UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2019

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number 001-33497

Amicus Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**71-0869350**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification Number)
1 Cedar Brook Drive, Cranbury, NJ	**08512**
(Address of Principal Executive Offices)	(Zip Code)

(609) 662-2000

(Registrant's Telephone Number, Including Area Code)

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	FOLD	NASDAQ Global Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒	Accelerated filer ☐
Non-accelerated filer ☐	Smaller reporting company ☐
	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. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The number of shares outstanding of the registrant's common stock, $0.01 par value per share, as of October 31, 2019 was 254,809,971 shares.

AMICUS THERAPEUTICS, INC.

Form 10-Q for the Quarterly Period Ended September 30, 2019

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks, uncertainties, and assumptions. Forward-looking statements are all statements, other than statements of historical facts, that discuss our current expectations and projections relating to our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans, and objectives of management. These statements may be preceded by, followed by, or include the words "aim," "anticipate," "believe," "can," "could," "estimate," "expect," "forecast," "intend," "likely," "may," "outlook," "plan," "potential," "predict," "project," "seek," "should," "will," "would," the negatives or plurals thereof, and other words and terms of similar meaning, although not all forward-looking statements contain these identifying words.

We have based these forward-looking statements on our current expectations and projections about future events. Although we believe that our assumptions made in connection with the forward-looking statements are reasonable, we cannot assure you that the assumptions and expectations will prove to be correct. You should understand that the following important factors could affect our future results and could cause those results or other outcomes to differ materially from those expressed or implied in our forward-looking statements:

- the progress and results of our preclinical and clinical trials of our drug candidates and gene therapy candidates;
- the cost of manufacturing drug supply for our clinical and preclinical studies, including the cost of manufacturing Pompe Enzyme Replacement Therapy ("ERT") and gene therapies;
- the scope, progress, results, and costs of preclinical development, laboratory testing, and clinical trials for our product candidates including those testing the use of pharmacological chaperones co-formulated and co-administered with ERT and for the treatment of lysosomal storage disorders and gene therapies for the treatment of rare genetic metabolic diseases;
- the future results of on-going preclinical research and subsequent clinical trials for cyclin-dependent kinase-like 5 ("CDKL5") deficiency, including our ability to obtain regulatory approvals and commercialize CDKL5 therapies and obtain market acceptance for such therapies;
- the costs, timing, and outcome of regulatory review of our product candidates;
- the number and development requirements of other product candidates that we pursue;
- the costs of commercialization activities, including product marketing, sales, and distribution;
- the emergence of competing technologies and other adverse market developments;
- our ability to successfully commercialize Galafold® ("migalastat HCl");
- our ability to manufacture or supply sufficient clinical or commercial products;
- our ability to obtain reimbursement for Galafold®;
- our ability to satisfy post-marketing commitments or requirements for continued regulatory approval of Galafold®;
- our ability to obtain market acceptance of Galafold®;
- the costs of preparing, filing, and prosecuting patent applications and maintaining, enforcing, and defending intellectual property-related claims;
- the extent to which we acquire or invest in businesses, products, and technologies;
- our ability to successfully integrate our acquired products and technologies into our business, including the possibility that the expected benefits of the transactions will not be fully realized by us or may take longer to realize than expected;
- our ability to establish collaborations and obtain milestone, royalty, or other payments from any such collaborators;
- our ability to adjust to changes in European and United Kingdom markets as the United Kingdom leaves the European Union;
- fluctuations in foreign currency exchange rates; and
- changes in accounting standards.

In light of these risks and uncertainties, we may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions, and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in Part I Item 1A — Risk Factors of the Annual Report on Form 10-K for the fiscal year ended December 31, 2018, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Those factors and the other risk factors described therein are not necessarily all of the important factors that could cause actual results or developments to differ materially from those expressed in any of our forward-looking statements. Other unknown or unpredictable factors also could harm our results. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, collaborations, or investments we may make. Consequently, there can be no assurance that actual results or developments anticipated by us will be realized or, even if substantially realized, that they will have the expected consequences to, or effects on, us. Given these uncertainties, investors are cautioned not to place undue reliance on such forward-looking statements.

You should read this Quarterly Report on Form 10-Q in conjunction with our Annual Report on Form 10-K for the fiscal year ended December 31, 2018 completely and with the understanding that our actual future results may be materially different from what we expect. These forward-looking statements speak only as of the date of this report. We undertake no obligation, and specifically decline any obligation, to publicly update or revise any forward-looking statements, even if experience or future developments make it clear that projected results expressed or implied in such statements will not be realized, except as may be required by law.

PART I. FINANCIAL INFORMATION

ITEM 1. CONSOLIDATED FINANCIAL STATEMENTS AND NOTES (UNAUDITED)

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

See accompanying notes to consolidated financial statements

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

See accompanying notes to consolidated financial statements

Amicus Therapeutics, Inc.
Consolidated Statements of Comprehensive Loss
(Unaudited)
(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Net loss	$ (61,809)	$ (159,163)	$ (266,659)	$ (270,914)
Other comprehensive (loss) gain:				
Foreign currency translation adjustment gain, net of tax impact of $207, $59, $237 and $168, respectively	584	665	661	1,167
Unrealized (loss) gain on available-for-sale securities, net of tax impact of $(23), $0, $197 and $0, respectively	(11)	244	551	225
Other comprehensive income	$ 573	$ 909	$ 1,212	$ 1,392
Comprehensive loss	$ (61,236)	$ (158,254)	$ (265,447)	$ (269,522)

See accompanying notes to consolidated financial statements

Amicus Therapeutics, Inc.
Consolidated Statements of Changes in Stockholders' Equity
(Unaudited)
(in thousands, except share amounts)

Three Months Ended September 30, 2019

	Common Stock		Additional Paid-In Capital	Warrants	Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount					
Balance at June 30, 2019	254,513,522	$ 2,589	$ 2,201,447	$ 12,387	$ 707	$ (1,617,072)	$ 600,058
Stock issued from exercise of stock options, net	212,995	2	1,046	—	—	—	1,048
Stock issued from equity financing	—	—	—	—	—	—	—
Restricted stock tax vesting	45,646	—	(446)	—	—	—	(446)
Stock-based compensation	—	—	8,843	—	—	—	8,843
Unrealized holding loss on available-for-sale securities	—	—	—	—	(11)	—	(11)
Foreign currency translation adjustment	—	—	—	—	584	—	584
Net loss	—	—	—	—	—	(61,809)	(61,809)
Balance at September 30, 2019	254,772,163	$ 2,591	$ 2,210,890	$ 12,387	$ 1,280	$ (1,678,881)	$ 548,267

Nine Months Ended September 30, 2019

	Common Stock		Additional Paid-In Capital	Warrants	Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount					
Balance at December 31, 2018	189,383,924	$ 1,942	$ 1,740,061	$ 13,063	$ 68	$ (1,412,222)	$ 342,912
Stock issued from exercise of stock options, net	1,352,623	13	7,795	—	—	—	7,808
Stock issued from equity financing	18,720,930	187	188,807	—	—	—	188,994
Restricted stock tax vesting	445,956	—	(3,001)	—	—	—	(3,001)
Stock issued for contingent consideration	771,804	8	9,308	—	—	—	9,316
Stock-based compensation	—	—	31,522	—	—	—	31,522
Warrants exercised	101,787	1	1,487	(676)	—	—	812
Equity component of the convertible notes	43,995,139	440	215,036	—	—	—	215,476
Termination of capped call confirmations	—	—	19,875	—	—	—	19,875
Unrealized holding gain on available-for-sale securities	—	—	—	—	551	—	551
Foreign currency translation adjustment	—	—	—	—	661	—	661
Net loss	—	—	—	—	—	(266,659)	(266,659)
Balance at September 30, 2019	254,772,163	$ 2,591	$ 2,210,890	$ 12,387	$ 1,280	$ (1,678,881)	$ 548,267

See accompanying notes to consolidated financial statements

Amicus Therapeutics, Inc.
Consolidated Statements of Changes in Stockholders' Equity
(Unaudited)
(in thousands, except share amounts)

Three Months Ended September 30, 2018

	Common Stock		Additional Paid-In Capital	Warrants	Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount					
Balance at June 30, 2018	189,053,214	$ 1,939	$ 1,723,865	$ 13,063	$ (1,994)	$ (1,174,978)	$ 561,895
Stock issued from exercise of stock options, net	178,992	2	909	—	—	—	911
Restricted stock tax vesting	22,135	—	(654)	—	—	—	(654)
Stock-based compensation	—	—	7,054	—	—	—	7,054
Unrealized holding gain on available-for-sale securities	—	—	—	—	244	—	244
Foreign currency translation adjustment	—	—	—	—	665	—	665
Net loss	—	—	—	—	—	(159,163)	(159,163)
Balance at September 30, 2018	189,254,341	$ 1,941	$ 1,731,174	$ 13,063	$ (1,086)	$ (1,334,141)	$ 410,951

Nine Months Ended September 30, 2018

	Common Stock		Additional Paid-In Capital	Warrants	Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount					
Balance at December 31, 2017	166,989,790	$ 1,721	$ 1,400,758	$ 16,076	$ (2,095)	$ (1,063,610)	$ 352,850
Stock issued from exercise of stock options, net	1,281,769	13	8,478	—	—	—	8,491
Stock issued from equity financing	20,239,839	202	294,382	—	—	—	294,584
Restricted stock tax vesting	289,729	—	(2,681)	—	—	—	(2,681)
Stock-based compensation	—	—	20,873	—	—	—	20,873
Reclassification upon ASU 2018-02 adoption	—	—	—	—	(383)	383	—
Warrants exercised	453,214	5	6,625	(3,013)	—	—	3,617
Change in fair value of derivatives	—	—	2,739	—	—	—	2,739
Unrealized holding gain on available-for-sale securities	—	—	—	—	225	—	225
Foreign currency translation adjustment	—	—	—	—	1,167	—	1,167
Net loss	—	—	—	—	—	(270,914)	(270,914)
Balance at September 30, 2018	189,254,341	$ 1,941	$ 1,731,174	$ 13,063	$ (1,086)	$ (1,334,141)	$ 410,951

See accompanying notes to consolidated financial statements

Amicus Therapeutics, Inc.
Consolidated Statements of Cash Flows
(Unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2019	**2018**
Operating activities		
Net loss	$ (266,659)	$ (270,914)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of debt discount and deferred financing	2,290	7,868
Depreciation and amortization	3,261	3,015
Stock-based compensation	31,522	20,873
Loss on exchange of convertible debt	40,624	—
Change in fair value of derivatives	—	2,739
Non-cash changes in the fair value of contingent consideration payable	2,652	2,700
Foreign currency remeasurement loss	2,665	775
Other	(136)	—
Changes in operating assets and liabilities:		
Accounts receivable	(12,644)	(5,182)
Inventories	(2,016)	(2,049)
Prepaid expenses and other current assets	(3,321)	2,633
Accounts payable and accrued expenses	8,714	3,684
Other non-current assets and liabilities	1,964	(420)
Deferred reimbursements	(1,500)	(5,000)
Net cash used in operating activities	$ (192,584)	$ (239,278)
Investing activities		
Sale and redemption of marketable securities	389,242	388,135
Purchases of marketable securities	(311,965)	(440,963)
Capital expenditures	(9,087)	(4,571)
Net cash provided by (used in) investing activities	$ 68,190	$ (57,399)
Financing activities		
Proceeds from issuance of common stock, net of issuance costs	188,994	294,584
Proceeds from senior secured term loan	—	146,622
Payment of finance leases	(177)	(218)
Purchase of vested restricted stock units	(3,001)	(2,681)
Proceeds from termination of capped call confirmations	19,875	—
Proceeds from exercise of stock options	7,808	8,492
Proceeds of exercise of warrants	812	3,617
Net cash provided by financing activities	$ 214,311	$ 450,416
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	$ (2,591)	$ (1,146)
Net increase in cash, cash equivalents, and restricted cash	87,326	152,593
Cash, cash equivalents, and restricted cash at beginning of period	82,375	51,237
Cash, cash equivalents, and restricted cash at end of period	$ 169,701	$ 203,830
Supplemental disclosures of cash flow information		
Cash paid during the period for interest	$ 13,145	$ 3,787
Capital expenditures, unpaid	$ 2,802	$ 538
Payment of contingent consideration in shares	$ 9,316	$ —

See accompanying notes to consolidated financial statements

Note 1. Business

Amicus Therapeutics, Inc. (the "Company") is a global patient-dedicated biotechnology company engaged in the discovery, development, and commercialization of a diverse set of novel treatments for patients living with rare diseases. The Company has a portfolio of product opportunities led by the novel medicine for Fabry disease that has achieved widespread global approval, a differentiated biologic for Pompe disease in the clinic, and an industry leading rare disease gene therapy portfolio.

The cornerstone of the Company's portfolio is Galafold® (also referred to as "migalastat"), the first and only approved oral precision medicine for people living with Fabry disease who have amenable genetic variants. Migalastat is currently approved under the trade name Galafold® in the United States ("U.S."), European Union ("E.U."), and Japan, with additional approvals granted and applications pending in several other geographies.

The lead biologics program of the Company's pipeline is Amicus Therapeutics GAA ("AT-GAA", also known as ATB200/AT2221), a novel, clinical-stage, potential best-in-class treatment paradigm for Pompe disease. In February 2019, the U.S. Food and Drug Administration ("FDA") granted Breakthrough Therapy Designation to AT-GAA for the treatment of late onset Pompe disease.

The Company has established an industry leading gene therapy portfolio of potential therapies for people living with rare metabolic diseases, through a license with Nationwide Children's Hospital ("NCH") and an expanded collaboration with the University of Pennsylvania ("Penn"). The Company's pipeline includes gene therapy programs in rare, neurologic lysosomal disorders ("LDs"), specifically: CLN6, CLN3, and CLN8 Batten disease, Pompe disease, Fabry disease, CDKL5 deficiency disorder ("CDD"), Niemann-Pick Type C (“NPC”), Mucopolysaccharidosis Type IIIB ("MPSIIIB"), as well as a next generation program in Mucopolysaccharidosis Type IIIA ("MPSIIIA"). This expanded collaboration with Penn also provides the Company with exclusive disease-specific access and option rights to develop potentially disruptive new gene therapy platform technologies and programs for most LDs and a broader portfolio of rare diseases, including Rett Syndrome, Angelman Syndrome, Myotonic Dystrophy, and select other muscular dystrophies.

During the second quarter of 2019, the Company completed an underwritten equity offering and issued 18.7 million shares of its common stock at $10.75 per share, inclusive of the fully exercised option to purchase additional shares from the initial offering. This transaction resulted in net proceeds of $189.0 million, after deducting underwriting discounts and commissions and offering expenses.

During the first and second quarters of 2019, the Company entered into separate, privately negotiated exchange agreements (the "Exchange Agreements") with a limited number of holders (the "Holders") of the unsecured Convertible Senior Notes due in 2023 ("Convertible Notes"). Under the terms of the Exchange Agreements, the Holders agreed to exchange an aggregate principal amount of $247.2 million of Convertible Notes held by them in exchange for an aggregate of approximately 44.0 million shares of the Company common stock, par value $0.01 per share.

The Company had an accumulated deficit of $1.7 billion as of September 30, 2019 and anticipates incurring losses through the fiscal year ending December 31, 2019 and beyond. The Company has historically funded its operations through stock offerings, debt issuances, Galafold® revenues, collaborations, and other financing arrangements.

The current cash position, including expected Galafold® revenues, is sufficient to fund ongoing Fabry, Pompe, and gene therapy program operations into the first half of 2022. Potential future business development collaborations, pipeline expansion, and investment in manufacturing capabilities could impact the Company's future capital requirements.

Note 2. Summary of Significant Accounting Policies

Basis of Presentation

The Company has prepared the accompanying unaudited consolidated financial statements in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10-01 of Regulation S-X. Accordingly, they do not include all of the information and disclosures required by U.S. GAAP for complete financial statements. In the opinion of management, the accompanying unaudited financial statements reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company's interim financial information.

The accompanying unaudited consolidated financial statements and related notes should be read in conjunction with the Company's financial statements and related notes as contained in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018. For a complete description of the Company's accounting policies, please refer to the Annual Report on Form 10-K for the fiscal year ended December 31, 2018.

Consolidation

The consolidated financial statements include the accounts of the Company and its subsidiaries. Intercompany accounts and transactions have been eliminated in consolidation.

Foreign Currency Transactions

The functional currency for most of the Company's foreign subsidiaries is their local currency. For non-U.S. subsidiaries that transact in a functional currency other than the U.S. dollar, assets and liabilities are translated at current rates of exchange at the balance sheet date. Income and expense items are translated at the average foreign exchange rates for the period. Adjustments resulting from the translation of the financial statements of the Company's foreign operations into U.S. dollars are excluded from the determination of net income and are recorded in accumulated other comprehensive income, a separate component of stockholders' equity.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates.

Reclassification

Certain prior year amounts have been reclassified for comparative purposes. The reclassifications did not affect results of operations, net assets, or cash flows.

Cash, Cash Equivalents, Marketable Securities, and Restricted Cash

The Company considers all highly liquid investments purchased with a maturity of three months or less at the date of acquisition to be cash equivalents. Marketable securities consist of fixed income investments with a maturity of greater than three months and other highly liquid investments that can be readily purchased or sold using established markets. These investments are classified as available-for-sale and are reported at fair value on the Consolidated Balance Sheets. Unrealized holding gains and losses are reported within comprehensive income (loss) in the Consolidated Statements of Comprehensive Loss. Fair value is based on available market information including quoted market prices, broker or dealer quotations, or other observable inputs.

Restricted cash consists primarily of funds held to satisfy the requirements of certain agreements that are restricted in their use and is included in non-current assets on the Consolidated Balance Sheets.

Concentration of Credit Risk

The Company's financial instruments that are exposed to concentration of credit risk consist primarily of cash, cash equivalents, and marketable securities. The Company maintains its cash and cash equivalents in bank accounts, which, at times, exceed federally insured limits. The Company invests its marketable securities in high-quality commercial financial instruments. The Company has not recognized any losses from credit risks on such accounts during any of the periods presented. The Company believes it is not exposed to significant credit risk on cash and cash equivalents or its marketable securities.

The Company is subject to credit risk from its accounts receivable related to its product sales of Galafold®. The Company's accounts receivable at September 30, 2019 have arisen from product sales primarily in the E.U. and U.S. The Company will periodically assess the financial strength of its customers to establish allowances for anticipated losses, if any. For accounts receivable that have arisen from named patient sales, the payment terms are predetermined and the Company evaluates the creditworthiness of each customer on a regular basis. As of September 30, 2019, the Company recorded an allowance for doubtful accounts of $0.2 million.

Revenue Recognition

The Company's net product sales consist of sales of Galafold® for the treatment of Fabry disease. The Company has recorded revenue on sales where Galafold® is available either on a commercial basis or through a reimbursed early access program ("EAP"). Orders for Galafold® are generally received from distributors and pharmacies with the ultimate payor often a government authority.

The Company recognizes revenue when its performance obligations to its customers have been satisfied, which occurs at a point in time when the pharmacies or distributors obtain control of Galafold®. The transaction price is determined based on fixed consideration in the Company's customer contracts and is recorded net of estimates for variable consideration, which are third party discounts and rebates. The identified variable consideration is recorded as a reduction of revenue at the time revenue from the sale of Galafold® is recognized. The Company recognizes revenue to the extent that it is probable that a significant revenue reversal will not occur in a future period. These estimates may differ from actual consideration received. The Company evaluates these estimates each reporting period to reflect known changes.

The following table summarizes the Company's net product sales from Galafold® disaggregated by geographic area:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2019**	**2018**	**2019**	**2018**
U.S.	$ 15,411	$ 757	$ 36,660	$ 757
Ex-U.S.	33,357	19,839	90,284	57,844
Total net product sales	$ 48,768	$ 20,596	$ 126,944	$ 58,601

Inventories and Cost of Goods Sold

Inventories are stated at the lower of cost and net realizable value, determined by the first-in, first-out method. Inventories are reviewed periodically to identify slow-moving or obsolete inventory based on projected sales activity as well as product shelf-life. In evaluating the recoverability of inventories produced, the probability that revenue will be obtained from the future sale of the related inventory is considered and inventory value is written down for inventory quantities in excess of expected requirements. Expired inventory is disposed of and the related costs are recognized as cost of goods sold in the Consolidated Statements of Operations.

Cost of goods sold includes the cost of inventory sold, manufacturing and supply chain costs, product shipping and handling costs, provisions for excess and obsolete inventory, as well as royalties payable. A portion of the inventory available-for-sale was expensed as research and development costs prior to regulatory approval and as such the cost of goods sold and related gross margins are not necessarily indicative of future cost of goods sold and gross margin.

Leases

The Company primarily enters into lease agreements for office space, equipment, and vehicles. The leases have varying terms, some of which could include options to renew, extend, and early terminate. The Company determines if an arrangement is a lease at contract inception. Operating leases are included in right-of-use ("ROU") assets and lease liabilities on the Consolidated Balance Sheets.

ROU assets represent the Company's right to control the use of an explicitly or implicitly identified fixed asset for a period of time and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Control of an underlying asset is conveyed to the Company if the Company obtains the rights to direct the use of and to obtain substantially all of the economic benefits from using the underlying asset. ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. The Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments.

Lease payments included in the measurement of the lease liability are comprised of fixed payments. Variable lease payments are excluded from the ROU asset and lease liability and are recognized in the period in which the obligation for those payments is incurred. Variable lease payments are presented in the Consolidated Statements of Operations in the same line item as expenses arising from fixed lease payments for operating leases. The Company has lease agreements that include lease and non-lease components, which the Company accounts for as a single lease component for all underlying asset categories.

The lease term for all of the Company's leases include the non-cancellable period of the lease plus any additional periods covered by either a Company option to extend (or not to terminate) the lease that the Company is reasonably certain to exercise, or an option to extend (or not to terminate) the lease controlled by the lessor.

Leases with an initial term of 12 months or less are not recorded on the Consolidated Balance Sheets. The Company recognizes lease expense for these leases on a straight-line basis over the lease term. The Company applies this policy to all underlying asset categories.

The information presented for the periods prior to January 1, 2019 has not been restated and is reported under the accounting standard in effect for those periods. For additional information, see " —Note 9. Leases" and "—Note 2. Summary of Significant Accounting Policies, Recent Accounting Developments - Guidance Adopted in 2019."

Recent Accounting Developments - Guidance Adopted in 2019

ASU 2016-02 - In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASU 2016-02"). ASU 2016-02 requires the recognition of lease assets and lease liabilities on the balance sheet for all lease obligations and disclosing key information about leasing arrangements. ASU 2016-02 requires the recognition of lease assets and lease liabilities by lessees for those leases classified as operating leases under previous generally accepted accounting principles. In August 2018, the FASB issued ASU 2018-11, *Leases (Topic 842): Targeted Improvements*, ("ASU 2018-11"). ASU 2018-11 provided entities with an additional transition method for adoption, whereby, an entity initially applies the new leases standard at the adoption date and recognizes a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Effective January 1, 2019 the Company adopted ASU 2016-02, along with the amendments issued in 2017 and 2018, and elected the transition method in ASU 2018-11. The Company elected the package of transition provisions available for expired or existing contracts, which allowed the Company to carry forward its historical assessments of (i) whether contracts are or contain leases, (ii) lease classification and (iii) initial direct costs. In addition, the Company applied the short-term lease recognition exemption for leases with terms at inception not greater than 12 months and will apply the practical expedient not to separate lease and non-lease components for new and modified leases commencing after adoption. The information presented for the periods prior to January 1, 2019 has not been restated and is reported under the accounting standard in effect for those periods. Upon adoption, the Company recorded a lease liability with a corresponding right-of-use asset of $17.6 million. The adoption did not have a material impact on the Consolidated Statements of Operations and the Consolidated Statements of Cash Flows.

In August 2018, the Securities Exchange Commission ("SEC") issued Final Rule 33-10532, *Disclosure Update and Simplification*, which amends certain disclosure requirements that were redundant, duplicative, overlapping, or superseded by other SEC disclosure requirements. The amendments generally eliminated or otherwise reduced certain disclosure requirements of various SEC rules and regulations. However, in some cases, the amendments require additional information to be disclosed, including changes in stockholders' equity in interim periods. The rule was effective 30 days after its publication in the Federal Register. The rule was posted on October 4, 2018. On September 25, 2018, the SEC released guidance advising it will not object to a registrant adopting the requirement to include changes in stockholders' equity in the Form 10-Q for the first quarter beginning after the effective date of the rule. The Company adopted the guidance for the period ended March 31, 2019.

Recent Accounting Developments - Guidance Not Yet Adopted

ASU 2018-13— In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820): Disclosure Framework-Changes to the Disclosure Requirements for Fair Value Measurement* ("ASU 2018-13"). The amendments modify the disclosure requirements in Topic 820. ASU 2018-13 is effective for all entities for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019. The amendments on changes (i) in unrealized gains and losses, (ii) the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and (iii) the narrative description of measurement uncertainty should be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. Early adoption is permitted. An entity is permitted to early adopt any removed or modified disclosures upon issuance of ASU 2018-13 and delay adoption of the additional disclosures until their effective date. The Company is currently assessing the impact that this standard will have on its consolidated financial statements upon adoption.

ASU 2017-04 — In January 2017, the FASB issued ASU 2017-04, *Intangibles - Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment* ("ASU 2017-04"). ASU 2017-04 simplifies the recognition and measurement of a goodwill impairment loss by eliminating Step 2 of the quantitative goodwill impairment test. The guidance requires a one-step impairment test in which an entity compares the fair value of a reporting unit with its carrying amount and recognizes an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value, if any. ASU 2017-04 is effective for fiscal years beginning after December 15, 2019 and should be applied on a prospective basis. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. The Company is currently assessing the impact that this standard will have on its consolidated financial statements upon adoption.

ASU 2016-13 — In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* ("ASU 2016-13"). ASU 2016-13 requires financial assets measured at amortized cost basis to be presented at the net amount expected to be collected and amends guidance on the impairment of financial instruments. ASU 2016-13 is effective for public companies who are SEC filers for fiscal years beginning after December 15, 2019, including interim periods within those years. The Company is currently assessing the impact that this standard will have on its consolidated financial statements upon adoption.

Note 3. Cash, Cash Equivalents, Marketable Securities, and Restricted Cash

As of September 30, 2019, the Company held $166.3 million in cash and cash equivalents and $347.9 million of available-for-sale debt securities which are reported at fair value on the Company's Consolidated Balance Sheets. Unrealized holding gains and losses are reported within accumulated other comprehensive loss in the Statements of Comprehensive Loss. If a decline in the fair value of a marketable security below the Company's cost basis is determined to be other-than-temporary, such marketable security is written down to its estimated fair value as a new cost basis and the amount of the write-down is included in earnings as an impairment charge.

The Company regularly invests excess operating cash in deposits with major financial institutions, money market funds, notes issued by the U.S. government, as well as fixed income investments and U.S. bond funds, both of which can be readily purchased and sold using established markets. The Company believes that the market risk arising from its holdings of these financial instruments is mitigated as many of these securities are either government backed or of the highest credit rating. Investments that have original maturities greater than three months but less than one year are classified as current, while investments that have maturities greater than one year are classified as non-current.

Cash, cash equivalents and marketable securities are classified as current unless mentioned otherwise below and consisted of the following:

	As of September 30, 2019			
(in thousands)	Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Cash and cash equivalents	$ 166,319	$ —	$ —	$ 166,319
Corporate debt securities	139,591	158	(4)	139,745
Commercial paper	114,713	95	—	114,808
Asset-backed securities	75,166	93	(4)	75,255
U.S. government agency bonds	17,683	—	(17)	17,666
Money market	350	—	—	350
Certificates of deposit	51	—	—	51
	$ 513,873	$ 346	$ (25)	$ 514,194
Included in cash and cash equivalents	$ 166,319	$ —	$ —	$ 166,319
Included in marketable securities [1]	347,554	346	(25)	347,875
Total cash, cash equivalents, and marketable securities	$ 513,873	$ 346	$ (25)	$ 514,194

[1] As of September 30, 2019, $27.5 million of marketable securities have maturity dates greater than 12 months and are available to convert into cash, if needed.

	As of December 31, 2018			
(in thousands)	Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Cash and cash equivalents	$ 79,749	$ —	$ —	$ 79,749
Corporate debt securities	240,969	7	(250)	240,726
Commercial paper	115,245	—	(104)	115,141
Asset-backed securities	68,215	4	(84)	68,135
Money market	350	—	—	350
Certificates of deposit	51	—	—	51
	$ 504,579	$ 11	$ (438)	$ 504,152
Included in cash and cash equivalents	$ 79,749	$ —	$ —	$ 79,749
Included in marketable securities	424,830	11	(438)	424,403
Total cash, cash equivalents, and marketable securities	$ 504,579	$ 11	$ (438)	$ 504,152

For the nine months ended September 30, 2019 there were no realized gains. For the fiscal year ended December 31, 2018, there were nominal realized gains. The cost of securities sold is based on the specific identification method.

Unrealized loss positions in the available-for-sale debt securities as of September 30, 2019 and December 31, 2018 reflect temporary impairments that have been in a loss position for less than twelve months and as such are recognized in other comprehensive gain (loss). The fair value of these available-for-sale debt securities in unrealized loss positions was $22.9 million and $403.1 million as of September 30, 2019 and December 31, 2018, respectively.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the Consolidated Balance Sheets that sum to the total of the same such amounts shown in the Consolidated Statements of Cash Flows.

(in thousands)	September 30, 2019	December 31, 2018	September 30, 2018	December 31, 2017
Cash and cash equivalents	$ 166,319	$ 79,749	$ 201,827	$ 49,060
Restricted cash	3,382	2,626	2,003	2,177
Cash, cash equivalents, and restricted cash shown in the Consolidated Statements of Cash Flows	$ 169,701	$ 82,375	$ 203,830	$ 51,237

Note 4. Inventories

Inventories consist of raw materials, work-in-process, and finished goods related to the manufacture of Galafold®. The following table summarizes the components of inventories:

(in thousands)	September 30, 2019	December 31, 2018
Raw materials	$ 3,459	$ 1,291
Work-in-process	2,733	3,485
Finished goods	2,962	3,614
Total inventories	$ 9,154	$ 8,390

The Company recorded a reserve for inventory of $0.2 million as of September 30, 2019 and December 31, 2018.

Note 5. Debt

Senior Secured Term Loan due 2023

In September 2018, the Company entered into a loan agreement with BioPharma Credit PLC as the lender. The loan agreement provides for a $150 million senior secured term loan ("Senior Secured Term Loan") with an interest rate equal to the 3-month LIBOR plus 7.50% per annum and matures 5 years from the maturity date. The Senior Secured Term Loan will be repaid in four quarterly payments equal to 12.50% thereof starting on the forty-eight month anniversary of the date of the first credit extension with the balance due on the Maturity Date. Interest is payable quarterly in arrears. The Senior Secured Term Loan contains certain customary representations and warranties, affirmative and negative covenants, and events of default applicable to the Company and certain of its subsidiaries, but does not include any financial covenants relating to the achievement or maintenance of revenue or cash flow. If an event of default occurs and is continuing, the lender may declare all amounts outstanding under the Senior Secured Term Loan to be immediately due and payable. The Company received net proceeds of $146.6 million in September 2018, after deducting fees and estimated expenses payable by the Company.

Convertible Notes due 2023

In December 2016, the Company issued at par value $250 million aggregate principal amount of Convertible Notes, which included the exercise in full of the $25 million over-allotment option granted to the initial purchasers of the Convertible Notes in a private offering to qualified institutional buyers pursuant to Rule 144A under the Securities Act (the "Note Offering"). Interest is payable semiannually on June 15 and December 15 of each year, beginning on June 15, 2017. The Convertible Notes will mature on December 15, 2023, unless earlier repurchased, redeemed, or converted in accordance with their terms. The Convertible Notes are convertible at the option of the Holders, under certain circumstances and during certain periods, into cash, shares of the Company's common stock or a combination thereof. The net proceeds from the Note Offering were $243.0 million, after deducting fees and estimated expenses payable by the Company. In addition, the Company used $13.5 million of the net proceeds from the issuance of the Convertible Notes to pay the cost of the capped call transactions ("Capped Call Confirmations") that the Company entered into in connection with the issuance of the Convertible Notes. In accounting for the issuance of the Convertible Notes, the Company separated the Convertible Notes into liability and equity components based on their relative values. The Convertible Notes were initially convertible into 40.8 million shares of the Company's common stock under certain circumstances prior to maturity at a conversion rate of 163.3987 shares per $1,000 principal amount of Convertible Notes, which represents a conversion price of $6.12 per share of the Company's common stock, subject to adjustment under certain conditions.

On February 15, 2018, the Company entered into an underwriting agreement relating to an underwritten public offering of 19.4 million shares of the Company's common stock. Under the terms of the underwriting agreement, the Company granted the underwriters an option, exercisable for 30 days after February 16, 2018, to purchase up to an additional 2.9 million shares of the Company's common stock, which was exercised with respect to 885,000 shares of the Company's common stock.

Subsequent to the underwritten public offering on February 15, 2018, the Company did not have sufficient unissued authorized shares to cover a conversion of the Convertible Notes. As a result, the Company accounted for the portion of the bifurcated conversion feature and of the Capped Call Confirmations that would not be able to be net share settled as a current derivative liability and as a derivative asset, respectively. The fair value of the derivative liability for the conversion feature and derivative asset for the Capped Call Confirmations at February 15, 2018 was determined to be $507.4 million and $13.6 million, respectively, of which the portion that was determined to not be able to be net share settled was recorded with a corresponding impact to additional-paid-in-capital. Subsequent changes to fair value of the derivatives were recorded in the second quarter of 2018 through earnings on the Consolidated Statements of Operations resulting in a change in fair value of derivatives for the nine months ended September 30, 2018 of $(2.7) million.

Following the approval by the stockholders of the Company on June 7, 2018, to increase the authorized shares of common stock to 500,000,000, the Company has sufficient unissued authorized shares to cover a conversion of the Convertible Notes. As a result, the derivative liability and derivative asset were reclassified into additional-paid-in-capital. The fair value of the derivative liability for the conversion feature and derivative asset for the Capped Call Confirmations at June 7, 2018 was determined to be $88.3 million and $2.4 million, respectively.

During the first and second quarter of 2019, the Company entered into separate, privately negotiated Exchange Agreements with the Holders of the Convertible Notes. Under the terms of the Exchange Agreements, the Holders agreed to exchange an aggregate principal amount of $247.2 million of Convertible Notes held by them in exchange for an aggregate of approximately 44.0 million shares of Company common stock, par value $0.01 per share. In addition, pursuant to the Exchange Agreements, the Company made aggregate cash payments of $1.3 million to the Holders to satisfy accrued and unpaid interest to the closing date of the transactions, along with cash in lieu of fractional shares. These transactions resulted in $215.0 million in additional paid-in-capital and common stock of $0.4 million on the Consolidated Balance Sheets as of September 30, 2019. Additionally, the Company recognized a net loss on the exchange of debt of $40.6 million on the Consolidated Statements of Operations during the nine months ended September 30, 2019. During the three months ended September 30, 2019, there were no additional debt conversion transactions.

The last reported sale price of the Company's common stock was equal to or more than 130% of the conversion price of the Convertible Notes for at least 20 trading days of the 30 consecutive trading days ending on the last day of the third quarter. As a result, the remaining Convertible Notes are currently convertible into the Company's common stock.

During the first and second quarter of 2019, the Company also terminated the Capped Call Confirmations related to the exchange of the Convertible Notes for proceeds of $19.9 million.

The Convertible Notes and Senior Secured Term Loan consist of the following:

Liability component (in thousands)	September 30, 2019	December 31, 2018
Principal	$ 152,825	$ 400,000
Less: debt discount [1]	(3,192)	(74,145)
Less: deferred financing [1]	(373)	(4,115)
Net carrying value of the debt	$ 149,260	$ 321,740

[1] Included in the Consolidated Balance Sheets within Convertible Notes and Senior Secured Term Loan and amortized to interest expense over the remaining life of the Convertible Notes and Senior Secured Term Loan using the effective interest rate method.

The following table sets forth total interest expense recognized related to the Convertible Notes and Senior Secured Term Loan for the three and nine months ended September 30, 2019 and 2018, respectively:

	Three Months Ended September 30,		Nine Months Ended September 30,	
Interest component (in thousands)	**2019**	**2018**	**2019**	**2018**
Contractual interest expense	$ 3,820	$ 1,969	$ 12,779	$ 5,744
Amortization of debt discount	182	2,609	2,164	7,620
Amortization of deferred financing	23	137	145	399
Total	$ 4,025	$ 4,715	$ 15,088	$ 13,763

Note 6. Stockholders' Equity

During the nine months ended September 30, 2019, 101,787 warrants were exercised at $7.98 per share of common stock resulting in gross cash proceeds of $0.8 million.

As discussed in "— Note 1. Business" during the second quarter of 2019, the Company completed an underwritten equity offering and issued 18.7 million shares of its common stock at $10.75 per share, inclusive of the fully exercised option to purchase additional shares from the initial offering. This transaction resulted in net proceeds of $189.0 million, after deducting underwriting discounts and commissions and offering expenses.

As discussed in "— Note 5. Debt" during the first and second quarter of 2019, the Company entered into separate, privately negotiated Exchange Agreements with the Holders of the Convertible Notes. Under the terms of the Exchange Agreements, the Holders agreed to exchange an aggregate principal amount of $247.2 million of Convertible Notes held by them in exchange for an aggregate of approximately 44.0 million shares of Company common stock, par value $0.01 per share.

As discussed in "— Note 8. Assets and Liabilities Measured at Fair Value", the Company reached a clinical milestone, which was the dosing of the first patient in a Phase 3 study, related to the contingent consideration from the acquisition of Callidus. The milestone for this event was $9.0 million, which was paid in Company common stock in the first quarter of 2019, and resulted in a $9.3 million impact on stockholder's equity.

Note 7. Share-Based Compensation

The Company's Equity Incentive Plans consist of the Amended and Restated 2007 Equity Incentive Plan (the "Plan") and the 2007 Director Option Plan (the "2007 Director Plan"). The Plan provides for the granting of restricted stock units and options to purchase common stock in the Company to employees, directors, advisors, and consultants at a price to be determined by the Company's Board of Directors. The Plan is intended to encourage ownership of stock by employees and consultants of the Company and to provide additional incentives for them to promote the success of the Company's business. The 2007 Director Plan is intended to promote the recruiting and retention of highly qualified eligible directors and strengthen the commonality of interest between directors and stockholders by encouraging ownership of common stock of the Company. The Board of Directors, or its committee, is responsible for determining the individuals to be granted options, the number of options each individual will receive, the option price per share, and the exercise period of each option.

Stock Option Grants

The fair value of the stock options granted is estimated on the date of grant using a Black-Scholes option pricing model with the following weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	**2018**	**2019**	**2018**
Expected stock price volatility	73.6%	75.5%	74.1%	80.7%
Risk free interest rate	1.6%	2.7%	2.4%	2.4%
Expected life of options (years) [(1)]	5.68	5.62	5.68	5.62
Expected annual dividend per share	$ —	$ —	$ —	$ —

[(1)] The average expected life is determined using actual historical data.

A summary of the Company's stock options for the nine months ended September 30, 2019 were as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life	Aggregate Intrinsic Value
	(in thousands)			(in millions)
Options outstanding, December 31, 2018	15,810	$ 8.63		
Granted	3,913	$ 10.37		
Exercised	(1,353)	$ 5.77		
Forfeited	(701)	$ 11.05		
Expired	(139)	$ 14.00		
Options outstanding, September 30, 2019	17,530	$ 9.10	6.5 years	$ 19.5
Vested and unvested expected to vest, September 30, 2019	16,792	$ 9.02	6.4 years	$ 19.4
Exercisable at September 30, 2019	10,896	$ 8.22	5.2 years	$ 16.9

As of September 30, 2019, the total unrecognized compensation cost related to non-vested stock options granted was $36.5 million and is expected to be recognized over a weighted average period of three years.

Restricted Stock Units and Performance-Based Restricted Stock Units (collectively "RSUs")

RSUs awarded under the Plan are generally subject to graded vesting and are contingent on an employee's continued service. RSUs are generally subject to forfeiture if employment terminates prior to the release of vesting restrictions. The Company expenses the cost of the RSUs, which is determined to be the fair market value of the shares of common stock underlying the RSUs at the date of grant, ratably over the period during which the vesting restrictions lapse. A summary of non-vested RSU activity under the Plan for the nine months ended September 30, 2019 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value	Weighted Average Remaining Years	Aggregate Intrinsic Value
	(in thousands)			(in millions)
Non-vested units as of December 31, 2018	3,712	$ 10.59		
Granted	3,412	$ 10.99		
Vested	(835)	$ 9.43		
Forfeited	(449)	$ 10.47		
Non-vested units as of September 30, 2019	5,840	$ 11.06	2.5 years	$ 46.8

All non-vested units granted as of September 30, 2019 are expected to vest over their normal term. As of September 30, 2019, there was $43.1 million of total unrecognized compensation cost related to unvested RSUs with service-based vesting conditions. These costs are expected to be recognized over a weighted average period of three years.

Compensation Expense Related to Equity Awards

The following table summarizes information related to compensation expense recognized in the Consolidated Statements of Operations related to the equity awards:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Equity compensation expense recognized in:				
Research and development expense	$ 3,106	$ 2,905	$ 12,090	$ 8,603
Selling, general, and administrative expense	5,737	4,149	19,432	12,270
Total equity compensation expense	$ 8,843	$ 7,054	$ 31,522	$ 20,873

Note 8. Assets and Liabilities Measured at Fair Value

The Company's financial assets and liabilities are measured at fair value and classified within the fair value hierarchy, which is defined as follows:

Level 1 — Quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.

Level 2 — Inputs other than quoted prices in active markets that are observable for the asset or liability, either directly or indirectly.

Level 3 — Inputs that are unobservable for the asset or liability.

A summary of the fair value of the Company's recurring assets and liabilities aggregated by the level in the fair value hierarchy within which those measurements fall as of September 30, 2019 are identified in the following table:

(in thousands)	Level 2	Total
Assets:		
Commercial paper	$ 114,808	$ 114,808
Asset-backed securities	75,255	75,255
Corporate debt securities	139,745	139,745
U.S. government agency bonds	17,666	17,666
Money market funds	4,328	4,328
	$ 351,802	$ 351,802

	Level 2	Level 3	Total
Liabilities:			
Contingent consideration payable	$ —	$ 22,036	$ 22,036
Deferred compensation plan liability	4,003	—	4,003
	$ 4,003	$ 22,036	$ 26,039

A summary of the fair value of the Company's recurring assets and liabilities aggregated by the level in the fair value hierarchy within which those measurements fall as of December 31, 2018 are identified in the following table:

(in thousands)	Level 2	Total
Assets:		
Commercial paper	$ 115,141	$ 115,141
Asset-backed securities	68,135	68,135
Corporate debt securities	240,726	240,726
Money market funds	3,082	3,082
	$ 427,084	$ 427,084

	Level 2	Level 3	Total
Liabilities:			
Contingent consideration payable	$ —	$ 19,700	$ 19,700
Deferred compensation plan liability	2,732	—	2,732
	$ 2,732	$ 19,700	$ 22,432

The Company's Convertible Notes fall into the Level 2 category within the fair value level hierarchy. The fair value was determined using broker quotes in a non-active market for valuation. The fair value of the Convertible Notes at September 30, 2019 was $4.2 million.

The Company's Senior Secured Term Loan fall into the Level 2 category within the fair value level hierarchy and the fair value was determined using quoted prices for similar liabilities in active markets, as well as inputs that are observable for the liability (other than quoted prices), such as interest rates that are observable at commonly quoted intervals. The carrying value of the Senior Secured Term Loan approximates the fair value.

The Company did not have any Level 3 assets as of September 30, 2019 or December 31, 2018.

Cash, Money Market Funds, and Marketable Securities

The Company classifies its cash within the fair value hierarchy as Level 1 as these assets are valued using quoted prices in an active market for identical assets at the measurement date. The Company considers its investments in marketable securities as available-for-sale debt securities and classifies these assets and the money market funds within the fair value hierarchy as Level 2 primarily utilizing broker quotes in a non-active market for valuation of these securities. No changes in valuation techniques or inputs occurred during the nine months ended September 30, 2019. No transfers of assets between Level 1 and Level 2 of the fair value measurement hierarchy occurred during the nine months ended September 30, 2019.

Contingent Consideration Payable

The contingent consideration payable resulted from the acquisition of Callidus Biopharma, Inc. ("Callidus") in November 2013. The most recent valuation was determined using a probability weighted discounted cash flow valuation approach. Using this approach, expected future cash flows are calculated over the expected life of the agreement, are discounted, and then exercise scenario probabilities are applied. The valuation is performed quarterly. Gains and losses are included in the Consolidated Statements of Operations.

The contingent consideration payable for Callidus has been classified as a Level 3 recurring liability as its valuation requires substantial judgment and estimation of factors that are not currently observable in the market. If different assumptions were used for the various inputs to the valuation approach, the estimated fair value could be significantly higher or lower than the fair value the Company determined. The Company may be required to record losses in future periods.

The following significant unobservable inputs were used in the valuation of the contingent consideration payable of Callidus for the ATB200 Pompe program:

Contingent Consideration Liability	Fair Value as of September 30, 2019	Valuation Technique	Unobservable Input	Range
	(in thousands)			
Clinical and regulatory milestones	$21,766	Probability weighted discounted cash flow	Discount rate	9.8%
			Probability of achievement of milestones	75% - 78%
			Projected year of payments	2021 - 2022

Contingent consideration liabilities are remeasured to fair value each reporting period using discount rates, probabilities of payment, and projected payment dates. Projected contingent payment amounts related to clinical and regulatory based milestones are discounted back to the current period using a discounted cash flow model. Increases in discount rates and the time to payment may result in lower fair value measurements. Increases or decreases in any of those inputs together, or in isolation, may result in a significantly lower or higher fair value measurement. There is no assurance that any of the conditions for the milestone payments will be met.

The Company reached a clinical milestone, which was the dosing of the first patient in a Phase 3 study, related to the contingent consideration from the acquisition of Callidus. The milestone for this event was $9.0 million, which was paid in Company common stock in the first quarter of 2019, resulting in $9.3 million impact on stockholder's equity.

The following table shows the change in the balance of contingent consideration payable for the three and nine months ended September 30, 2019 and 2018, respectively:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Balance, beginning of the period	$ 21,247	$ 26,800	$ 28,700	$ 25,400
Payment of contingent consideration in stock	—	—	(9,316)	—
Changes in fair value during the period, included in the Consolidated Statements of Operations	789	1,300	2,652	2,700
Balance, end of the period	$ 22,036	$ 28,100	$ 22,036	$ 28,100

Deferred Compensation Plan - Investment and Liability

The Deferred Compensation Plan (the "Deferral Plan") provides certain key employees and members of the Board of Directors with an opportunity to defer the receipt of such participant's base salary, bonus, and director's fees, as applicable. Deferral Plan assets are classified as trading securities and recorded at fair value with changes in the investment's fair value recognized in the period they occur. The asset investments consist of market exchanged mutual funds. The Company considers its investments in marketable securities as available-for-sale and classifies these assets and related liability within the fair value hierarchy as Level 2, primarily utilizing broker quotes in a non-active market for valuation of these securities.

Note 9. Leases

The Company currently has operating leases for office and research laboratory space, equipment, and vehicles under agreements expiring at various dates through 2044, which include renewal options on leases which the Company is reasonably certain to exercise.

For the three and nine months ended September 30, 2019, operating lease expense was $3.0 million and $7.8 million, respectively. For the nine months ended September 30, 2019, the Company paid $3.5 million for amounts included in the measurement of operating lease liabilities and recorded $0.6 million of right-of-use assets obtained in exchange for new operating lease liabilities.

Commitments under finance leases are not significant.

Supplemental balance sheet information related to operating leases was as follows:

(in thousands, except year and discount rate amounts)	September 30, 2019
Operating lease ROU asset	$ 35,814
Current portion of the operating lease liabilities	$ 6,356
Non-current portion of the operating lease liabilities	49,686
Total operating lease liability	$ 56,042
Weighted-average remaining lease terms (years)	17.7
Weighted-average discount rate	13.1%

At September 30, 2019, the future minimum lease payments were as follows:

(in thousands)	Operating Leases
2019 (excludes the nine months ended September 30, 2019)	$ 1,767
2020	9,650
2021	10,597
2022	10,380
2023	10,751
Thereafter	174,475
Total lease payments	217,620
Less lease incentives	(28,939)
Less imputed interest	(132,639)
Total operating lease liability	$ 56,042

At December 31, 2018, the future minimum lease payments were as follows:

(in thousands)	Operating Leases
2019	$ 6,244
2020	4,063
2021	3,560
2022	3,371
2023	3,611
Thereafter	10,038
Total lease payments	$ 30,887

Note 10. Basic and Diluted Net Loss per Common Share

The following table provides a reconciliation of the numerator and denominator used in computing basic and diluted net loss attributable to common stockholders per common share:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except per share amounts)	2019	2018	2019	2018
Numerator:				
Net loss attributable to common stockholders	$ (61,809)	$ (159,163)	$ (266,659)	$ (270,914)
Denominator:				
Weighted average common shares outstanding — basic and diluted	254,674,422	189,162,841	235,527,540	184,606,790

Dilutive common stock equivalents would include the dilutive effect of common stock options, convertible debt units, RSUs, and warrants for common stock equivalents. Potentially dilutive common stock equivalents were excluded from the diluted earnings per share denominator for all periods because of their anti-dilutive effect.

The table below presents potential shares of common stock that were excluded from the computation as they were anti-dilutive using the treasury stock method:

	As of September 30,	
(in thousands)	**2019**	**2018**
Options to purchase common stock	17,530	15,769
Convertible notes	462	40,850
Outstanding warrants, convertible to common stock	2,555	2,657
Unvested restricted stock units	5,840	3,635
Vested restricted stock units, unissued	192	103
Total number of potentially issuable shares	26,579	63,014

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Overview

We are a global patient-dedicated biotechnology company engaged in the discovery, development, and commercialization of a diverse set of novel treatments for patients living with rare diseases. We have a portfolio of product opportunities led by our novel medicine for Fabry disease that has achieved widespread global approval, a differentiated biologic for Pompe disease in the clinic, and an industry leading rare disease gene therapy portfolio.

The cornerstone of our portfolio is Galafold® (also referred to as "migalastat"), the first and only approved oral precision medicine for people living with Fabry disease who have amenable genetic variants. Migalastat is currently approved under the trade name Galafold® in the United States ("U.S."), European Union ("E.U."), and Japan, with additional approvals granted and applications pending in several geographies.

The lead biologics program of our pipeline is Amicus Therapeutics GAA ("AT-GAA", also known as ATB200/AT2221), a novel, clinical-stage, potential best-in-class treatment paradigm for Pompe disease. In February 2019, the U.S. Food and Drug Administration ("FDA") granted Breakthrough Therapy designation to AT-GAA for the treatment of late onset Pompe disease.

We have established an industry leading gene therapy portfolio of potential therapies for people living with rare metabolic diseases, through a license with Nationwide Children's Hospital ("NCH") and an expanded collaboration with the University of Pennsylvania ("Penn"). Our pipeline includes gene therapy programs in rare, neurologic lysosomal disorders ("LDs"), specifically: CLN6, CLN3, and CLN8 Batten disease, Pompe disease, Fabry disease, CDKL5 deficiency disorder ("CDD"), Niemann-Pick Type C (“NPC”), Mucopolysaccharidosis Type IIIB ("MPSIIIB"), as well as a next generation program in Mucopolysaccharidosis Type IIIA ("MPSIIIA"). This expanded collaboration with Penn also provides us with exclusive disease-specific access and the option rights to develop potentially disruptive new gene therapy platform technologies and programs for most LDs and a broader portfolio of rare diseases, including Rett Syndrome, Angelman Syndrome, Myotonic Dystrophy, and select other muscular dystrophies.

Our Strategy

Our strategy is to create, manufacture, test, and deliver the highest quality medicines for people living with rare metabolic diseases through internally developed, acquired, or in-licensed products and product candidates that have the potential to obsolete current treatments, provide significant benefits to patients, and be first- or best-in-class. In addition to our programs in Fabry and Pompe, we have begun to leverage our global capabilities to develop and expand our robust pipeline through our recent entry into genomic medicine. We have made significant progress toward fulfilling our vision to build a leading global biotechnology company focused on rare metabolic diseases.

Highlights of our progress in the first nine months of 2019 include:

- *Commercial and regulatory success in Fabry disease*. During the nine months ended September 30, 2019, Galafold® revenue totaled $126.9 million, an increase of $68.3 million compared to the same period in the prior year. We continue to see strong momentum throughout all of our markets and continue to expand into additional geographies. In the countries we have been operating the longest, such as Germany and the United Kingdom, we see an increasing proportion of previously untreated patients come onto Galafold®. In the U.S., we continue to see a significant increase in patients from a growing and very wide prescriber base. Across all markets, we see a high rate of compliance and adherence to this oral treatment option.
- *Pompe clinical program milestones*. We reported positive data from a Phase 1/2 clinical study to evaluate Pompe disease patients treated with our novel treatment paradigm AT-GAA. The U.S. FDA also granted Breakthrough Therapy designation for AT-GAA for the treatment of late-onset Pompe disease. We are currently enrolling a global pivotal study of AT-GAA (ATB200-03, also known as PROPEL) which is on track to enroll approximately 100 participants with late-onset Pompe disease at up to 90 global sites.
- *Pipeline growth.* With our recent gene therapy program expansion, we have established an industry leading gene therapy portfolio of medicines for people living with rare metabolic diseases. Through our license with NCH, we acquired worldwide development and commercial rights for ten gene therapy programs in rare, neurologic LDs with programs in CLN6, CLN3, and CLN8 Batten disease. Additionally, four programs were added to the pipeline through ongoing collaborations with Penn to pursue research and development of novel gene therapies for Pompe disease, Fabry disease, CDD, NPC, MPSIIIB, as well as a next generation program in MPSIIIA.

- *Manufacturing*. We successfully scaled up manufacturing of our Pompe biologic to commercial scale (1,000L) for our pivotal PROPEL study and commercial supply. Our supply agreement with WuXi Biologics and current capacity are expected to produce sufficient quantities to support commercial needs as quickly as possible after receipt of applicable regulatory approvals. For gene therapy, we have recently entered into strategic partnerships with two best-in-class contract development and manufacturing organizations: Catalent Biologics and Thermo Fisher Scientific. Catalent Biologics will support our clinical manufacturing capabilities and capacity for multiple active preclinical lysosomal disorder programs that are currently in development in collaboration with Penn. Thermo Fisher will assist with late-stage clinical and commercial-scale capabilities and provides us with immediate clinical and commercial manufacturing capabilities and capacity for the Amicus intrathecal AAV Batten disease gene therapy programs.
- *Financial strength.* Total cash, cash equivalents, and marketable securities of $514.2 million at September 30, 2019 compared to $504.2 million at December 31, 2018. The current cash position, including expected Galafold® revenues, is sufficient to fund ongoing Fabry, Pompe, and gene therapy program operations into the first half of 2022. Potential future business development collaborations, pipeline expansion, and investment in manufacturing capabilities could impact our future capital requirements.

Our Commercial Product and Product Candidates

Galafold® (Migalastat HCl) for Fabry Disease

Our oral precision medicine Galafold® was granted accelerated approval by the FDA in August 2018 under the brand name Galafold® 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. The FDA approved Galafold® for 348 amenable GLA variants. Galafold® was approved in the E.U. in May 2016 as a first-line therapy for long-term treatment of adults and adolescents, aged 16 years and older, with a confirmed diagnosis of Fabry disease and who have an amenable variant. The approved E.U. label includes 367 Fabry-causing variants, which represent up to half of all patients with Fabry disease. Approvals have also been granted in Japan and other countries around the world, with additional applications pending. We have been granted pricing and reimbursement in 27 countries. We plan to continue to launch Galafold® in additional countries during 2019.

As an orally administered monotherapy, Galafold® is designed to bind to and stabilize an endogenous alpha-galactosidase A ("alpha-Gal A") enzyme in those patients with genetic variants identified as amenable in a GLP cell-based amenability assay. Galafold® is an oral precision medicine intended to treat Fabry disease in patients who have amenable genetic variants and, at this time, it is not intended for concomitant use with ERT.

Gene Therapy for Fabry Disease

We are committed to continued innovation for all people living with Fabry disease. For people living with Fabry disease who have non-amenable variants, which are not suitable for Galafold® as a monotherapy, our strategy is to develop a Fabry gene therapy. In October 2018, we further expanded our gene therapy portfolio through a collaboration agreement with Penn to pursue research and development of novel gene therapies for Fabry disease.

Novel ERT for Pompe Disease

We are leveraging our biologics capabilities to develop AT-GAA, a novel treatment paradigm for Pompe disease. AT-GAA consists of a uniquely engineered rhGAA enzyme, ATB200, with an optimized carbohydrate structure to enhance lysosomal uptake, administered in combination with a pharmacological chaperone, AT2221, to improve activity and stability. We initiated a global Phase 3 clinical study ("ATB200-03", or "PROPEL") of AT-GAA in adult patients with late onset Pompe disease in 2018, with the first patient dosed in December 2018.

The pharmacological chaperone, AT2221 is not an active ingredient that contributes directly to GAA substrate reduction but instead acts to stabilize ATB200. The small molecule pharmacological chaperone AT2221 binds and stabilizes ATB200 to improve the uptake of active enzyme in key disease-relevant tissues, resulting in increased clearance of accumulated substrate, glycogen.

Our strategy is to enhance the body of clinical data for AT-GAA in ongoing clinical studies. The PROPEL pivotal study delivers this potential new therapy to as many people living with late onset Pompe disease as soon as possible. Based on regulatory feedback from both the U.S. FDA and the European Medicines Agency ("EMA"), the PROPEL study is expected to support approval for a broad indication, including ERT-switch and treatment-naïve patients, if the results are favorable.

In October 2019, we reported additional interim data from our clinical study ATB200-02 at the 24th International Annual Congress of the World Muscle Society. Highlights included muscle function, safety and tolerability data in patients as well as pharmacodynamic data (muscle damage biomarker, creatine kinase, and disease substrate biomarker, urine hexose tetrasaccharide). Muscle function improved in 16 out of 18 patients at 24 months. Mean six-minute walk test ("6MWT") improved in both ERT-naïve and ERT-switch patients with continued benefit observed out to month 24. All 5 ERT-naive patients showed increases from baseline in 6MWT distance at all time points out to month 24. To date, adverse events have been generally mild and transient. AT-GAA has resulted in a low rate of infusion-associated reactions ("IARs") following over 1,500+ infusions (28 events of IARs in eight patients). The clinical pharmacokinetic profile has been consistent with previously reported preclinical data. Treatment with AT-GAA resulted in persistent and durable reductions in creatine kinase and urine hexose tetrasaccharide across all patient cohorts up to month 24.

Gene Therapy for Pompe Disease

As part of our long-term commitment to provide multiple solutions to address the significant unmet needs of the Pompe community, we are also advancing a next-generation gene therapy treatment for Pompe disease. In October 2018, we further expanded our gene therapy portfolio through a collaboration agreement with Penn to pursue research and development of novel gene therapies for, among other indications, Pompe disease.

In April 2019, we presented initial preclinical data from our investigational adeno-associated viral ("AAV") gene therapy program for Pompe disease. This initial preclinical study in Pompe knockout mice administered a single high dose of AAV gene therapy with either unmodified wild-type hGAA ("unmodified hGAA") or an Amicus/Penn engineered hGAA transgene with a Lysosomal-Targeting Cell receptor binding motif ("engineered hGAA"). The Amicus/Penn engineered hGAA AAV gene therapy demonstrated more uniform cellular uptake and lysosomal targeting compared to unmodified hGAA AAV gene therapy, as well as, robust glycogen reduction in all key tissues in Pompe disease that were assessed. In the central nervous system, the engineered hGAA AAV gene therapy showed robust glycogen reduction in neuronal cells, suggesting this may be an effective way to address neuronal aspects of Pompe disease. Unmodified hGAA AAV gene therapy showed minimal glycogen reduction in neuronal cells. This preclinical study provides initial validation for combining Amicus-engineered transgenes with Penn's AAV gene therapy technologies.

Batten Disease Product Candidates

We are researching potential first-in-class gene therapies for multiple forms of Batten disease. Batten disease is the common name for a broad class of rare, fatal, inherited disorders of the nervous system also known as neuronal ceroid lipofuscinoses, or NCLs. In these diseases, a defect in a specific gene triggers a cascade of problems that interferes with a cell's ability to recycle certain molecules. Each gene is called CLN (ceroid lipofuscinosis, neuronal) and given a different number designation as its subtype. There are 13 known forms of Batten disease often referred to as CLN1-8; 10-14. The various types of Batten disease have similar features and symptoms but vary in severity and age of onset.

The two clinical stage gene therapies are in CLN3 and CLN6 Batten disease. The CLN6 Batten disease Phase 1/2 study completed target enrollment, with twelve patients receiving a single administration of adeno-associated virus serotype 9 AAV-CLN6 gene therapy. In August 2019, we reported positive interim clinical data from the first eight patients in the study. The AAV-CLN6 gene therapy demonstrated a positive impact on motor and language function. Seven out of eight patients maintained stable Hamburg Motor and Language scores or had an initial change (+1 to -1 points) followed by stabilization. In October 2019, we reported additional interim clinical data further supporting the impact of one-time intrathecal AAV gene therapy in children with CLN6 Batten disease. This interim data suggested stabilization of various components of the Hamburg Motor, Language, Seizure and Vision scores in most patients from baseline to month 12 or 24, in particular those patients treated at a younger age.

In the CLN3 Batten disease study, a total of three patients were dosed in the low dose group with no serious adverse events after up to 5 months following a single administration of AAV-CLN3 gene therapy. Based on the safety profile to date, the data safety monitoring board cleared Amicus to begin enrollment in the high dose cohort of up to three additional patients.

CDKL5 Deficiency Disorder

We are researching a potential first-in-class protein replacement therapy approach for CDD. In addition, through our collaboration with Penn, we are researching a gene therapy for CDD. CDKL5 is a gene on the X-chromosome encoding the CDKL5 protein that regulates the expression of several essential proteins for normal brain development. Genetic mutations in the CDKL5 gene result in CDKL5 protein deficiency and CDD. This disorder manifests clinically as persistent seizures starting in infancy, followed by severe impairment in neurological development. Most children affected by CDD cannot walk or care for themselves and may also suffer from scoliosis, visual impairment, sensory issues, and gastrointestinal complications.

Strategic Alliances and Arrangements

We will continue to evaluate business development opportunities as appropriate that build stockholder value and provide us with access to the financial, technical, clinical, and commercial resources necessary to develop and market technologies or products with a focus on rare metabolic diseases. We are exploring potential collaborations, alliances, and other business development opportunities on a regular basis. These opportunities may include the acquisition of preclinical-stage, clinical-stage, or marketed products so long as such transactions are consistent with our strategic plan to develop and provide therapies to patients living with rare and orphan diseases.

Consolidated Results of Operations

Three Months Ended September 30, 2019 compared to September 30, 2018

The following table provides selected financial information for the Company:

	Three Months Ended September 30,		
(in thousands)	**2019**	**2018**	**Change**
Net product sales	$ 48,768	$ 20,596	$ 28,172
Cost of goods sold	5,596	4,310	1,286
Cost of goods sold as a percentage of net product sales	11.5%	20.9%	(9.4)%
Operating expenses:			
Research and development	58,892	138,227	(79,335)
Selling, general, and administrative	39,680	31,867	7,813
Changes in fair value of contingent consideration payable	789	1,300	(511)
Depreciation and amortization	1,116	1,073	43
Other income (expense):			
Interest income	2,752	2,721	31
Interest expense	(4,026)	(4,715)	689
Other expense	(3,481)	(1,039)	(2,442)
Income tax benefit	251	51	200
Net loss attributable to common stockholders	$ (61,809)	$ (159,163)	$ 97,354

Net Product Sales. Net product sales increased $28.2 million during the three months ended September 30, 2019 compared to the same period in the prior year. The increase was primarily due to Galafold® being approved for sale in the U.S. in the third quarter of 2018, as well as continued growth in the E.U. and Japan markets.

Cost of Goods Sold. Cost of goods sold includes manufacturing costs as well as royalties associated with sales of our product. Cost of goods sold as a percentage of net product sales was 11.5% during the three months ended September 30, 2019 compared to 20.9% during the same period in the prior year, primarily due to the proportion of sales in countries subject to a higher royalty burden.

Research and Development Expense. The following table summarizes our principal product development programs for each product candidate in development, and the out-of-pocket, third party expenses incurred with respect to each product candidate:

(in thousands)	Three Months Ended September 30,	
Projects	**2019**	**2018**
Third party direct project expenses		
Galafold® (Fabry Disease)	$ 4,986	$ 2,610
AT-GAA (Pompe Disease)	15,122	12,312
Gene therapy programs	9,503	—
Pre-clinical and other programs	145	254
Total third-party direct project expenses	29,756	15,176
Other project costs		
Personnel costs	19,125	15,584
Other costs	10,011	7,467
Total other project costs	29,136	23,051
Business development transactions	—	100,000
Total research and development costs	$ 58,892	$ 138,227

The $79.3 million decrease in research and development costs was primarily due to $100 million in expenses associated with the acquisition of ten gene therapy assets with the Celenex transaction in 2018. This was primarily offset by increases in gene therapy programs driven by the pipeline growth and clinical research and manufacturing costs with the advancement and enrollment of clinical studies in the Pompe program, as well as support for ongoing regulatory requirements, approval in new geographies, and pediatric and other studies to support label expansion of Galafold®. There were also increases in personnel and other costs associated with the advancement and enrollment of clinical studies and investments in manufacturing.

Selling, General, and Administrative Expense. Selling, general, and administrative expense increased $7.8 million primarily due to the expanded geographic scope of the ongoing commercial launch of Galafold® and related operational costs of our global business, including establishing commercial organizations and related teams in the U.S.

Other Income (Expense). The $2.4 million increase in expense was primarily due to the variance of unrealized losses on foreign exchange transactions.

Nine Months Ended September 30, 2019 compared to September 30, 2018

The following table provides selected financial information for the Company:

(in thousands)	Nine Months Ended September 30, 2019	2018	Change
Net product sales	$ 126,944	$ 58,601	$ 68,343
Cost of goods sold	15,018	10,060	4,958
Cost of goods sold as a percentage of net product sales	11.8%	17.2%	(5.4)%
Operating expenses:			
Research and development	194,466	213,685	(19,219)
Selling, general, and administrative	126,561	88,435	38,126
Changes in fair value of contingent consideration payable	2,652	2,700	(48)
Depreciation and amortization	3,261	3,015	246
Other income (expense):			
Interest income	7,990	7,371	619
Interest expense	(15,105)	(13,763)	(1,342)
Loss on exchange of convertible notes	(40,624)	—	(40,624)
Change in fair value of derivatives	—	(2,739)	2,739
Other expense	(3,272)	(3,593)	321
Income tax (expense) benefit	(634)	1,104	(1,738)
Net loss attributable to common stockholders	$ (266,659)	$ (270,914)	$ 4,255

Net Product Sales. Net product sales increased $68.3 million during the nine months ended September 30, 2019 compared to the same period in the prior year. The increase was primarily due to the approval of Galafold® for sale in the U.S. and Japan in the third quarter of 2018 and second quarter of 2018, respectively, as well as continued growth in the E.U. market.

Cost of Goods Sold. Cost of goods sold includes manufacturing costs as well as royalties associated with sales of our product. Cost of goods sold as a percentage of net product sales was 11.8% during the nine months ended September 30, 2019 compared to 17.2% during the same period in the prior year primarily due to the proportion of sales in countries subject to a higher royalty burden.

Research and Development Expense. The following table summarizes our principal product development programs for each product candidate in development, and the out-of-pocket, third party expenses incurred with respect to each product candidate:

(in thousands)	Nine Months Ended September 30,	
Projects	**2019**	**2018**
Third party direct project expenses		
Galafold® (Fabry Disease)	$ 13,595	$ 10,044
AT-GAA (Pompe Disease)	73,046	37,364
Gene therapy programs	19,448	—
Pre-clinical and other programs	861	1,054
Total third-party direct project expenses	106,950	48,462
Other project costs		
Personnel costs	57,580	44,501
Other costs	29,936	20,722
Total other project costs	87,516	65,223
Business development transactions	—	100,000
Total research and development costs	$ 194,466	$ 213,685

The $19.2 million decrease in research and development costs was primarily due to $100 million in expenses associated with the acquisition of ten gene therapy assets with the Celenex transaction in 2018. This was primarily offset by increases in clinical research and manufacturing costs with the advancement and enrollment of clinical studies in the Pompe program and an increase in gene therapy programs driven by the pipeline growth, as well as support for ongoing regulatory requirements, approval in new geographies, and pediatric and other studies to support label expansion of Galafold®. There were also increases in personnel and other costs with the advancement and enrollment of clinical studies and investments in manufacturing.

Selling, General, and Administrative Expense. Selling, general, and administrative expense increased $38.1 million primarily due to the expanded geographic scope of the ongoing commercial launch of Galafold® and related operational costs of our global business, including establishing commercial organizations and related teams in the U.S and Japan.

Loss on Exchange of Convertible Notes. During the first and second quarters of 2019, the Company entered into separate, privately negotiated Exchange Agreements with a limited number of holders of the Convertible Notes. As a result of this exchange, the Company recognized a loss on exchange of debt of $40.6 million in the Consolidated Statements of Operations, and $215.0 million in additional paid-in-capital and common stock of $0.4 million in the Consolidated Balance Sheets for the nine months ended September 30, 2019.

Change in Fair Value of Derivatives. Subsequent to the underwritten public offerings in February 2018, we did not have sufficient unissued authorized shares to cover a conversion of the Convertible Notes. The fair value of the derivative liability for the conversion feature and derivative asset for the Capped Call Confirmations was determined and subsequent changes to the fair value of the derivatives were recorded through earnings on the Consolidated Statements of Operations resulting in a change in fair value of derivatives for the nine months ended September 30, 2018 of $2.7 million.

Income Tax (Expense) Benefit. The income tax expense for the nine months ended September 30, 2019 was $0.6 million. We are subject to income taxes in various jurisdictions. Our tax liabilities are largely dependent on the distributions of pre-tax earnings among the many jurisdictions in which we operate. The income tax benefit for the nine months ended September 30, 2018 of $1.1 million was primarily due to a discrete tax item.

Liquidity and Capital Resources

As a result of our significant research and development expenditures, as well as expenditures to build a commercial organization to support the launch of Galafold®, we have not been profitable and have generated operating losses since we were incorporated in 2002. We have historically funded our operations through stock offerings, debt issuances, Galafold® revenues, collaborations, and other financing arrangements.

Sources of Liquidity

During the first and second quarter of 2019, we entered into separate, privately negotiated Exchange Agreements with a limited number of holders of the Convertible Notes. Under the terms of the Exchange Agreements, the limited number of holders agreed to exchange an aggregate principal amount of $247.2 million of Convertible Notes held by them in exchange for an aggregate of approximately 44.0 million shares of our common stock, par value $0.01 per share. Additionally, we terminated the Capped Call Confirmations related to the exchange of the Convertible Notes for cash proceeds of $19.9 million.

During the second quarter of 2019, we completed an underwritten equity offering and issued 18.7 million shares of common stock at $10.75 per share, inclusive of the fully exercised option to purchase additional shares from the initial offering. This transaction resulted in net proceeds of $189.0 million, after deducting underwriting discounts, commissions and offering expenses.

Cash Flow Discussion

As of September 30, 2019, we had cash, cash equivalents, and marketable securities of $514.2 million. We invest cash in excess of our immediate requirements in regard to liquidity and capital preservation in a variety of interest-bearing instruments, including obligations of U.S. government agencies and money market accounts. Wherever possible, we seek to minimize the potential effects of concentration and degrees of risk. Although we maintain cash balances with financial institutions in excess of insured limits, we do not anticipate any losses with respect to such cash balances. For more details on the cash, cash equivalents, and marketable securities, refer to "—Note 3. Cash, Cash Equivalents, Marketable Securities, and Restricted Cash," in our Notes to Consolidated Financial Statements.

Net Cash Used in Operating Activities

Net cash used in operations for the nine months ended September 30, 2019 was $192.6 million. The components of net cash used in operations included the net loss for the nine months ended September 30, 2019 of $266.7 million and the net change in operating assets and liabilities of $8.8 million. The change in operating assets was primarily due to an increase in accounts receivable by $12.6 million due to increased commercial sales of Galafold®, an increase in prepaid and other current assets of $3.3 million to support commercial activities for Galafold® launch and an increase in inventory of $2.0 million. The net cash used in operations was also impacted by an increase in accounts payable and accrued expenses of $8.7 million, mainly related to program expenses and support for the commercial launch of Galafold®, partially offset by a decrease in deferred reimbursement of $1.5 million due to payment of a milestone.

Net cash used in operations for the nine months ended September 30, 2018 was $239.3 million. The components of net cash used in operations included the net loss for the nine months ended September 30, 2018 of $270.9 million and the net change in operating assets and liabilities of $6.3 million. The change in operating assets was primarily due to an increase in accounts receivable by $5.2 million and an increase in inventory of $2.0 million due to commercial sales of Galafold®, partially offset by a decrease in prepaid and other current assets of $2.6 million to support commercial activities for Galafold® launch. The net cash used in operations was also impacted by an increase in accounts payable and accrued expenses of $3.7 million, mainly related to program expenses and support for the commercial launch of Galafold®, partially offset by a decrease in deferred reimbursement of $5.0 million due to payment of a milestone.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2019 was $68.2 million. Our investing activities have consisted primarily of purchases and sales and maturities of investments and capital expenditures. Net cash provided by investing activities reflects $389.2 million for the sale and redemption of marketable securities, partially offset by $312.0 million for the purchase of marketable securities and $9.1 million for the acquisition of property and equipment.

Net cash used in investing activities for the nine months ended September 30, 2018 was $57.4 million. Our investing activities have consisted primarily of purchases and sales and maturities of investments and capital expenditures. Net cash used in investing activities reflects $441.0 million for the purchase of marketable securities, and $4.6 million for the acquisition of property and equipment, partially offset by $388.1 million for the sale and redemption of marketable securities.

Net Cash Provided by Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2019 was $214.3 million. Net cash provided by financing activities primarily reflects $189.0 million from the issuance of common stock, net of issuance costs paid, $19.9 million from partial termination of capped call and $8.6 million from the exercise of stock options and warrants, partially offset by $3.0 million from the purchase of vested restricted stock units.

Net cash provided by financing activities for the nine months ended September 30, 2018 was $450.4 million. Net cash provided by financing activities primarily reflects $294.6 million from the issuance of common stock, net of issuance costs, $146.6 million in proceeds from the Senior Secured Term Loan, net of issuance costs and estimated fees payable, and $12.1 million from the exercise of stock options and warrants, partially offset by $2.7 million from the purchase of vested restricted stock units.

Funding Requirements

We expect to incur losses from operations for the foreseeable future primarily due to research and development expenses, including expenses related to conducting clinical trials. Our future capital requirements will depend on a number of factors, including:

- the progress and results of our preclinical and clinical trials of our drug candidates and gene therapy candidates;
- the cost of manufacturing drug and gene therapy supply for our clinical and preclinical studies, including the significant cost of manufacturing Pompe ERT and gene therapies;
- the scope, progress, results, and costs of preclinical development, laboratory testing and clinical trials for our product candidates including those testing the use of pharmacological chaperones co-formulated and co-administered with ERT and for the treatment of LDs and gene therapies for the treatment of rare genetic metabolic diseases;

- the future results of on-going preclinical research and subsequent clinical trials for CDD, including our ability to obtain regulatory approvals and commercialize CDKL5 therapies and obtain market acceptance for such therapies;
- the costs, timing, and outcome of regulatory review of our product candidates;
- the number and development requirements of other product candidates that we pursue;
- the costs of commercialization activities, including product marketing, sales, and distribution;
- the emergence of competing technologies and other adverse market developments;
- our ability to successfully commercialize Galafold® ("migalastat HCl");
- our ability to manufacture or supply sufficient clinical or commercial products;
- our ability to obtain reimbursement for Galafold®;
- our ability to satisfy post-marketing commitments or requirements for continued regulatory approval of Galafold®;
- our ability to obtain market acceptance of Galafold®;
- the costs of preparing, filing, and prosecuting patent applications and maintaining, enforcing, and defending intellectual property-related claims;
- the extent to which we acquire or invest in businesses, products, and technologies;
- our ability to successfully integrate our acquired products and technologies into our business, including the possibility that the expected benefits of the transactions will not be fully realized by us or may take longer to realize than expected;
- our ability to establish collaborations and obtain milestone, royalty, or other payments from any such collaborators;
- our ability to adjust to changes in European and United Kingdom markets as the United Kingdom leaves the E.U.; and
- fluctuations in foreign currency exchange rates; and changes in accounting standards.

While we continue to generate revenue from product sales, in the absence of additional funding, we expect our continuing operating losses to result in increases in our cash used in operations over the next several quarters and years. We may seek additional funding through public or private financings of debt or equity. We believe that our current cash position, including expected Galafold® revenues, is sufficient to fund ongoing Fabry, Pompe, and gene therapy program operations into the first half of 2022. Potential future business development collaborations, pipeline expansion, and investment in manufacturing capabilities could impact our future capital requirements.

Financial Uncertainties Related to Potential Future Payments

Milestone Payments / Royalties

Celenex - With our acquisition of Celenex in 2018, we agreed to pay up to an additional $15 million in connection with the achievement of certain development milestones, $262 million in connection with the achievement of certain regulatory approval milestones across multiple programs and up to $75 million in tiered sales milestone payments.

NCH - Celenex has an exclusive license agreement with NCH. Under this license agreement, NCH is eligible to receive development and sales-based milestones of up to $7.8 million from us for each product.

Penn - Under our expanded collaboration agreement with Penn, Penn is eligible to receive certain milestone, royalty and discovery research payments with respect to licensed products for each indication. Milestone payments are payable following the achievement of certain development and commercial milestone events in each indication, up to an aggregate of $86.5 million per indication. Royalty payments are based on net sales of licensed products on a licensed product-by-licensed product and country-by-country basis. We will provide $10.0 million each year during the five-year agreement to fund the discovery research program.

MSSM - We acquired exclusive worldwide patent rights to develop and commercialize migalastat and other pharmacological chaperones for the prevention or treatment of human diseases or clinical conditions by increasing the activity of wild-type and mutant enzymes pursuant to a license agreement with Mount Sinai School of Medicine ("MSSM"). This agreement expired upon expiration of the last of the licensed patent rights, which occurred in 2018 in the U.S. and 2019 in Europe and Japan for monotherapy.

GSK - In November 2013, we entered into the Revised Agreement (the "Revised Agreement") with GlaxoSmithKline ("GSK"), pursuant to which we have obtained global rights to develop and commercialize migalastat as a monotherapy and in combination with ERT for Fabry disease. The Revised Agreement amends and replaces in its entirety the earlier agreement entered into between us and GSK in July 2012 (the "Original Collaboration Agreement"). Under the terms of the Revised Agreement, there was no upfront payment from us to GSK. For migalastat monotherapy, GSK is eligible to receive post-approval and sales-based milestones up to $40 million, as well as tiered royalties in the mid-teens in eight major markets outside the United States. In addition, because we reacquired worldwide rights to migalastat, we are no longer eligible to receive any milestones or royalties we would have been eligible to receive under the Original Collaboration Agreement.

Under our license agreements, if we owe royalties on net sales for one of our products to more than one of the above licensors, we have the right to reduce the royalties owed to one licensor for royalties paid to another. The amount of royalties to be offset is generally limited in each license and can vary under each agreement. For the nine months ended September 30, 2019, under the MSSM and GSK license and collaboration agreements, we paid $11.7 million in royalties and $1.5 million in sales-based milestones.

Critical Accounting Policies and Significant Judgments

The discussion and analysis of our financial condition and results of operations are based on our financial statements, which we have prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses during the reporting periods. On an ongoing basis, we evaluate our estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There were no significant changes during the nine months ended September 30, 2019 to the items that we disclosed as our significant accounting policies and estimates described in "—Note 2. Summary of Significant Accounting Policies" to the Company's financial statements as contained in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018, except as it relates to the adoption of ASU 2016-02, Leases (Topic 842), which is described below.

Leases

The Company primarily enters into lease agreements for office space, equipment, and vehicles. The leases have varying terms, some of which could include options to renew, extend, and early terminate. The Company determines if an arrangement is a lease at contract inception. Operating leases are included in right-of-use ("ROU") assets and lease liabilities on the Consolidated Balance Sheets.

ROU assets represent the Company's right to control the use of an explicitly or implicitly identified fixed asset for a period of time and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Control of an underlying asset is conveyed to the Company if the Company obtains the rights to direct the use of and to obtain substantially all of the economic benefits from using the underlying asset. ROU assets and liabilities are recognized at commencement date based on the present value of lease payments over the lease term. The Company uses its incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments.

Lease payments included in the measurement of the lease liability are comprised of fixed payments. Variable lease payments are excluded from the ROU asset and lease liability and are recognized in the period in which the obligation for those payments is incurred. Variable lease payments are presented in the Consolidated Statements of Operations in the same line item as expenses arising from fixed lease payments for operating leases. The Company has lease agreements that include lease and non-lease components, which the Company accounts for as a single lease component for all underlying asset categories.

The lease term for all of the Company's leases include the non-cancellable period of the lease plus any additional periods covered by either a Company option to extend (or not to terminate) the lease that the Company is reasonably certain to exercise, or an option to extend (or not to terminate) the lease controlled by the lessor.

Leases with an initial term of 12 months or less are not recorded on the Consolidated Balance Sheets. The Company recognizes lease expense for these leases on a straight-line basis over the lease term. The Company applies this policy to all underlying asset categories.

The information presented for the periods prior to January 1, 2019 has not been restated and is reported under the accounting standard in effect for those periods. For additional information, see " —Note 9. Leases" and "—Note 2. Summary of Significant Accounting Policies, Recent Accounting Developments - Guidance Adopted in 2019."

Recent Accounting Pronouncements

Please refer to "—Note 2. Summary of Significant Accounting Policies," in our Notes to Consolidated Financial Statements.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Market risk is the risk of change in fair value of a financial instrument due to changes in interest rates, equity prices, creditworthiness, financing, exchange rates, or other factors. Our primary market risk exposure relates to changes in interest rates in our cash, cash equivalents, and marketable securities. We place our investments in high-quality financial instruments, primarily money market funds, corporate debt securities, asset backed securities, and U.S. government agency notes with maturities of less than one year, which we believe are subject to limited interest rate and credit risk. The securities in our investment portfolio are not leveraged, are classified as available-for-sale and, due to the short-term nature, are subject to minimal interest rate risk. We believe that a 1% (100 basis points) change in average interest rates would either increase or decrease the market value of our investment portfolio by $1.6 million as of September 30, 2019. We currently do not hedge interest rate exposure and consistent with our investment policy, we do not use derivative financial instruments in our investment portfolio.

We are exposed to interest rate risk with respect to variable rate debt. At December 31, 2018, we had $150 million aggregate principal amount of variable rate debt through our Senior Secured Term Loan. We do not currently hedge our variable interest rate debt. The average variable interest rate for our variable rate debt as of September 30, 2019 was 9.9%. A hypothetical 100 basis point increase or decrease in the average interest rate on our variable rate debt would not result in a material change in the interest expense.

We face foreign exchange risk as a result of entering into transactions denominated in currencies other than U.S. dollars. We are not currently engaged in any foreign currency hedging activities. The current exposures arise primarily from cash, accounts receivable, intercompany receivables and payables, and net product sales denominated in foreign currencies. Both positive and negative impacts to our international product sales from movements in foreign currency exchange rates may be partially mitigated by the natural, opposite impact that foreign currency exchange rates have on our international operating expenses. A hypothetical 10% change in foreign exchange rates during any of the periods presented would not have had a material impact on our consolidated financial statements.

For information regarding our exposure to certain market risks, see Item 7A, Quantitative and Qualitative Disclosures About Market Risk, in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018. There have been no material changes in our financial instrument portfolio or market risk exposures since our fiscal year ended December 31, 2018.

ITEM 4. CONTROLS AND PROCEDURES

As of the end of the period covered by this Quarterly Report on Form 10-Q, an evaluation of the effectiveness of our disclosure controls and procedures (pursuant to Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act") was carried out under the supervision of our Principal Executive Officer and Principal Financial Officer, with the participation of our management. Based on that evaluation, the Principal Executive Officer and the Principal Financial Officer concluded that, as of the end of such period, our disclosure controls and procedures are effective in recording, processing, summarizing and reporting, on a timely basis, information required to be disclosed by us in the reports that we file or submit under the Exchange Act and are effective in ensuring that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is accumulated and communicated to our management, including our Principal Executive Officer and Principal Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

During the fiscal quarter covered by this report, there has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the last fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We are not currently a party to any legal proceedings.

ITEM 1A. RISK FACTORS

There have been no material changes to the risk factors previously disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2018.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

None.

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

None.

ITEM 4. MINE SAFETY DISCLOSURES

None.

ITEM 5. OTHER INFORMATION

None.

ITEM 6. EXHIBITS

Exhibit Number	Description
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14 and 15d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended
31.2	Certification of Principal Financial Officer pursuant to Rules 13a-14 and 15d-14 promulgated pursuant to the Securities Exchange Act of 1934, as amended
32.1	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

SIGNATURES

Pursuant to the requirements of the Securities and Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

AMICUS THERAPEUTICS, INC.

Date:	November 12, 2019 By:	/s/ John F. Crowley
		John F. Crowley
		Chairman and Chief Executive Officer
		(Principal Executive Officer)
Date:	November 12, 2019 By:	/s/ Daphne Quimi
		Daphne Quimi
		Chief Financial Officer
		(Principal Financial Officer)

Exhibit 31.1

CERTIFICATIONS PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002
CERTIFICATION BY PRINCIPAL EXECUTIVE OFFICER

I, John F. Crowley, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Amicus Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2019

/s/ John F. Crowley

John F. Crowley

Chairman and Chief Executive Officer

Exhibit 31.2

CERTIFICATIONS PURSUANT TO SECTION 302 OF
THE SARBANES-OXLEY ACT OF 2002
CERTIFICATION BY PRINCIPAL FINANCIAL OFFICER

I, Daphne Quimi, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Amicus Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

(a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

(c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

(d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 12, 2019

/s/ Daphne Quimi

Daphne Quimi

Chief Financial Officer

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Each of the undersigned hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in his capacity as an officer of Amicus Therapeutics, Inc. (the "Company"), that, to his knowledge, the Quarterly Report of the Company on Form 10-Q for the period ended September 30, 2019, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 78o(d)) and that the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of the Company. This written statement is being furnished to the Securities and Exchange Commission as an exhibit to such Form 10-Q. A signed original of this statement has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Date: November 12, 2019 By: /s/ John F. Crowley

John F. Crowley

Chairman and Chief Executive Officer

Date: November 12, 2019 By: /s/ Daphne Quimi

Daphne Quimi

Chief Financial Officer