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 June 30, 2022

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)
3675 Market Street, Philadelphia, PA	**19104**
(Address of Principal Executive Offices)	(Zip Code)

(215) 921-7600

(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, par value $0.01 per share	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 July 27, 2022 was 280,498,461 shares.

AMICUS THERAPEUTICS, INC.

Form 10-Q for the Quarterly Period Ended June 30, 2022

We have filed applications to register certain trademarks in the United States and abroad, including AMICUS THERAPEUTICS and design, AMICUS ASSIST and design, CHART and design, AT THE FOREFRONT OF THERAPIES FOR RARE AND ORPHAN DISEASES, HEALING BEYOND DISEASE, OUR GOOD STUFF, and Galafold® and design.

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 expectation 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 scope, progress, results and costs of our clinical trials of our drug candidates;
- the cost of manufacturing drug supply for our commercial, clinical and preclinical studies, including the cost of manufacturing Pompe Enzyme Replacement Therapy ("ERT" or "ATB200" or "cipaglucosidase alfa");
- the future results of preclinical research and subsequent clinical trials for pipeline candidates we may identify from time to time, including our ability to obtain regulatory approvals and commercialize these therapies and obtain market acceptance for such therapies;
- the costs, timing, and outcome of regulatory review of our product candidates, including AT-GAA;
- any changes in regulatory standards relating to the review of our product candidates, including AT-GAA;
- 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® (also referred to as "migalastat HCl") and, if our regulatory applications are approved, AT-GAA;
- our ability to manufacture or supply sufficient clinical or commercial products, including Galafold® and AT-GAA;
- our ability to obtain reimbursement for Galafold® and, if our regulatory applications are approved, AT-GAA;
- our ability to satisfy post-marketing commitments or requirements for continued regulatory approval of Galafold®, and, if approved and applicable, AT-GAA;
- our ability to obtain market acceptance of Galafold® and, if our regulatory applications are approved, AT-GAA;
- the costs of preparing, filing, and prosecuting patent applications and maintaining, enforcing, and defending intellectual property-related claims, including Hatch-Waxman litigation;
- the impact of litigation that has been or may be brought against us or of litigation that we are pursuing or may pursue against others;
- 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, or successfully divest or license existing products and technologies from 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 licensing agreements, collaborations, partnerships or other similar arrangements and to obtain milestone, royalty, or other payments from any such collaborators;
- the extent to which our business could be adversely impacted by the effects of the novel coronavirus ("COVID-19") outbreak, including due to actions by us, governments, our customers, our suppliers, or other third parties to control the spread of COVID-19, or by other health epidemics or pandemics;
- the costs associated with, and our ability to comply with, emerging environmental, social and governance standards;
- our ability to accurately forecast revenue, operating expenditures, or other metrics impacting profitability;

- 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, 2021, 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 herein 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 collaborations, alliances, business combinations, partnerships, strategic out-licensing of certain assets, the acquisition of preclinical-stage, clinical-stage, marketed products or platform technologies or other 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, 2021 (including the documents incorporated by reference therein) 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)

	June 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 235,639	$ 245,197
Investments in marketable securities	151,202	237,299
Accounts receivable	52,556	52,672
Inventories	20,879	26,818
Prepaid expenses and other current assets	37,367	34,848
Total current assets	497,643	596,834
Operating lease right-of-use assets, net	30,447	20,586
Property and equipment, less accumulated depreciation of $22,188 and $19,882 at June 30, 2022 and December 31, 2021, respectively	33,657	42,496
In-process research & development	23,000	23,000
Goodwill	197,797	197,797
Other non-current assets	18,045	24,427
Total Assets	$ 800,589	$ 905,140
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 23,113	$ 21,513
Accrued expenses and other current liabilities	114,703	98,153
Contingent consideration payable	19,266	18,900
Operating lease liabilities	7,543	7,409
Total current liabilities	164,625	145,975
Long-term debt	390,652	389,357
Operating lease liabilities	52,844	43,363
Deferred reimbursements	5,906	5,906
Deferred income taxes	4,930	4,930
Other non-current liabilities	8,207	8,240
Total liabilities	627,164	597,771
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.01 par value, 500,000,000 shares authorized, 280,456,667 and 278,912,800 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	2,811	2,808
Additional paid-in capital	2,631,110	2,595,419
Accumulated other comprehensive (loss) gain:		
Foreign currency translation adjustment	(16,603)	5,251
Unrealized loss on available-for-sale securities	(637)	(270)
Warrants	83	83
Accumulated deficit	(2,443,339)	(2,295,922)
Total stockholders' equity	173,425	307,369
Total Liabilities and Stockholders' Equity	$ 800,589	$ 905,140

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 June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Net product sales	$ 80,731	$ 77,413	$ 159,446	$ 143,815
Cost of goods sold	8,197	8,380	15,779	14,919
Gross profit	72,534	69,033	143,667	128,896
Operating expenses:				
Research and development	78,319	63,003	159,836	127,120
Selling, general, and administrative	53,379	42,276	111,495	89,002
Changes in fair value of contingent consideration payable	115	1,021	(1,073)	1,492
Loss on impairment of assets	—	—	6,616	—
Depreciation and amortization	1,334	1,567	2,745	3,171
Total operating expenses	133,147	107,867	279,619	220,785
Loss from operations	(60,613)	(38,834)	(135,952)	(91,889)
Other (expense) income:				
Interest income	356	50	489	215
Interest expense	(8,257)	(8,150)	(16,404)	(16,142)
Other income	7,268	234	9,170	(2,966)
Loss before income tax	(61,246)	(46,700)	(142,697)	(110,782)
Income tax expense	(911)	(4,525)	(4,720)	(6,107)
Net loss attributable to common stockholders	$ (62,157)	$ (51,225)	$ (147,417)	$ (116,889)
Net loss attributable to common stockholders per common share — basic and diluted	$ (0.21)	$ (0.19)	$ (0.51)	$ (0.44)
Weighted-average common shares outstanding — basic and diluted	291,970,562	266,398,516	288,646,587	265,384,865

See accompanying Notes to Consolidated Financial Statements

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Net loss	$ (62,157)	$ (51,225)	$ (147,417)	$ (116,889)
Other comprehensive (loss) gain:				
Foreign currency translation adjustment (loss) gain	$ (16,183)	$ 235	$ (21,854)	$ 843
Unrealized (loss) gain on available-for-sale securities	$ (29)	$ 12	$ (367)	$ 12
Other comprehensive (loss) gain	$ (16,212)	$ 247	$ (22,221)	$ 855
Comprehensive loss	$ (78,369)	$ (50,978)	$ (169,638)	$ (116,034)

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 June 30, 2022

	Common Stock		Additional Paid-In Capital	Warrants	Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount					
Balance at March 31, 2022	280,133,856	$ 2,809	$ 2,617,935	$ 83	$ (1,028)	$ (2,381,182)	$ 238,617
Stock options exercised, net	189,256	2	997	—	—	—	999
Vesting of restricted stock units, net of taxes	133,555	—	(285)	—	—	—	(285)
Stock-based compensation	—	—	12,463	—	—	—	12,463
Unrealized holding loss on available-for-sale securities	—	—	—	—	(29)	—	(29)
Foreign currency translation adjustment	—	—	—	—	(16,183)	—	(16,183)
Net loss	—	—	—	—	—	(62,157)	(62,157)
Balance at June 30, 2022	280,456,667	$ 2,811	$ 2,631,110	$ 83	$ (17,240)	$ (2,443,339)	$ 173,425

Six Months Ended June 30, 2022

	Common Stock		Additional Paid-In Capital	Warrants	Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount					
Balance at December 31, 2021	278,912,800	$ 2,808	$ 2,595,419	$ 83	$ 4,981	$ (2,295,922)	$ 307,369
Stock options exercised, net	334,705	3	1,855	—	—	—	1,858
Vesting of restricted stock units, net of taxes	1,209,162	—	(9,278)	—	—	—	(9,278)
Stock-based compensation	—	—	43,114	—	—	—	43,114
Unrealized holding loss on available-for-sale securities	—	—	—	—	(367)	—	(367)
Foreign currency translation adjustment	—	—	—	—	(21,854)	—	(21,854)
Net loss	—	—	—	—	—	(147,417)	(147,417)
Balance at June 30, 2022	280,456,667	$ 2,811	$ 2,631,110	$ 83	$ (17,240)	$ (2,443,339)	$ 173,425

Three Months Ended June 30, 2021

	Common Stock		Additional Paid-In Capital	Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at March 31, 2021	266,007,718	$ 2,680	$ 2,350,507	$ 8,835	$ (2,111,126)	$ 250,896
Stock options exercised, net	434,551	5	2,495	—	—	2,500
Vesting of restricted stock units, net of taxes	90,267	—	(244)	—	—	(244)
Stock-based compensation	—	—	11,736	—	—	11,736
Unrealized holding gain on available-for-sale securities	—	—	—	12	—	12
Foreign currency translation adjustment	—	—	—	235	—	235
Net loss	—	—	—	—	(51,225)	(51,225)
Balance at June 30, 2021	266,532,536	$ 2,685	$ 2,364,494	$ 9,082	$ (2,162,351)	$ 213,910

Six Months Ended June 30, 2021

	Common Stock		Additional Paid-In Capital	Warrants	Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount					
Balance at December 31, 2020	262,063,461	$ 2,650	$ 2,308,578	$ 12,387	$ 8,227	$ (2,045,462)	$ 286,380
Stock options exercised, net	922,662	9	6,652	—	—	—	6,661
Vesting of restricted stock units, net of taxes	987,330	—	(14,438)	—	—	—	(14,438)
Stock-based compensation	—	—	32,090	—	—	—	32,090
Warrants exercised	2,554,999	26	31,591	(12,387)	—	—	19,230
Equity component of the convertible notes	4,084	—	21	—	—	—	21
Unrealized holding gain on available-for-sale securities	—	—	—	—	12	—	12
Foreign currency translation adjustment	—	—	—	—	843	—	843
Net loss	—	—	—	—	—	(116,889)	(116,889)
Balance at June 30, 2021	266,532,536	$ 2,685	$ 2,364,494	$ —	$ 9,082	$ (2,162,351)	$ 213,910

See accompanying Notes to Consolidated Financial Statements

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

	Six Months Ended June 30,	
	2022	**2021**
Operating activities		
Net loss	$ (147,417)	$ (116,889)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of debt discount and deferred financing	1,295	1,200
Depreciation and amortization	2,745	3,171
Stock-based compensation	43,114	32,090
Non-cash changes in the fair value of contingent consideration payable	(1,073)	1,492
Foreign currency remeasurement loss	353	3,235
Asset impairment charges and other asset write-offs	12,265	—
Changes in operating assets and liabilities:		
Accounts receivable	(4,424)	(3,127)
Inventories	3,537	(4,445)
Prepaid expenses and other current assets	(4,481)	5,265
Accounts payable, accrued expenses, and other current liabilities	22,671	(28,485)
Other non-current assets and liabilities	(2,762)	(1,784)
Net cash used in operating activities	$ (74,177)	$ (108,277)
Investing activities		
Sale and redemption of marketable securities	184,061	258,767
Purchases of marketable securities	(98,330)	(145,255)
Capital expenditures	(1,226)	(1,234)
Net cash provided by investing activities	$ 84,505	$ 112,278
Financing activities		
Payment of finance leases	(41)	(389)
Proceeds from warrants exercised	—	19,230
Purchase of vested restricted stock units, net of taxes	(9,278)	(14,438)
Proceeds from stock options exercised, net	1,858	6,661
Net cash (used in) provided by financing activities	$ (7,461)	$ 11,064
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	$ (12,462)	$ (1,439)
Net (decrease) increase in cash, cash equivalents, and restricted cash at the end of the period	(9,595)	13,626
Cash, cash equivalents, and restricted cash at the beginning of period	249,456	166,162
Cash, cash equivalents, and restricted cash at the end of period	$ 239,861	$ 179,788
Supplemental disclosures of cash flow information		
Cash paid during the period for interest	$ 15,108	$ 15,109
Cash paid for taxes	$ 710	$ 4,526
Capital expenditures unpaid at the end of period	$ 53	$ 191
Tenant improvements paid through lease incentives	$ —	$ 67

See accompanying Notes to Consolidated Financial Statements

Amicus Therapeutics, Inc.
Notes to the Consolidated Financial Statements
(Unaudited)

1. Description of Business

Amicus Therapeutics, Inc. (the "Company") is a global, patient-dedicated biotechnology company focused on discovering, developing, and delivering novel medicines for rare diseases. The Company has a portfolio of product opportunities including the first, oral monotherapy for Fabry disease that has achieved widespread global approval and a differentiated biologic for Pompe disease, that is under review with the U.S. Food and Drug Administration ("FDA") as well as the European Medicines Agency ("EMA"). The Company is committed to discovering and developing next generation therapies in Fabry and Pompe diseases.

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."), United Kingdom ("U.K."), and Japan, with multiple additional approvals granted and applications pending in several geographies around the world.

The lead biologics program of the Company's pipeline is Amicus Therapeutics GAA ("AT-GAA", also known as ATB200/AT2221, or cipaglucosidase alfa/miglustat), a novel, two-component, potential best-in-class treatment for Pompe disease. In February 2019, the FDA granted Breakthrough Therapy designation ("BTD") to AT-GAA for the treatment of late onset Pompe disease. In September 2021, the FDA set the Prescription Drug User Fee Act ("PDUFA") target action date of May 29, 2022 for the New Drug Application ("NDA") for miglustat and July 29, 2022 for the Biologics License Application ("BLA") for cipaglucosidase alfa. The EMA validated the Marketing Authorization Application (“MAA”) in the fourth quarter of 2021. On May 9, 2022, the FDA extended the review period for the NDA for miglustat and the BLA for cipaglucosidase alfa resulting in revised PDUFA action dates of August 29, 2022 and October 29, 2022, respectively.

The Company's operations have not been significantly impacted by the novel coronavirus (“COVID-19”) pandemic to date. The Company continued to observe increased lag time between patient identification and Galafold® initiation due to the continued prevalence of COVID-19 and its ongoing impact on access to treatment for people living with Fabry disease in certain markets. The Company has maintained operations in all geographies, secured its global supply chain for its commercial and clinical products, as well as maintained the operational integrity of its clinical trials, with minimal disruptions. Whether the Company will continue to operate without any significant disruptions will depend on the continued health of its employees, the ongoing demand for Galafold® and the continued operation of its global supply chain. The Company has continued to provide uninterrupted access to medicines for those in need of treatment, while prioritizing the health and safety of its global workforce. However, the Company's results of operations in future periods may be negatively impacted by unknown future impacts from the COVID-19 pandemic.

The Company had an accumulated deficit of $2.4 billion as of June 30, 2022 and anticipates incurring losses through the fiscal year ending December 31, 2022 and beyond. The Company has historically funded its operations through stock offerings, Galafold® revenues, debt issuances, collaborations, and other financing arrangements.

Based on its current operating model, the Company believes that the current cash position, which includes expected revenues, is sufficient to fund the Company's operations and ongoing research programs to achieve self-sustainability. Potential impacts of the COVID-19 pandemic, business development collaborations, pipeline expansion, and investment in manufacturing capabilities could impact the Company's future capital requirements.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company has prepared the accompanying unaudited Consolidated Financial Statements in accordance with the U.S. generally accepted accounting principles ("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 Consolidated 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, 2021. 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, 2021.

Consolidation

The Consolidated Financial Statements include the accounts of the Company and its subsidiaries. Intercompany accounts and transactions are 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.

Additionally, the Company assessed the impact COVID-19 pandemic has had on its operations and financial results as of June 30, 2022 and through the issuance of these financial statements. The Company’s analysis was informed by the facts and circumstances as they were known to the Company. This assessment considered the impact COVID-19 may have on financial estimates and assumptions that affect the reported amounts of assets and liabilities and revenue and expenses.

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 Company's Consolidated Balance Sheets. Unrealized holding gains and losses are reported within other comprehensive loss in the Company's 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 other current assets and other non-current assets on the Company's 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 its cash, cash equivalents, or 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 June 30, 2022 have arisen from product sales primarily in Europe and the 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 June 30, 2022, the Company recorded an allowance for doubtful accounts of $0.1 million.

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Depreciation is calculated over the estimated useful lives of the respective assets, which range from three to five years, or the lesser of the related initial term of the lease or useful life for leasehold improvements.

The initial cost of property and equipment consists of its purchase price and any directly attributable costs of bringing the asset to its working condition and location for its intended use. Expenditures incurred after the fixed assets have been put into operation, such as repairs and maintenance, are charged to income in the period in which the costs are incurred. Major replacements, improvements, and additions are capitalized in accordance with Company policy.

The Company evaluates long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset group may not be recoverable. If indications of impairment exist, projected future undiscounted cash flows associated with the asset or asset group are compared to the carrying value of the asset to determine whether the asset or asset group's value is recoverable. If impairment is determined, the Company writes down the asset to its estimated fair value and records an impairment loss equal to the excess of the carrying value of the long-lived asset over its estimated fair value in the period at which such a determination is made.

During the six months ended June 30, 2022, in connection with the strategic prioritization of its gene therapy portfolio, the Company performed an assessment of its fixed assets. As a result, the Company recognized an impairment charge of $6.6 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. 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 June 30,		Six Months Ended June 30,	
(in thousands)	2022	2021	2022	2021
U.S.	$ 27,540	$ 23,678	$ 51,718	$ 44,5
Ex-U.S.	53,191	53,735	107,728	99,2
Total net product sales	$ 80,731	$ 77,413	$ 159,446	$ 143,8

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.

Research and Development Costs

Research and development costs are expensed as incurred. Research and development expense consist primarily of costs related to personnel, including salaries and other personnel related expenses, consulting fees, and the cost of facilities and support services used in drug development. Assets acquired that are used for research and development and have no future alternative use are expensed as in-process research and development.

In the second quarter of 2022, as part of the Company’s strategic prioritization of its gene therapy portfolio, the Company recorded a non-recurring $20.0 million liability associated with the expense of contractual obligations from which the Company will no longer receive further economic benefit. A liability for costs that will continue to be incurred under a contract for its remaining term without economic benefit to the entity is recognized at the cease-use date. This liability is presented as a component of accrued expenses and other current liabilities within the Company's Consolidated Balance Sheets.

Recent Accounting Developments

The Company has evaluated recent accounting pronouncements and believes that none of them will have a material effect on the Company's Consolidated Financial Statements or related disclosures.

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

As of June 30, 2022, the Company held $235.6 million in cash and cash equivalents and $151.2 million of marketable securities which are reported at fair value on the Company's Consolidated Balance Sheets. Unrealized holding gains and losses are generally reported within other comprehensive loss in the Company's Consolidated 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 or if an available-for-sale debt security’s fair value is determined to be less than the amortized cost and the Company intends or is more than likely to sell the security before recovery and it is not considered a credit loss, such 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. If the unrealized loss of an available-for-sale debt security is determined to be a result of credit loss, the Company would recognize an allowance and the corresponding credit loss would be included in earnings.

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.

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

	As of June 30, 2022			
(in thousands)	Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Cash and cash equivalents	$ 235,639	$ —	$ —	$ 235,639
Commercial paper	103,084	1	(239)	102,846
U.S. government agency bonds	45,157	—	(193)	44,964
Asset-backed securities	3,000	—	(9)	2,991
Money market	350	—	—	350
Certificates of deposit	51	—	—	51
	$ 387,281	$ 1	$ (441)	$ 386,841
Included in cash and cash equivalents	$ 235,639	$ —	$ —	$ 235,639
Included in marketable securities	151,642	1	(441)	151,202
Total cash, cash equivalents, and marketable securities	$ 387,281	$ 1	$ (441)	$ 386,841

	As of December 31, 2021			
(in thousands)	Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Cash and cash equivalents	$ 245,197	$ —	$ —	$ 245,197
Commercial paper	174,578	7	(54)	174,531
Corporate debt securities	32,322	—	(11)	32,311
Asset-backed securities	30,070	—	(14)	30,056
Money market	350	—	—	350
Certificate of deposit	51	—	—	51
	$ 482,568	$ 7	$ (79)	$ 482,496
Included in cash and cash equivalents	$ 245,197	$ —	$ —	$ 245,197
Included in marketable securities	237,371	7	(79)	237,299
Total cash, cash equivalents, and marketable securities	$ 482,568	$ 7	$ (79)	$ 482,496

For both the six months ended June 30, 2022 and the fiscal year ended December 31, 2021, there were no realized gains or losses. The cost of securities sold is based on the specific identification method.

Unrealized loss positions in the marketable securities as of June 30, 2022 and December 31, 2021 reflect temporary impairments and are not a result of credit loss. Additionally, as these positions have been in a loss position for less than twelve months and the Company does not intend to sell these securities before recovery, the losses are recognized in other comprehensive (loss) gain. The fair value of these marketable securities in unrealized loss positions was $140.5 million and $173.4 million as of June 30, 2022 and December 31, 2021, 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.

	As of June 30,	
(in thousands)	2022	2021
Cash and cash equivalents	$ 235,639	$ 176,538
Restricted cash	4,222	3,250
Cash, cash equivalents, and restricted cash shown in the Consolidated Statements of Cash Flows	$ 239,861	$ 179,788

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)	June 30, 2022	December 31, 2021
Raw materials	$ 11,508	$ 12,289
Work-in-process	5,943	10,699
Finished goods	3,428	3,830
Total inventories	$ 20,879	$ 26,818

The Company recorded a reserve for inventory of $1.1 million as of both June 30, 2022 and December 31, 2021.

5. Debt

The Company's debt consists of the following:

(in thousands)	June 30, 2022	December 31, 2021
Senior Secured Term Loan due 2026:		
Principal	$ 400,000	$ 400,00
Less: debt discount (1)	(5,334)	(6,07
Less: deferred financing (1)	(4,014)	(4,56
Net carrying value of Long-term debt	$ 390,652	$ 389,35

(1) Included in the Consolidated Balance Sheets within long-term debt and amortized to interest expense over the remaining life of the Senior Secured Term Loan due 2026 using the effective interest rate method.

Interest Expense

The following table sets forth interest expense recognized related to the Company's debt for the three and six months ended June 30, 2022 and 2021, respectively:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	2022	2021	2022	2021
Contractual interest expense	$ 7,589	$ 7,604	$ 15,089	$ 15,1
Amortization of debt discount	$ 375	$ 383	$ 739	$ 7
Amortization of deferred financing	$ 283	$ 262	$ 556	$ 4

6. Share-Based Compensation

The Company's Amended and Restated 2007 Equity Incentive 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 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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Expected stock price volatility	61.3 %	65.5 %	62.2 %	66.4
Risk free interest rate	3.0 %	0.7 %	1.6 %	0.5
Expected life of options (years)	5.3	5.4	5.3	
Expected annual dividend per share	$ —	$ —	$ —	$ —

A summary of the Company's stock options for the six months ended June 30, 2022 were as follows:

	Number of Shares (in thousands)	Weighted Average Exercise Price	Weighted Average Remaining Years	Aggregate Intrinsic Value (in millions)
Options outstanding, December 31, 2021	14,731	$ 11.08		
Granted	5,402	$ 11.55		
Exercised	(339)	$ 5.60		
Forfeited	(333)	$ 12.36		
Expired	(178)	$ 11.98		
Options outstanding, June 30, 2022	19,283	$ 11.28	7.0	$ 22
Vested and unvested expected to vest, June 30, 2022	17,589	$ 11.18	6.8	$ 21
Exercisable at June 30, 2022	10,377	$ 10.38	5.2	$ 18

As of June 30, 2022, the total unrecognized compensation cost related to non-vested stock options granted was $39.5 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 six months ended June 30, 2022 is as follows:

	Number of Shares (in thousands)	Weighted Average Grant Date Fair Value	Weighted Average Remaining Years	Aggregate Intrinsic Value (in millions)
Non-vested units as of December 31, 2021	7,341	$ 13.90		
Granted	4,815	$ 11.97		
Vested	(1,738)	$ 12.40		
Forfeited	(252)	$ 12.10		
Non-vested units as of June 30, 2022	10,166	$ 13.13	2.4	$ 109.

All non-vested units are expected to vest over their normal term. As of June 30, 2022, there was $65.8 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 two 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:

	Three Months Ended June 30,		Six Months Ended June 30,	
(in thousands)	**2022**	**2021**	**2022**	**2021**
Research and development expense	$ 4,379	$ 3,152	$ 13,744	$ 9,4
Selling, general, and administrative expense	8,084	8,584	29,370	22,6
Total equity compensation expense	$ 12,463	$ 11,736	$ 43,114	$ 32,0

7. 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 June 30, 2022 are identified in the following tables:

(in thousands)	**Level 2**	**Total**
Assets:		
Commercial paper	$ 102,846	$ 102,84
U.S. government agency bonds	44,964	44,96
Asset-backed securities	2,991	2,99
Money market	5,362	5,36
	$ 156,163	$ 156,16

(in thousands)	**Level 2**	**Level 3**	**Total**
Liabilities:			
Contingent consideration payable	$ —	$ 19,266	$ 19,266
Deferred compensation plan liability	4,977	—	4,977
	$ 4,977	$ 19,266	$ 24,243

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, 2021 are identified in the following tables:

(in thousands)	**Level 2**	**Total**
Assets:		
Commercial paper	$ 174,531	$ 174,53
Corporate debt securities	32,311	32,31
Asset-backed securities	30,056	30,05
Money market	5,150	5,15
	$ 242,048	$ 242,04

(in thousands)	**Level 2**	**Level 3**	**Total**
Liabilities:			
Contingent consideration payable	$ —	$ 20,339	$ 20,339
Deferred compensation plan liability	4,800	—	4,800
	$ 4,800	$ 20,339	$ 25,139

The Company's Senior Secured Term Loan due 2026 falls 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 due 2026 approximates the fair value.

The Company did not have any Level 3 assets as of June 30, 2022 or December 31, 2021.

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 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.

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

Contingent Consideration Liability	Fair Value as of June 30, 2022		Valuation Technique	Unobservable Input	Range
	(in thousands)				
				Discount rate	7.5%
Clinical and regulatory milestones	$	19,266	Probability weighted discounted cash flow	Probability of achievement of milestones	75% - 88%
				Projected year of payments	2022 - 202

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 following table shows the change in the balance of contingent consideration payable for the three and six months ended June 30, 2022 and 2021, respectively:

	Three Months Ended June 30,				Six Months Ended June 30,			
(in thousands)	2022		2021		2022		2021	
Balance, beginning of the period	$	19,151	$	26,296	$	20,339	$	25,8
Changes in fair value during the period, included in the Consolidated Statements of Operations		115		1,021		(1,073)		1,4
Balance, end of the period [1]	$	19,266	$	27,317	$	19,266	$	27,3

[1] As certain milestones are expected to be reached within the next twelve months, the June 30, 2022 balance was recorded as a current liability in the Consolidated Balance Sheets.

8. 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 June 30,		Six Months Ended June 30,	
(in thousands, except per share amounts)	**2022**	**2021**	**2022**	**2021**
Numerator:				
Net loss attributable to common stockholders	$ (62,157)	$ (51,225)	$ (147,417)	$ (116,8
Denominator:				
Weighted average common shares outstanding — basic and diluted	291,970,562	266,398,516	288,646,587	265,384,8

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. Weighted average common shares outstanding includes outstanding pre-funded warrants with an exercise price of $0.01.

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 June 30,	
(in thousands)	**2022**	**2021**
Options to purchase common stock	19,283	14,9
Unvested restricted stock units	10,166	7,4
Convertible notes	—	4
Total number of potentially issuable shares	29,449	22,8

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

The following discussion should be read in conjunction with the unaudited Consolidated Financial Statements and the notes thereto included in this Quarterly Report on Form 10-Q and the audited Consolidated Financial Statements and the notes thereto included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021. Some of the statements we make in this section are forward-looking statements within the meaning of the federal securities laws. For a complete discussion of forward-looking statements, see the section in this Quarterly Report on Form 10-Q entitled "Special Note Regarding Forward-Looking Statements". Certain risk factors may cause actual results, performance or achievements to differ materially from those expressed or implied by the following discussion. For a discussion of such risk factors, see the section in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 entitled "Risk Factors".

Overview

We are a global, patient-dedicated biotechnology company focused on discovering, developing, and delivering novel medicines for rare diseases. We have a portfolio of product opportunities including the first, oral monotherapy for Fabry disease that has achieved widespread global approval and a differentiated biologic for Pompe disease that is under review with the U.S. Food and Drug Administration ("FDA") as well as the European Medicines Agency ("EMA"). We are committed to discovering and developing next generation therapies in Fabry and Pompe diseases.

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."), United Kingdom ("U.K."), and Japan, with multiple additional approvals granted and applications pending in several geographies around the world.

The lead biologics program of our pipeline is Amicus Therapeutics GAA ("AT-GAA", also known as ATB200/AT2221, or cipaglucosidase alfa/miglustat), a novel, two-component, potential best-in-class treatment for Pompe disease. In February 2019, the FDA granted Breakthrough Therapy designation ("BTD") to AT-GAA for the treatment of late onset Pompe disease. In September 2021, the FDA set the Prescription Drug User Fee Act ("PDUFA") target action date of May 29, 2022 for the New Drug Application ("NDA") for miglustat and July 29, 2022 for the Biologics License Application ("BLA") for cipaglucosidase alfa. The EMA validated the Marketing Authorization Application ("MAA") in the fourth quarter of 2021. On May 9, 2022, the FDA extended the review period for the NDA for miglustat and the BLA for cipaglucosidase alfa resulting in revised PDUFA action dates of August 29, 2022 and October 29, 2022, respectively.

Our Strategy

Our strategy is to create, manufacture, test, and deliver the highest quality medicines for people living with rare diseases through internally developed, jointly 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. We are leveraging our global capabilities to develop and broaden our lead franchises in Fabry and Pompe disease, with focused discovery work on next generation therapies and novel platform technologies.

Our operations have not been significantly impacted by the novel coronavirus ("COVID-19") pandemic thus far. The Company continued to observe increased lag time between patient identification and Galafold® initiation due to the continued prevalence of COVID-19 and its ongoing impact on access to treatment for people living with Fabry disease in certain markets. We have maintained operations in all geographies, secured our global supply chain for our commercial and clinical products, as well as maintained the operational integrity of our clinical trials, with minimum disruptions. Our ability to continue to operate without any significant disruptions will depend on the continued health of our employees, the ongoing demand for Galafold® and the continued operation of our global supply chain. We have continued to provide uninterrupted access to medicines for those in need of treatment, while prioritizing the health and safety of our global workforce. However, our results of operations in future periods may be negatively impacted by unknown future impacts from the COVID-19 pandemic.

Highlights of our progress include:

- *Commercial and regulatory success in Fabry disease.* For the six months ended June 30, 2022, Galafold® revenue totaled $159.4 million, an increase of $15.6 million compared to the same period in the prior year. We continue to see strong commercial momentum and expansion into additional geographies. In countries where we have been operating the longest, 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 disease clinical program milestones.* In February 2021, we reported topline results from the Phase 3 study of AT-GAA (ATB200-03, also known as "PROPEL"). In June 2021, the MHRA granted AT-GAA a positive scientific opinion through the Early Access to Medicines Scheme ("EAMS") which permits eligible adults living with late-onset Pompe disease ("LOPD") who have received alglucosidase alfa for at least 2 years to switch to AT-GAA prior to marketing authorization in the U.K. We completed the submission of the rolling BLA and NDA to the FDA, which was accepted for review in September 2021, and in the fourth quarter of 2021, the MAA was submitted and validated by the EMA. In March 2022, we announced positive long-term data from our ongoing phase 1/2 clinical study. Study participants treated with AT-GAA for up to 36 months demonstrated persistent and durable effects on six-minute walk test distance and measures of motor function and muscle strength, stability, or increase in forced vital capacity, and reductions in biomarkers of muscle damage and disease substrate. In June 2022, the French National Agency for the Medicines and Health Products Safety granted the first reimbursed access to AT-GAA under their compassionate access program.
- *Pipeline advancement and growth.* We are leveraging our global capabilities to develop and broaden our lead franchises in Fabry and Pompe disease, with focused discovery work on next generation therapies and novel platform technologies.
- *Manufacturing.* We have managed our clinical and commercial supply chains during the COVID-19 pandemic such that as of the date hereof we have not experienced supply impacts. We have been able to continue to meet required commercial demand for Galafold® as well as supply our ongoing Pompe disease clinical studies and access programs including EAMS without interruption. We have secured supply for our continued needs for the Pompe disease program through a long-term supply agreement with Wuxi Biologics. The agreement allows for the continuous manufacture of our biologic to support future clinical needs and our anticipated commercial requirements should we garner regulatory approvals as planned. We have contracts in place to supply miglustat, our small molecule component of AT-GAA, to support both clinical and future commercial requirements.
- *Financial strength*. Total cash, cash equivalents, and marketable securities as of June 30, 2022 was $386.8 million. Based on the current operating model, we believe that the current cash position, which includes expected revenues, is sufficient to fund our operations and ongoing research programs to achieve self-sustainability. Potential impacts of the COVID-19 pandemic, 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 has approved Galafold® for 350 amenable GLA variants. Galafold® was approved in the E.U. and U.K. 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 mutation (variant). The approved E.U. and U.K. labels include 1,384 mutations amenable to Galafold® treatment, which represent up to half of all patients with Fabry disease. In countries where mutations are provided only on the amenability website, these 1,384 amenable mutations are now available. Marketing authorization approvals have been granted in over 40 countries around the world, including the U.S., E.U., U.K., Japan, and others. In July 2021, Galafold® was approved in the E.U. for adolescents aged 12 years and older weighing 45 kg or more. We plan to continue to launch Galafold® in additional countries during 2022, including for adolescents aged 12 years and older.

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.

The Galafold® U.S. patent portfolio encompasses 44 orange book listed patents, including 4 U.S. Composition of Matter patents, of which 27 provide protection through at least 2038.

Next Generation for Fabry Disease

We are committed to continued innovation for all people living with Fabry disease. Our pipeline includes a Fabry gene therapy and an academic research collaboration agreement with the University of Seville to explore next generation pharmacological chaperones 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, or cipaglucosidase alfa, with an optimized carbohydrate structure to enhance lysosomal uptake, administered in combination with AT2221, or miglustat, that functions as an enzyme stabilizer. Miglustat binds to and stabilizes ATB200 preventing inactivation of rhGAA in circulation to improve the uptake of active enzyme in key disease-relevant tissues, resulting in increased clearance of accumulated substrate, ("glycogen"). Miglustat is not an active ingredient that contributes directly to glycogen reduction.

In February 2021, we reported topline results from the Phase 3 PROPEL study. Of the Pompe disease patients enrolled, 77% were being treated with alglucosidase alfa (n=95) immediately prior to enrollment (“Switch”) and 23% had never been treated with any ERT (n=28) (“Naïve”). Nearly all patients from the PROPEL study continue to be treated with AT-GAA in the extension clinical study. The clinical data from the PROPEL study, the extension study as well as the Phase 1/2 study were included in the AT-GAA submissions to the FDA and the EMA.

In March 2022, we announced positive long-term data from our ongoing phase 1/2 clinical study. Study participants treated with AT-GAA for up to 36 months demonstrated persistent and durable effects on six-minute walk test distance and measures of motor function and muscle strength, stability, or increase in forced vital capacity, and reductions in biomarkers of muscle damage and disease substrate.

In addition, we are conducting ongoing clinical studies in pediatric patients for both LOPD and infantile-onset Pompe disease ("IOPD") populations.

Next Generation for Pompe Disease

As part of our long-term commitment to provide multiple solutions to address the significant unmet needs of the Pompe disease community, we are also continuing discovery for next-generation genetic medicines for Pompe disease.

CDKL5 Deficiency Disorder

We are researching a potential first-in-class genetic medicine for CDKL5 deficiency disorder consisting of a CDKL5 protein engineered for cross correction, delivered as either a protein replacement or as a gene therapy through our collaboration with Penn. We are collaborating with the LouLou Foundation to assess the natural history of the disease to identify endpoints for potential use in future studies.

Additional Next Generation Programs

We have a number of additional gene therapies in clinical and preclinical development, including potential gene therapies in multiple forms of Batten disease.

Strategic Alliances and Arrangements

We will continue to evaluate business development opportunities as appropriate to 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 and orphan diseases. We are exploring potential collaborations, alliances, and other business development opportunities on a regular basis. These opportunities may include business combinations, partnerships, the strategic out-licensing of certain assets, or the acquisition of preclinical-stage, clinical-stage, or marketed products or platform technologies 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 June 30, 2022 compared to June 30, 2021

The following table provides selected financial information for the Company:

(in thousands)	Three Months Ended June 30, 2022		Three Months Ended June 30, 2021		Change
Net product sales	$ 80,731		$ 77,413		$ 3,318
Cost of goods sold	8,197		8,380		(183)
Cost of goods sold as a percentage of net product sales	10.2	%	10.8	%	(0.6)
Operating expenses:					
Research and development	78,319		63,003		15,316
Selling, general, and administrative	53,379		42,276		11,103
Changes in fair value of contingent consideration payable	115		1,021		(906)
Depreciation and amortization	1,334		1,567		(233)
Other (expense) income:					
Interest income	356		50		306
Interest expense	(8,257)		(8,150)		(107)
Other income	7,268		234		7,034
Income tax expense	(911)		(4,525)		3,614
Net loss attributable to common stockholders	$ (62,157)		$ (51,225)		$ (10,932)

Net Product Sales. Net product sales increased $3.3 million during the three months ended June 30, 2022 compared to the same period in the prior year. The increase was primarily due to continued growth in the U.S., Europe and Japan markets, partially offset by the $6.7 million unfavorable impact of foreign currency exchange.

Research and Development Expense. The following table summarizes our principal development programs and the out-of-pocket, third-party expenses incurred:

(in thousands) *Projects*	Three Months Ended June 30, 2022	Three Months Ended June 30, 2021
Third party direct project expenses		
Galafold® (Fabry Disease)	$ 3,419	$ 1,375
AT-GAA (Pompe Disease)	21,585	23,840
Gene therapy programs	27,225	14,648
Pre-clinical and other programs	—	552
Total third-party direct project expenses	52,229	40,415
Other project costs		
Personnel costs	18,152	15,986
Other costs	7,938	6,602
Total other project costs	26,090	22,588
Total research and development costs	$ 78,319	$ 63,003

The $15.3 million increase in research and development costs was primarily driven by the strategic prioritization of our gene therapy portfolio resulting in the non-recurring expense of a contractual obligation from which we will no longer receive further economic benefit. Additionally, personnel costs increased primarily due to share-based compensation.

Selling, General, and Administrative Expense. Selling, general, and administrative expense increased $11.1 million, primarily driven by the strategic prioritization of our gene therapy portfolio that resulted in the write-off of cloud computing costs and software licensing fees.

Other Income. The $7.0 million variance was primarily related to foreign exchange gains caused by local currency remeasurement of U.S. dollar balances.

Income Tax Expense. The income tax expense for the three months ended June 30, 2022 was $0.9 million. We are subject to income taxes in various jurisdictions. Our tax liabilities are largely dependent on the distribution of pre-tax earnings among the many jurisdictions in which we operate.

Six Months Ended June 30, 2022 compared to June 30, 2021

The following table provides selected financial information for the Company:

	Six Months Ended June 30, 2022		
(in thousands)	**2022**	**2021**	**Change**
Net product sales	$ 159,446	$ 143,815	$ 15,631
Cost of goods sold	15,779	14,919	860
Cost of goods sold as a percentage of net product sales	9.9 %	10.4 %	(0.5)%
Operating expenses:			
Research and development	159,836	127,120	32,716
Selling, general, and administrative	111,495	89,002	22,493
Changes in fair value of contingent consideration payable	(1,073)	1,492	(2,565)
Loss on impairment of assets	6,616	—	6,616
Depreciation and amortization	2,745	3,171	(426)
Other (expense) income:			
Interest income	489	215	274
Interest expense	(16,404)	(16,142)	(262)
Other income (expense)	9,170	(2,966)	12,136
Income tax expense	(4,720)	(6,107)	1,387
Net loss attributable to common stockholders	$ (147,417)	$ (116,889)	$ (30,528)

Net Product Sales. Net product sales increased $15.6 million during the six months ended June 30, 2022 compared to the same period in the prior year. The increase was primarily due to continued growth in the U.S., Europe and Japan markets, partially offset by the $9.9 million unfavorable impact of foreign currency exchange.

Research and Development Expense. The following table summarizes our principal development programs and the out-of-pocket, third-party expenses incurred:

(in thousands)	Six Months Ended June 30,	
Projects	**2022**	**2021**
Third party direct project expenses		
Galafold® (Fabry Disease)	$ 7,039	$ 3,602
AT-GAA (Pompe Disease)	48,563	44,954
Gene therapy programs	44,917	28,464
Pre-clinical and other programs	93	620
Total third-party direct project expenses	100,612	77,640
Other project costs		
Personnel costs	43,827	36,165
Other costs	15,397	13,315
Total other project costs	59,224	49,480
Total research and development costs	$ 159,836	$ 127,120

The $32.7 million increase in research and development costs was primarily due to the strategic prioritization of our gene therapy portfolio resulting in the non-recurring expense of contractual obligations from which we will no longer receive further economic benefit, an increase in personnel costs primarily due to share-based compensation, an increase in the Pompe disease program associated with the timing of manufacturing costs, and an increase in clinical research costs in the Fabry disease program.

Selling, General, and Administrative Expense. Selling, general, and administrative expense increased $22.5 million, primarily driven by the strategic prioritization of our gene therapy portfolio that resulted in the write-off of cloud computing costs and software licensing fees and an increase in share-based compensation and marketing expenses.

Loss on Impairment of Assets. In connection with the strategic prioritization of our gene therapy portfolio, the Company performed an assessment of its assets and recognized a $6.6 million loss on impairment of assets.

Other Income (Expense). The $12.1 million variance was primarily related to foreign exchange gains caused by local currency remeasurement of U.S. dollar balances.

Income Tax Expense. The income tax expense for the six months ended June 30, 2022 was $4.7 million. We are subject to income taxes in various jurisdictions. Our tax liabilities are largely dependent on the distribution of pre-tax earnings among the many jurisdictions in which we operate.

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, Galafold® revenues, debt issuance, collaborations, and other financing arrangements.

Cash Flow Discussion

As of June 30, 2022, we had cash, cash equivalents, and marketable securities of $386.8 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 six months ended June 30, 2022 was $74.2 million. The components of net cash used in operations included the net loss for the six months ended June 30, 2022 of $147.4 million offset by $43.1 million of stock compensation, $15.6 million of other non-cash adjustments, and a net increase in changes in operating assets and liabilities of $14.5 million. The changes in operating assets and liabilities were primarily due to an increase in accounts payable and accrued expenses of $22.7 million associated with the strategic prioritization of our gene therapy portfolio resulting in the non-recurring expense of contractual obligations from which we will no longer receive further economic benefit and tax accruals, offset by payments of contract manufacturing, third party research and development services, and annual performance bonus. The net cash used in operations was also impacted by an increase in accounts receivable of $4.4 million due to increased commercial sales of Galafold®.

Net cash used in operations for the six months ended June 30, 2021 was $108.3 million. The components of net cash used in operations included the net loss for the six months ended June 30, 2021 of $116.9 million and an overall decrease in cash from changes in operating assets and liabilities of $32.6 million, primarily related to the timing of contract manufacturing and research payments. This was partially offset by $32.1 million of stock compensation and $9.1 million of other non-cash adjustments.

Net Cash Provided by Investing Activities

Net cash provided by investing activities for the six months ended June 30, 2022 was $84.5 million. Our investing activities have consisted primarily of purchases, sales, and maturities of investments and capital expenditures. Net cash provided by investing activities reflects $184.1 million for the sale and redemption of marketable securities, partially offset by $98.3 million for the purchase of marketable securities and $1.2 million for capital expenditures.

Net cash provided by investing activities for the six months ended June 30, 2021 was $112.3 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 $258.8 million for the sale and redemption of marketable securities, partially offset by $145.3 million for the purchase of marketable securities and $1.2 million for capital expenditures.

Net Cash (Used in) Provided by Financing Activities

Net cash used in financing activities for the six months ended June 30, 2022 was $7.5 million. Net cash used in financing activities primarily reflects the purchase of vested restricted stock units of $9.3 million, partially offset by $1.9 million of proceeds from the exercise of stock options.

Net cash provided by financing activities for the six months ended June 30, 2021 was $11.1 million. Net cash provided by financing activities primarily reflects $19.2 million from the exercise of the remaining outstanding warrants and $6.7 million from the exercise of stock options, partially offset by $14.4 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 scope, progress, results and costs of our clinical trials of our drug candidates;
- the cost of manufacturing drug supply for our commercial, clinical and preclinical studies, including the cost of manufacturing Pompe Enzyme Replacement Therapy ("ERT" or "ATB200" or "cipaglucosidase alfa");
- the future results of preclinical research and subsequent clinical trials for pipeline candidates we may identify from time to time, including our ability to obtain regulatory approvals and commercialize these therapies and obtain market acceptance for such therapies;
- the costs, timing, and outcome of regulatory review of our product candidates, including AT-GAA;
- any changes in regulatory standards relating to the review of our product candidates, including AT-GAA;
- 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® (also referred to as "migalastat HCl") and, if our regulatory applications are approved, AT-GAA;
- our ability to manufacture or supply sufficient clinical or commercial products, including Galafold® and AT-GAA;
- our ability to obtain reimbursement for Galafold® and, if our regulatory applications are approved, AT-GAA;
- our ability to satisfy post-marketing commitments or requirements for continued regulatory approval of Galafold®, and, if approved and applicable, AT-GAA;
- our ability to obtain market acceptance of Galafold® and, if our regulatory applications are approved, AT-GAA;
- the costs of preparing, filing, and prosecuting patent applications and maintaining, enforcing, and defending intellectual property-related claims, including Hatch-Waxman litigation;
- the impact of litigation that has been or may be brought against us or of litigation that we are pursuing or may pursue against others;
- 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, or successfully divest or license existing products and technologies from 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 licensing agreements, collaborations, partnerships or other similar arrangements and to obtain milestone, royalty, or other payments from any such collaborators;
- the extent to which our business could be adversely impacted by the effects of the novel coronavirus ("COVID-19") outbreak, including due to actions by us, governments, our customers, our suppliers, or other third parties to control the spread of COVID-19, or by other health epidemics or pandemics;
- the costs associated with, and our ability to comply with, emerging environmental, social and governance standards;
- our ability to accurately forecast revenue, operating expenditures, or other metrics impacting profitability;
- 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 net cash used over the next several quarters and years. We may seek additional funding through public or private financings of debt or equity. Based on our current operating model, we believe that the current cash position, which includes expected revenues, is sufficient to fund our operations and ongoing research programs to achieve self-sustainability. Potential impacts of the COVID-19 pandemic, 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

Callidus - In connection with our acquisition of Callidus in 2013, we agreed to pay up to an additional $35 million in connection with the achievement of certain clinical milestones and up to $80 million in connection with the achievement of certain regulatory approval milestones. As of June 30, 2022, $20 million and $68 million remain outstanding, respectively. Refer to “— Note 7. Assets and Liabilities Measured at Fair Value,” to the Consolidated Financial Statements.

Celenex - In connection with our acquisition of Celenex in 2018, we agreed to pay up to an additional $10 million in connection with the achievement of certain development milestones, $220 million in connection with the achievement of certain regulatory approval milestones across multiple programs and up to $75 million in tiered sales milestone payments.

Nationwide Children’s Hospital - Celenex has an exclusive license agreement with Nationwide Children's Hospital ("Nationwide Children’s"). Under this license agreement, Nationwide Children’s is eligible to receive development and sales-based milestones of up to $7.8 million from us for each product.

University of Pennsylvania - Under our collaboration agreement with the University of Pennsylvania ("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 $88.0 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 provide $10.0 million each year during the five-year agreement to fund the discovery research program.

GlaxoSmithKline - In July 2012, as amended in November 2013, we entered into an agreement with GlaxoSmithKline ("GSK"), pursuant to which we obtained global rights to develop and commercialize Galafold® as a monotherapy and in combination with ERT for Fabry disease (“Collaboration Agreement”). Under the terms of the Collaboration Agreement, 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 U.S.

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 six months ended June 30, 2022 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, 2021.

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

Our market risks, and the way we manage them, are summarized in Part II, Item 7A, "Quantitative and Qualitative Disclosures About Market Risk" of our Annual Report on Form 10-K for the fiscal year ended December 31, 2021. As of June 30, 2022, there have been no material changes to our market risks or to our management of such risks since December 31, 2021.

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 material 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, 2021.

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

Recent Sales of Unregistered Securities

None.

Issuer Purchases of Equity Securities

The following table provides certain information with respect to purchase of our common stock during the three months ended June 30, 2022:

Period	Total Number of Shares Purchased [(1)]	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares That May Yet Be Purchased Under the Plans or Programs
April 1, 2022 through April 30, 2022	6,588	$ 8.31	—	—
May 1, 2022 through May 31, 2022	23,164	$ 7.64	—	—
June 1, 2022 through June 30, 2022	11,060	$ 9.13	—	—
Total	40,812	$ 8.15	—	—

[(1)] Represents shares of common stock withheld to satisfy taxes associated with the vesting of restricted stock units

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 in Inline XBRL and included 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:	August 4, 2022	By:	/s/ Bradley L. Campbell
			Bradley L. Campbell President and Chief Executive Officer (Principal Executive Officer)
Date:	August 4, 2022	By:	/s/ Daphne Quimi
			Daphne Quimi Chief Financial Officer (Principal Financial Officer) (Principal Accounting Officer)

Exhibit 31.1

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

I, Bradley L. Campbell, 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: August 4, 2022

/s/ Bradley L. Campbell
Bradley L. Campbell
President 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: August 4, 2022

/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 or her capacity as an officer of Amicus Therapeutics, Inc. (the “Company”), that, to his or her knowledge, the Quarterly Report of the Company on Form 10-Q for the period ended June 30, 2022, 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: August 4, 2022	By:	/s/ Bradley L. Campbell
		Bradley L. Campbell
		President and Chief Executive Officer
Date: August 4, 2022	By:	/s/ Daphne Quimi
		Daphne Quimi
		Chief Financial Officer