to visual acuity and other visual tests that will be coming up in the future. So we'll share that when we have that analyzed as well. And on the seizure subscale as well showing stabilization of seizure activity in all, but the most advanced patients. That was what we had shown, and I'll let Jeff comment on the other question about intravitreal or other administration?

Jeffrey P. Castelli: Yes. So there actually is a published preclinical manuscript with our CLN6 gene therapy showing an improvement in the eye in the animal studies. So we are hopeful that the initial intrathecal treatment can at least partially address the vision defects. And as we continue to see more data, we'll assess if there could be a benefit of adding an additional route down the line. But right now, we're optimistic that the intrathecal approach will have an improvement across all the different functions. And like we've seen older patients may continue to decline some, whereas, we hope to see really more affecting the younger kids in terms of stabilization.

John F. Crowley: Great. Yes, I'll just comment on the second question then for the Pompe gene therapy, dig on. I guess this is the initial data that we presented at the Gene Therapy meeting in Washington back in April. Again, this was something that we and Jim Wilson and his team, we're incredibly pleased to see these results that we presented back in April. We continued preclinical proof of concepts through the summer into the early fall. And then we -- of course, we had the additional data that we showed at Analyst Day that allowed us to declare this as the candidate to move forward here.

Look, there are a lot of people now involved in Pompe gene therapy, which I think, is excellent. I think it offers a lot of promise to people living with Pompe. It kind of takes me back to 21 years ago when I read my first paper on Pompe gene therapy. And now after all these years to finally see people moving forward, I think, is a very good thing. What we're doing at Amicus, though, is a very differentiated approach to a gene therapy here. And what our goal is, is to provide a complete approach to addressing this disease through gene therapy, through many steps that we've taken with Dr. Wilson and his team. These include the protein engineering to optimize secretion, expression and targeting the key tissues of disease that includes muscle and very importantly, CNS targeting to reach within motor neurons. Again, Pompe is a neuromuscular

	disease and a disease of motor neurons. So those steps, coupled with what we believe to be the optimal promoter and the right vector, we think, could lead to a highly differentiated program and something we're very eager now to move forward.
Operator:	And our next question comes from Mohit Bansal of Citi.
Keith Richard Tapper: Citigroup Inc, Research Division - Research Analyst	This is Keith on for Mohit. Of course, congrats on the progress this quarter. Just wanted one quick question for you. Could you walk us through what the R&D and cash runway guidance reflects as we approach the end of 2019? And then for the flat year-over-year guidance for 2020? What beyond the current programs has baked in? Or should we expect higher spending in connection with expanded programs, particularly with respect to the agreement with Penn?
John F. Crowley:	Sure. I think we were pretty clear on the call, but we're happy to repeat it. Daphne, do you want to tackle those?
Daphne Quimi:	Sure. So what's included in the R&D spend is -- are the key priorities that John discussed at the beginning of the call, which is to continue to move AT-GAA forward through approval and then focus in on our gene therapy pipeline. So all of that spend is included in the cash runway guidance as well as the operating expense guidance that we've given.
John F. Crowley:	Yes. Again, I -- thank you, Daphne. I just want to be perfectly clear, again, what we're doing now is we've laid the foundation through very significant investments in R&D for our crown jewel, for AT-GAA. And we've also made some early investments in gene therapy. With the R&D expenses, a significant amount that we've invested over the last couple of years, that total dollar amount, you should expect to remain relatively flat in the coming years. And AT-GAA is a very expensive program, the largest lysosomal study and the most expensive, I'm sure. lysosomal study ever conducted, again, to fund this crown jewel. That spending now is going to be able to be redeployed as AT-GAA moves from clinical development toward approval and commercialization. We can take the expenditures there, move them to multiple gene therapy programs. Depending on the gene therapy programs, we can fund 5 to 10 clinical-stage gene therapy programs, including all the R&D necessary to support these programs for the AT-GAA program. In addition, on the SG&A side, we've enabled a very capable -- highly capable commercial organization, now globally, to deliver Galafold successfully. It's now preparing in

	the early stages for a launch for AT-GAA. When we launch AT-GAA, we think we need to hire maybe 20 additional people globally to support that, so effectively remaining flat. So highly leverageable infrastructure. So with all of that, this year, again, operating expenses, SG&A and R&D at $410 million to $420 million, we're very confident will come in, in that range. And that range should be one that carries forward for at least the next 3 years through the end of 2022 to reflect the advancement of all these programs.
Operator:	(Operator Instructions) And our next question comes from Earl DeSouza of H.C. Wainwright.
Earl DeSouza: H.C. Wainwright & Co, LLC, Research Division - Associate	Most of our questions have been answered already, but I had a quick housekeeping question. So is there any significant room to lower your COGS from the 12% range, given the anticipated volume growth?
John F. Crowley:	Yes. The only thing we'd say is, from a manufacturing perspective, it's a pretty steady-state process at this point and distribution as well. The one place where you see a little bit of movement, as Daphne highlighted, is in the royalty. Our royalties are limited to ex-U.S. geographies. And so as the U.S. and non-royalty producing countries continue to be a higher contribution of sales, you might see that number creep down a little bit. But really, that's just a function of the distribution of revenue between royalty and non-royalty. We should not expect further savings from an operating cost of goods perspective.
Operator:	And our next question comes from Yun Zhong of Janney.
Yun Zhong: Janney Montgomery Scott LLC, Research Division - Equity Research Analyst & Director of Biotechnology Research	So the question, it's on the -- on Pompe gene therapy program. I believe you've talked about potential additional animal species for preclinical study and also alternative route of administration. So I wondered, do you think IV is still the best way to deliver? And do you plan to study the candidate in -- for example, nonhuman primate. And also at which point do you plan to disclose what kind of AAV of each capsid that is?
John F. Crowley:	Sure. I'll ask Jeff Castelli to field that.
Jeffrey P. Castelli:	Yes. Sure. So we are moving forward with all of our preclinical IND-enabling studies, which will include primate studies. As we've mentioned before, we are definitely going to address the CNS aspects or look to address the CNS aspects. While we've

seen in our mouse studies that IV administration led to a robust impact in the CNS. As we go through those primate studies, we might determine that we need to do a combination of IV plus intrathecal to make sure we address the CNS. And we will provide that data as we have it. But right now, we're really excited by the overall construct and its potential whether it's dosed IV alone or IV plus intrathecal.

Operator: And our next question comes from Salveen Richter of Goldman Sachs.

Andrea R. Tan: This is Andrea on for Salveen. My first one is, when you think about your goal of moving Galafold for mostly switch patients to predominantly treatment-naive patients. Can you help us understand the gating factors to achieving this transition?

Goldman Sachs Group Inc., Research Division - Research Analyst

John F. Crowley: Yes. Bradley, please?

Bradley L. Campbell: Yes, sure. And remember, we still have quite a bit of room left to grow from a switch perspective. U.S. and Japan, as an example, are more recently launched countries. And our strategy has always been to focus on the switch patients first because they're the ones that are already in the system. They're getting treated every other week with an alternative therapy. And so that's the initial population, and there's lots of switch patients still to move. That being said, in our more mature launch markets, we're starting to see roughly equal rate of growth from switch and naive patients. And I think there are a number of things there. First of all, again, those patients are not coming in every other week for their infusion, so you have to reach out to those patients through the physicians. I think also as experience builds with the product that gives physicians and patients more confidence to take a therapy -- a relatively new therapy as their first treatment for their Fabry disease. And obviously, also, it's a big factor of the diagnosis rates, we're seeing -- we continue to see a 10% to 20% diagnosis rate in Fabry disease. That's driven by newborn screening, targeted-population screening, other diagnostic initiatives. So that will also contribute to that increasing rate of previously untreated patients coming on to Galafold.

Operator: Thank you. And at this time, I would now like to turn the conference back to Mr. John Crowley, Chairman and CEO, for closing remarks.

John F. Crowley:	Great. Thank you, operator. Thank you all for listening again, a very, very successful quarter. And again, we remain focused on delivering on our mission for patients and for shareholders. Thank you for listening. Have a great day.
Operator:	This concludes today's conference call. Thank you, and have a great day.