UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2023

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)
47 Hulfish Street, Princeton, NJ	**08542**
(Address of Principal Executive Offices)	(Zip Code)

(609) 662-2000

(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, 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 October 25, 2023 was 293,245,738 shares.

AMICUS THERAPEUTICS, INC.

Form 10-Q for the Quarterly Period Ended September 30, 2023

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," "might," "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 clinical trials for our drug candidates;
- the cost of manufacturing drug supply for our commercial, clinical and preclinical studies, including the cost of manufacturing Pombiliti™ (also referred to as "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;
- any changes in regulatory standards relating to the review of our product candidates;
- the number and development requirements of other product candidates that we pursue;
- the costs of commercialization activities, including product marketing, sales, and distribution;
- the emergence of competing technologies and other adverse market developments;
- the estimates regarding the potential market opportunity for our products and product candidates;
- our ability to successfully commercialize Galafold® (also referred to as "migalastat HCl");
- our ability to successfully commercialize Pombiliti™ and Opfolda™ (together, also referred to as "AT-GAA") in the E.U., U.K., and U.S., and elsewhere, if regulatory applications are approved;
- our ability to manufacture or supply sufficient clinical or commercial products, including Galafold®, Pombiliti™ and Opfolda™;
- our ability to obtain reimbursement for Galafold®, Pombiliti™ and Opfolda™;
- our ability to satisfy post-marketing commitments or requirements for continued regulatory approval of Galafold®, Pombiliti™ and Opfolda™;
- our ability to obtain market acceptance of Galafold®, Pombiliti™ and Opfolda™;
- 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, including Hatch-Waxman litigation;
- 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 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, 2022, 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, 2022 (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)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 263,320	$ 148,813
Investments in marketable securities	16,980	144,782
Accounts receivable	73,331	66,196
Inventories	56,936	23,816
Prepaid expenses and other current assets	52,689	40,209
Total current assets	463,256	423,816
Operating lease right-of-use assets, net	29,511	29,534
Property and equipment, less accumulated depreciation of $25,018 and $22,281 at September 30, 2023 and December 31, 2022, respectively	31,072	30,778
Intangible assets, less accumulated amortization of $1,682 and $0 at September 30, 2023 and December 31, 2022, respectively	21,318	23,000
Goodwill	197,797	197,797
Other non-current assets	21,130	19,242
Total Assets	$ 764,084	$ 724,167
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 23,154	$ 15,413
Accrued expenses and other current liabilities	138,535	93,636
Contingent consideration payable	—	21,417
Operating lease liabilities	7,765	8,552
Total current liabilities	169,454	139,018
Long-term debt	394,071	391,990
Operating lease liabilities	52,454	51,578
Deferred reimbursements	5,906	4,656
Deferred income taxes	—	4,939
Other non-current liabilities	8,962	8,939
Total liabilities	630,847	601,120
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.01 par value, 500,000,000 shares authorized, 290,667,041 and 281,108,273 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	2,890	2,815
Additional paid-in capital	2,787,275	2,664,744
Accumulated other comprehensive loss:		
Foreign currency translation adjustment	(6,573)	(11,989)
Unrealized loss on available-for-sale securities	(195)	(116)
Warrants	71	83
Accumulated deficit	(2,650,231)	(2,532,490)
Total stockholders' equity	133,237	123,047
Total Liabilities and Stockholders' Equity	$ 764,084	$ 724,167

See accompanying Notes to Consolidated Financial Statements

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Net product sales	$ 103,501	$ 81,691	$ 284,274	$ 241,137
Cost of goods sold	9,946	13,436	26,002	29,215
Gross profit	93,555	68,255	258,272	211,922
Operating expenses:				
Research and development	40,704	52,970	117,352	212,806
Selling, general, and administrative	65,651	47,272	205,031	158,767
Changes in fair value of contingent consideration payable	1,995	567	2,583	(506)
Loss on impairment of assets	—	—	1,134	6,616
Depreciation and amortization	2,228	1,286	5,691	4,031
Total operating expenses	110,578	102,095	331,791	381,714
Loss from operations	(17,023)	(33,840)	(73,519)	(169,792)
Other income (expense):				
Interest income	1,471	563	5,407	1,052
Interest expense	(12,986)	(9,620)	(37,322)	(26,024)
Other income (expense)	3,833	13,634	(13,007)	22,804
Loss before income tax	(24,705)	(29,263)	(118,441)	(171,960)
Income tax benefit (expense)	3,128	(4,023)	700	(8,743)
Net loss attributable to common stockholders	$ (21,577)	$ (33,286)	$ (117,741)	$ (180,703)
Net loss attributable to common stockholders per common share — basic and diluted	$ (0.07)	$ (0.12)	$ (0.40)	$ (0.63)
Weighted-average common shares outstanding — basic and diluted	295,759,435	289,223,709	293,314,167	288,841,092

See accompanying Notes to Consolidated Financial Statements

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Net loss	$ (21,577)	$ (33,286)	$ (117,741)	$ (180,703)
Other comprehensive (loss) gain:				
Foreign currency translation adjustment (loss) gain	(10,910)	(22,121)	5,416	(43,975)
Unrealized (loss) gain on available-for-sale securities	(18)	283	(79)	(84)
Other comprehensive (loss) gain	(10,928)	(21,838)	5,337	(44,059)
Comprehensive loss	$ (32,505)	$ (55,124)	$ (112,404)	$ (224,762)

See accompanying Notes to Consolidated Financial Statements

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

Three Months Ended September 30, 2023

	Common Stock		Additional Paid-In Capital	Warrants	Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount					
Balance at June 30, 2023	286,992,923	$ 2,856	$ 2,733,148	$ 71	$ 4,160	$ (2,628,654)	$ 111,581
Stock options exercised, net	372,467	4	3,438	—	—	—	3,442
Vesting of restricted stock units, net of taxes	299,297	—	(2,347)	—	—	—	(2,347)
Stock-based compensation	—	—	16,511	—	—	—	16,511
Issuance of shares in connection with at-the-market offering, net of issuance costs	3,002,354	30	36,525	—	—	—	36,555
Unrealized loss on available-for-sale securities	—	—	—	—	(18)	—	(18)
Foreign currency translation adjustment	—	—	—	—	(10,910)	—	(10,910)
Net loss	—	—	—	—	—	(21,577)	(21,577)
Balance at September 30, 2023	290,667,041	$ 2,890	$ 2,787,275	$ 71	$ (6,768)	$ (2,650,231)	$ 133,237

Nine Months Ended September 30, 2023

	Common Stock		Additional Paid-In Capital	Warrants	Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount					
Balance at December 31, 2022	281,108,273	$ 2,815	$ 2,664,744	$ 83	$ (12,105)	$ (2,532,490)	$ 123,047
Stock options exercised, net	1,025,684	11	7,836	—	—	—	7,847
Vesting of restricted stock units, net of taxes	2,068,048		(16,355)	—	—	—	(16,355)
Stock-based compensation	—	—	67,982	—	—	—	67,982
Warrants exercised	1,220,100	12	12	(12)	—	—	12
Issuance of shares in connection with at-the-market offering, net of issuance costs	5,244,936	52	63,056	—	—	—	63,108
Unrealized loss on available-for-sale securities	—	—	—	—	(79)	—	(79)
Foreign currency translation adjustment	—	—	—	—	5,416	—	5,416
Net loss	—	—	—	—	—	(117,741)	(117,741)
Balance at September 30, 2023	290,667,041	$ 2,890	$ 2,787,275	$ 71	$ (6,768)	$ (2,650,231)	$ 133,237

Three Months Ended September 30, 2022

	Common Stock		Additional Paid-In Capital	Warrants	Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount					
Balance at June 30, 2022	280,456,667	$ 2,811	$ 2,631,110	$ 83	$ (17,240)	$ (2,443,339)	$ 173,425
Stock options exercised, net	172,118	2	1,331	—	—	—	1,333
Vesting of restricted stock units, net of taxes	258,351	—	(1,841)	—	—	—	(1,841)
Stock-based compensation	—	—	14,772	—	—	—	14,772
Unrealized gain on available-for-sale securities	—	—	—	—	283	—	283
Foreign currency translation adjustment	—	—	—	—	(22,121)	—	(22,121)
Net loss	—	—	—	—	—	(33,286)	(33,286)
Balance at September 30, 2022	280,887,136	$ 2,813	$ 2,645,372	$ 83	$ (39,078)	$ (2,476,625)	$ 132,565

Nine Months Ended September 30, 2022

	Common Stock		Additional Paid-In Capital	Warrants	Other Comprehensive 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	506,823	5	3,186	—	—	—	3,191
Vesting of restricted stock units, net of taxes	1,467,513	—	(11,119)	—	—	—	(11,119)
Stock-based compensation	—	—	57,886	—	—	—	57,886
Unrealized loss on available-for-sale securities	—	—	—	—	(84)	—	(84)
Foreign currency translation adjustment	—	—	—	—	(43,975)	—	(43,975)
Net loss	—	—	—	—	—	(180,703)	(180,703)
Balance at September 30, 2022	280,887,136	$ 2,813	$ 2,645,372	$ 83	$ (39,078)	$ (2,476,625)	$ 132,565

See accompanying Notes to Consolidated Financial Statements

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

	Nine Months Ended September 30,	
	2023	**2022**
Operating activities		
Net loss	$ (117,741)	$ (180,703)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of debt discount and deferred financing	2,080	1,963
Depreciation and amortization	5,691	4,031
Stock-based compensation	67,982	57,886
Non-cash changes in the fair value of contingent consideration payable	2,583	(506)
Foreign currency remeasurement loss	18,121	2,828
Deferred taxes	(4,939)	—
Asset impairment charges and other asset write-offs	2,360	17,271
Changes in operating assets and liabilities:		
Accounts receivable	(8,614)	(7,426)
Inventories	(42,233)	4,913
Prepaid expenses and other current assets	(26,010)	(5,583)
Accounts payable, accrued expenses, and other current liabilities	41,101	25,465
Other non-current assets and liabilities	(4,993)	(5,942)
Payment of contingent consideration	(7,937)	—
Net cash used in operating activities	$ (72,549)	$ (85,803)
Investing activities		
Sale and redemption of marketable securities	180,828	259,920
Purchases of marketable securities	(53,098)	(99,811)
Capital expenditures	(5,709)	(1,089)
Net cash provided by investing activities	$ 122,021	$ 159,020
Financing activities		
Payment of finance leases	(82)	(92)
Withholding taxes paid on vested restricted stock units	(16,355)	(11,119)
Proceeds from stock options exercised, net	7,847	3,191
Proceeds from warrants exercised, net	12	—
Proceeds from the issuance of shares in connection with at-the-market offering, net of issuance costs	63,108	—
Payment of contingent consideration	(1,063)	—
Net cash provided by (used in) financing activities	$ 53,467	$ (8,020)
Effect of exchange rate changes on cash, cash equivalents, and restricted cash	$ 10,218	$ (33,120)
Net increase in cash, cash equivalents, and restricted cash at the end of the period	113,157	32,077
Cash, cash equivalents, and restricted cash at the beginning of period	153,115	249,456
Cash, cash equivalents, and restricted cash at the end of period	$ 266,272	$ 281,533
Supplemental disclosures of cash flow information		
Cash paid during the period for interest	$ 35,448	$ 24,058
Cash paid for taxes	$ 6,473	$ 935
Capital expenditures unpaid at the end of period	$ 877	$ 53

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 developed and commercialized the first oral monotherapy for Fabry disease that has achieved widespread global approval and the first two-component therapy for late-onset Pompe disease that has been approved in the European Union (“E.U.”), the United Kingdom (“U.K.”), and in the United States (“U.S.”). 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 U.S., E.U., U.K., and Japan, with multiple additional approvals granted and applications pending in several geographies around the world.

Pombiliti™ + Opfolda™ (also referred to as AT-GAA, ATB200/AT2221, or cipaglucosidase alfa-atga/miglustat), is a novel, two-component treatment for late-onset Pompe disease that was approved by the European Commission ("EC") in June 2023, the U.K. Medicines and Healthcare products Regulatory Agency ("MHRA") in August 2023, and the U.S. Food and Drug Administration ("FDA") in September 2023. The Company began launch activities for Pombiliti™ + Opfolda™ in these markets and have commenced the reimbursement processes with healthcare authorities in additional European countries.

The Company had an accumulated deficit of $2.7 billion as of September 30, 2023 and anticipates incurring losses through the fiscal year ending December 31, 2023. The Company has historically funded its operations through stock offerings, Galafold® revenues, debt issuances, collaborations, and other financing arrangements.

In October 2023, the Company entered into a $400 million loan agreement (the “Senior Secured Term Loan due 2029”) with Blackstone Alternative Credit Advisors LP and Blackstone Life Sciences Advisors L.L.C. (collectively, “Blackstone”) with an interest rate equal to 3-month Term SOFR, subject to a 2.5% floor, plus a Term SOFR adjustment of 0.26161% and a margin of 6.25% that requires interest-only payments until early-2027 and matures in six years in 2029. This transaction resulted in net proceeds of $387.4 million, after deducting fees and estimated expenses. There were no warrants or equity conversion features associated with the Senior Secured Term Loan due 2029. Simultaneously, the Company also entered into a securities purchase agreement with funds managed by Blackstone, for the private placement of an aggregate of 2,467,104 shares of the Company’s common stock, at a purchase price of $12.16 per share. Proceeds from the private placement, net of offering costs, were $29.8 million.

The Company used proceeds from the Senior Secured Term Loan due 2029 and the private placement to prepay the Senior Secured Term Loan due 2026, inclusive of the outstanding principal amount, accrued interest and prepayment premium. The remaining proceeds will be used to fund ongoing operations.

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 for at least the next 12 months. Potential 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, 2022. 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, 2022.

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.

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 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 primarily related to its product sales of Galafold®. The Company's accounts receivable at September 30, 2023 have arisen from product sales primarily in Europe, the U.S., and Japan. The Company will periodically assess the financial strength of its customers to establish allowances for anticipated losses, if any. For accounts receivable that have arisen from named patient sales, the payment terms are predetermined, and the Company evaluates the creditworthiness of each customer on a regular basis. As of September 30, 2023, the Company's allowance for doubtful accounts was $0.1 million.

Revenue Recognition

The Company has recorded revenue on sales where its products are available either on a commercial basis or through a reimbursed early access program. Product orders 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. 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 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 disaggregated by product:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2023**	**2022**	**2023**	**2022**
Galafold®	$ 100,733	$ 81,631	$ 281,177	$ 241,056
Pombiliti™ + Opfolda™	2,768	60	3,097	81
Total net product sales	$ 103,501	$ 81,691	$ 284,274	$ 241,137

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2023**	**2022**	**2023**	**2022**
U.S.	$ 37,801	$ 30,222	$ 103,760	$ 81,940
Ex-U.S.	65,700	51,469	180,514	159,197
Total net product sales	$ 103,501	$ 81,691	$ 284,274	$ 241,137

Inventories and Cost of Goods Sold

Until regulatory approval of Pombiliti™ + Opfolda™, the Company expensed all manufacturing costs as research and development expense. Upon regulatory approval, the Company began capitalizing costs related to the purchase and manufacture of Pombiliti™ + Opfolda™.

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 Company's Consolidated Statements of Operations.

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

Intangible Assets and Goodwill

The Company records goodwill in a business combination when the total consideration exceeds the fair value of the net tangible and identifiable intangible assets acquired. Goodwill is assessed annually for impairment on October 1 and whenever events or circumstances indicate that the carrying amount of an asset may not be recoverable. The Company first assesses the qualitative factors to determine if a quantitative test is necessary. If required, or if the Company elects to bypass the qualitative assessment, a quantitative goodwill impairment test is conducted. If it is determined the Company's single reporting unit's carrying value, including goodwill, exceeds its fair value, an impairment loss is recorded for the difference.

Finite-lived intangible assets are recorded at cost, net of accumulated amortization, and, if applicable, impairment charges. Amortization of finite-lived intangible assets is recorded over the assets' estimated useful lives on a straight-line basis or based on the pattern in which economic benefits are consumed, if reliably determinable. The Company reviews finite-lived intangible assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be 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 asset over its estimated fair value in the period at which such a determination is made.

No indicators of impairment were noted during the nine months ended September 30, 2023.

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. Intangible Assets

As of September 30, 2023, the Company's intangible assets consisted of lead enzyme replacement therapy assets acquired with the Callidus Biopharma, Inc. acquisition in 2013, previously accounted for as in-process research and development. In March 2023, as a result of the EC's approval of Pombiliti™, the Company began amortizing the assets over the initial regulatory exclusivity period of 7 years. The Company completed an impairment assessment before changing the classification to definite-lived intangible asset noting no impairment. Amortization expense for the three and nine months ended September 30, 2023 was $0.8 million and $1.7 million, respectively. Total estimated amortization for the finite-lived intangible assets is estimated to be $2.5 million for the year ending December 31, 2023 and $3.3 million for the next four years thereafter.

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

As of September 30, 2023, the Company held $263.3 million in cash and cash equivalents and $17.0 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) gain 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 and money market funds, as well as fixed income investments 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, in accordance with Company policy, securities are of high 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 September 30, 2023			
(in thousands)	**Cost**	**Gross Unrealized Gain**	**Gross Unrealized Loss**	**Fair Value**
Cash and cash equivalents	$ 263,320	$ —	$ —	$ 263,320
Commercial paper	16,826	3	—	16,829
Money market	100	—	—	100
Certificates of deposit	51	—	—	51
	$ 280,297	$ 3	$ —	$ 280,300
Included in cash and cash equivalents	$ 263,320	$ —	$ —	$ 263,320
Included in marketable securities	16,977	3	—	16,980
Total cash, cash equivalents, and marketable securities	$ 280,297	$ 3	$ —	$ 280,300

	As of December 31, 2022			
(in thousands)	**Cost**	**Gross Unrealized Gain**	**Gross Unrealized Loss**	**Fair Value**
Cash and cash equivalents	$ 148,813	$ —	$ —	$ 148,813
Commercial paper	144,299	82	—	144,381
Money market	350	—	—	350
Certificate of deposit	51	—	—	51
	$ 293,513	$ 82	$ —	$ 293,595
Included in cash and cash equivalents	$ 148,813	$ —	$ —	$ 148,813
Included in marketable securities	144,700	82	—	144,782
Total cash, cash equivalents, and marketable securities	$ 293,513	$ 82	$ —	$ 293,595

For both the nine months ended September 30, 2023 and the fiscal year ended December 31, 2022, 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 September 30, 2023 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 Company had no securities in an unrealized loss position as of both September 30, 2023 and December 31, 2022.

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

	As of September 30,	
(in thousands)	**2023**	**2022**
Cash and cash equivalents	$ 263,320	$ 277,592
Restricted cash	2,952	3,941
Cash, cash equivalents, and restricted cash shown in the Consolidated Statements of Cash Flows	$ 266,272	$ 281,533

5. Inventories

Inventories as of September 30, 2023 and December 31, 2022 consisted of the following:

(in thousands)	**September 30, 2023**	**December 31, 2022**
Raw materials	$ 36,062	$ 10,054
Work-in-process	14,316	9,615
Finished goods	6,558	4,147
Total inventories	$ 56,936	$ 23,816

The Company's reserve for inventory was $0.3 million and $0.4 million as of September 30, 2023 and December 31, 2022, respectively.

6. Debt

The Company's debt consists of the following:

(in thousands)	**September 30, 2023**	**December 31, 2022**
Senior Secured Term Loan due 2026:		
Principal	$ 400,000	$ 400,00
Less: debt discount [1]	(3,384)	(4,57
Less: deferred financing [1]	(2,545)	(3,43
Net carrying value of Long-term debt[2]	$ 394,071	$ 391,9

[1] Included in the Company's 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.

[2] The Company classifies the current portion of long-term debt as non-current liabilities on the Consolidated Balance Sheets when it has the intent and ability to refinance the obligations on a long-term basis, in accordance with ASC 470-50 “Debt.” Accordingly, as of September 30, 2023, the debt was recorded as a long-term liability in the Company’s Consolidated Balance Sheet.

In October 2023, the Company entered into a $400 million loan agreement (the “Senior Secured Term Loan due 2029”) with Blackstone with an interest rate equal to 3-month Term SOFR, subject to a 2.5% floor, plus a Term SOFR adjustment of 0.26161% and a margin of 6.25% that requires interest-only payments until early-2027 and matures in six years in 2029. This transaction resulted in net proceeds of $387.4 million, after deducting fees and estimated expenses. There were no warrants or equity conversion features associated with the Senior Secured Term Loan due 2029.

The Company used proceeds from the Senior Secured Term Loan due 2029 and the private placement to prepay the Senior Secured Term Loan due 2026, inclusive of the outstanding principal amount, accrued interest and prepayment premium. In connection with the prepayment, the Company expects to record a loss from early extinguishment of debt of approximately $13.9 million in the fourth quarter of 2023, primarily related to the prepayment premium and write-off of unamortized debt discount and deferred financing costs.

Interest Expense

The following table sets forth interest expense recognized related to the Company's debt for the three and nine months ended September 30, 2023 and 2022, respectively:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2023**	**2022**	**2023**	**2022**
Contractual interest expense	$ 12,270	$ 8,945	$ 35,289	$ 24,03
Amortization of debt discount	$ 411	$ 382	$ 1,187	$ 1,12
Amortization of deferred financing	$ 310	$ 286	$ 893	$ 84

7. Stockholder's Equity

During the three and nine months ended September 30, 2023, the Company issued and sold an aggregate of 3,002,354 and 5,244,936 shares, respectively, through its at-the-market equity program ("ATM program") at weighted-average public offering prices of $12.68 and $12.50 per share, resulting in net proceeds of $36.6 million and $63.1 million, respectively. As of September 30, 2023, an aggregate of $184.4 million worth of shares remain available to be issued and sold under the ATM program.

In October 2023, in connection with the Senior Secured Term Loan due 2029, the Company entered into a securities purchase agreement with funds managed by Blackstone, for the private placement of an aggregate of 2,467,104 shares of the Company’s common stock, at a purchase price of $12.16 per share. Proceeds from the private placement, net of offering costs, were $29.8 million.

8. Stock-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 September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Expected stock price volatility	58.4 %	61.0 %	59.2 %	62.2 %
Risk free interest rate	4.3 %	3.1 %	3.9 %	1.7 %
Expected life of options (years)	5.5	5.3	5.5	5.3
Expected annual dividend per share	$ —	$ —	$ —	$ —

A summary of the Company's stock options for the nine months ended September 30, 2023 were as follows:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Years	Aggregate Intrinsic Value
	(in thousands)			(in millions)
Options outstanding, December 31, 2022	19,064	$ 11.31		
Granted	5,522	$ 12.03		
Exercised	(1,032)	$ 7.61		
Forfeited	(248)	$ 11.51		
Expired	(50)	$ 14.39		
Options outstanding, September 30, 2023	23,256	$ 11.64	6.7	$ 32
Vested and unvested expected to vest, September 30, 2023	21,389	$ 11.58	6.5	$ 31
Exercisable at September 30, 2023	13,246	$ 11.12	5.1	$ 27

As of September 30, 2023, the total unrecognized compensation cost related to non-vested stock options granted was $39.8 million and is expected to be recognized over a weighted average period of three years.

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

RSUs awarded under the Plan are generally subject to graded vesting and are contingent on an employee's continued service. RSUs are generally subject to forfeiture if employment terminates prior to the release of vesting restrictions. The Company expenses the cost of the RSUs, which is determined to be the fair market value of the shares of common stock underlying the RSUs at the date of grant, ratably over the period during which the vesting restrictions lapse. A summary of non-vested RSU activity under the Plan for the nine months ended September 30, 2023 is as follows:

	Number of Shares	Weighted Average Grant Date Fair Value	Weighted Average Remaining Years	Aggregate Intrinsic Value
	(in thousands)			(in millions)
Non-vested units as of December 31, 2022	9,717	$ 13.07		
Granted	4,514	$ 13.08		
Vested	(3,252)	$ 12.25		
Forfeited	(648)	$ 10.07		
Non-vested units as of September 30, 2023	10,331	$ 13.56	2.2	$ 125

As of September 30, 2023, there was $63.1 million of total unrecognized compensation cost related to unvested RSUs with service-based vesting conditions. These costs are expected to be recognized over a weighted average period of two years.

Compensation Expense Related to Equity Awards

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2023	2022	2023	2022
Research and development expense	$ 4,380	$ 5,428	$ 16,987	$ 19,1
Selling, general, and administrative expense	12,131	9,344	50,995	38,7
Total equity compensation expense	$ 16,511	$ 14,772	$ 67,982	$ 57,8

9. Assets and Liabilities Measured at Fair Value

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

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

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

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

A summary of the fair value of the Company's recurring assets and liabilities aggregated by the level in the fair value hierarchy within which those measurements fall as of September 30, 2023 are identified in the following tables:

(in thousands)	Level 2	Total
Assets:		
Commercial paper	$ 16,829	$ 16,82
Money market	6,818	6,81
	$ 23,647	$ 23,64

(in thousands)	Level 2	Total
Liabilities:		
Deferred compensation plan liability	$ 6,718	$ 6,718
	$ 6,718	$ 6,718

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, 2022 are identified in the following tables:

(in thousands)	Level 2	Total
Assets:		
Commercial paper	$ 144,381	$ 144,38
Money market	5,808	5,80
	$ 150,189	$ 150,18

(in thousands)	Level 2	Level 3	Total
Liabilities:			
Contingent consideration payable	$ —	$ 21,417	$ 21,417
Deferred compensation plan liability	5,458	—	5,458
	$ 5,458	$ 21,417	$ 26,875

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. Deferred compensation plan liability is recorded as a component of other non-current liabilities on the Company's Consolidated Balance Sheets.

The Company did not have any Level 3 assets as of September 30, 2023 or December 31, 2022. Liabilities measured at fair value using Level 3 inputs consisted of contingent consideration.

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 Company reached regulatory milestones of $9.0 million in March 2023 and $15.0 million in September 2023 associated with the approval of Pombiliti™ by the EC and FDA, respectively. The $9.0 million milestone payment was paid in the second quarter of 2023 and the $15.0 million milestone payment, which is payable in cash, is recorded as a component of accounts payable on the Company's Consolidated Balance Sheets as of September 30, 2023.

The following table shows the change in the balance of contingent consideration payable for the three and nine months ended September 30, 2023 and 2022, respectively:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	**2023**	**2022**	**2023**	**2022**
Balance, beginning of the period	$ 13,005	$ 19,266	$ 21,417	$ 20,339
Changes in fair value during the period, included in the Consolidated Statements of Operations	1,995	567	2,583	(506)
Milestone paid or payable in cash	(15,000)	—	(24,000)	—
Balance, end of the period	$ —	$ 19,833	$ —	$ 19,833

10. Basic and Diluted Net Loss per Common Share

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except per share amounts)	**2023**	**2022**	**2023**	**2022**
Numerator:				
Net loss attributable to common stockholders	$ (21,577)	$ (33,286)	$ (117,741)	$ (180,703)
Denominator:				
Weighted average common shares outstanding — basic and diluted	295,759,435	289,223,709	293,314,167	288,841,092

Dilutive common stock equivalents would include the dilutive effect of outstanding common stock options and unvested RSUs. 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 September 30,	
(in thousands)	**2023**	**2022**
Options to purchase common stock	23,256	19,23
Unvested restricted stock units	10,331	9,83
Total number of potentially issuable shares	33,587	29,07

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, 2022. 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, 2022 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 developed and commercialized the first oral monotherapy for Fabry disease that has achieved widespread global approval and the first two-component therapy for late-onset Pompe disease that has been approved in the European Union ("E.U."), the United Kingdom ("U.K."), and in the United States ("U.S."). 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 U.S., E.U., U.K., and Japan, with multiple additional approvals granted and applications pending in several geographies around the world.

Pombiliti™ + Opfolda™ (also referred to as AT-GAA, ATB200/AT2221, or cipaglucosidase alfa-atga/miglustat), is a novel, two-component treatment for late-onset Pompe disease that was approved by the European Commission ("EC") in June 2023, the U.K. Medicines and Healthcare products Regulatory Agency ("MHRA") in August 2023, and the U.S. Food and Drug Administration ("FDA") in September 2023. We began launch activities for Pombiliti™ + Opfolda™ in these markets and have commenced the reimbursement processes with healthcare authorities in additional European countries.

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.

Highlights of our progress include:

- *Commercial and regulatory success in Fabry disease.* For the nine months ended September 30, 2023, Galafold® revenue was $281.2 million of consolidated revenue. 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® as compared to treatment experienced patients. 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 program milestones.* Pombiliti™ + Opfolda™ were approved by the EC in June 2023, the MHRA in August 2023, and the FDA in September 2023. Additionally, multiple expanded access mechanisms are in place around the globe.
- *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.
- *Financial strength*. Total cash, cash equivalents, and marketable securities as of September 30, 2023 was $280.3 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 for at least the next 12 months. Potential business development collaborations, pipeline expansion, and investment in manufacturing capabilities could impact

our future capital requirements.

Our Commercial Products 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 351 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. Marketing authorization approvals as well as approvals for adolescents aged 12 years and older weighing 45 kg or more have been granted in over 40 countries around the world. We plan to continue to launch Galafold® in additional countries, 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 Good Laboratory Practice ("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 54 Orange Book listed patents, including 10 composition-of-matter patents, of which 38 provide protection through at least 2038.

Next Generation for Fabry Disease

We are committed to continued innovation for all people living with Fabry disease. As part of our long-term commitment, we are also continuing discovery for next-generation genetic medicines and have an academic research collaboration agreement to explore next generation pharmacological chaperones for Fabry disease.

Pombiliti™ (cipaglucosidase alfa-atga) + Opfolda™ (miglustat) for Pompe Disease

We have leveraged our biologics capabilities to develop Pombiliti™ + Opfolda™, a novel treatment paradigm for late-onset Pompe disease. Pombiliti™ + Opfolda™ consists of a uniquely engineered rhGAA enzyme, ATB200, or cipaglucosidase alfa-atga, 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 reducing inactivation of rhGAA in circulation to improve the uptake of active enzyme in key disease-relevant tissues. Miglustat is not an active ingredient that contributes directly to glycogen reduction.

Pombiliti™ + Opfolda™ were approved by the EC in June 2023, the MHRA in August 2023, and the FDA in September 2023. We began launch activities for Pombiliti™ + Opfolda™ in these markets and have commenced the reimbursement processes with healthcare authorities in additional European countries.

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

Next Generation for Pompe Disease

We are committed to continued innovation for all people living with Pompe disease. As part of our long-term commitment, we are also continuing discovery for next-generation genetic medicines for Pompe 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 September 30, 2023 compared to September 30, 2022

The following table provides selected financial information for the Company:

	Three Months Ended September 30,		
(in thousands)	**2023**	**2022**	**Change**
Net product sales	$ 103,501	$ 81,691	$ 21,810
Cost of goods sold	9,946	13,436	(3,490)
Cost of goods sold as a percentage of net product sales	9.6 %	16.4 %	(6.8)
Operating expenses:			
Research and development	40,704	52,970	(12,266)
Selling, general, and administrative	65,651	47,272	18,379
Changes in fair value of contingent consideration payable	1,995	567	1,428
Depreciation and amortization	2,228	1,286	942
Other income (expense):			
Interest income	1,471	563	908
Interest expense	(12,986)	(9,620)	(3,366)
Other income	3,833	13,634	(9,801)
Income tax benefit (expense)	3,128	(4,023)	7,151
Net loss attributable to common stockholders	$ (21,577)	$ (33,286)	$ 11,709

Net Product Sales. Net product sales increased $21.8 million during the three months ended September 30, 2023 compared to the same period in the prior year. The increase was primarily due to continued growth of Galafold® in the U.S., Europe and Japan markets, launch of Pombiliti™ + Opfolda™ in Europe, and a $3.8 million favorable impact of foreign currency exchange.

Cost of goods sold. Cost of goods sold includes manufacturing costs as well as royalties associated with net product sales of Galafold®. Cost of goods sold as a percentage of net product sales decreased 6.8% primarily due to inventory write-offs in the prior year.

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

(in thousands)	Three Months Ended September 30,	
Projects	**2023**	**2022**
Third party direct project expenses		
Galafold® (Fabry Disease)	$ 4,505	$ 2,613
Pombiliti™ + Opfolda™ (Pompe Disease)	15,233	24,052
Gene therapy programs	1,137	462
Pre-clinical and other programs	616	6
Total third-party direct project expenses	21,491	27,133
Other project costs		
Personnel costs	15,194	18,691
Other costs	4,019	7,146
Total other project costs	19,213	25,837
Total research and development costs	$ 40,704	$ 52,970

The $12.3 million decrease in research and development costs was primarily driven by a decrease in Pompe disease program spend due to reduced clinical manufacturing costs. Personnel and other costs decreased in connection with the reallocation of resources to support our Pombiliti™ + Opfolda™ commercial launch and continued growth of Galafold®.

Selling, General, and Administrative Expense. Selling, general, and administrative expense increased $18.4 million, primarily driven by personnel costs including the reallocation of resources to support our Pombiliti™ + Opfolda™ commercial launch activities and third-party professional fees.

Interest Expense. The $3.4 million increase was due to a higher variable interest rate on debt period over period.

Other Income. The $9.8 million variance was primarily related to movement in foreign exchange rates caused by remeasurement of foreign-denominated balances.

Income Tax Benefit. We are subject to income taxes in various jurisdictions. The income tax benefit was primarily due to the discrete treatment of certain tax matters that resulted in changes to the forecasted income in our tax jurisdictions.

Consolidated Results of Operations

Nine Months Ended September 30, 2023 compared to September 30, 2022

The following table provides selected financial information for the Company:

	Nine Months Ended September 30,		
(in thousands)	**2023**	**2022**	**Change**
Net product sales	$ 284,274	$ 241,137	$ 43,137
Cost of goods sold	26,002	29,215	(3,213)
Cost of goods sold as a percentage of net product sales	9.1 %	12.1 %	(3.0)
Operating expenses:			
Research and development	117,352	212,806	(95,454)
Selling, general, and administrative	205,031	158,767	46,264
Changes in fair value of contingent consideration payable	2,583	(506)	3,089
Loss on impairment of assets	1,134	6,616	(5,482)
Depreciation and amortization	5,691	4,031	1,660
Other (expense) income:			
Interest income	5,407	1,052	4,355
Interest expense	(37,322)	(26,024)	(11,298)
Other (expense) income	(13,007)	22,804	(35,811)
Income tax benefit (expense)	700	(8,743)	9,443
Net loss attributable to common stockholders	$ (117,741)	$ (180,703)	$ 62,962

Net Product Sales. Net product sales increased $43.1 million during the nine months ended September 30, 2023 compared to the same period in the prior year. The increase was primarily due to continued growth of Galafold® in the U.S., Europe and Japan markets, and the launch of Pombiliti™ + Opfolda™ in Europe.

Cost of goods sold. Cost of goods sold includes manufacturing costs as well as royalties associated with net product sales of Galafold®. Cost of goods sold as a percentage of net product sales decreased 3.0% primarily due to inventory write-offs in the prior year.

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

(in thousands)	Nine Months Ended September 30,	
Projects	**2023**	**2022**
Third party direct project expenses		
Galafold® (Fabry Disease)	$ 10,971	$ 9,652
Pombiliti™ + Opfolda™ (Pompe Disease)	44,126	72,615
Gene therapy programs	1,892	45,379
Pre-clinical and other programs	1,326	99
Total third-party direct project expenses	58,315	127,745
Other project costs		
Personnel costs	47,108	62,518
Other costs	11,929	22,543
Total other project costs	59,037	85,061
Total research and development costs	$ 117,352	$ 212,806

The $95.5 million decrease in research and development costs was primarily driven by the strategic deprioritization of our gene therapy portfolio, which resulted in the recognition of contract exit costs in the prior year. Additionally, Pompe disease program spend decreased due to reduced clinical manufacturing costs. Personnel and other costs decreased in connection with the reallocation of resources to support our Pombiliti™ + Opfolda™ commercial launch and continued growth of Galafold®.

Selling, General, and Administrative Expense. Selling, general, and administrative expense increased $46.3 million, primarily driven by personnel costs in connection with the reallocation of resources to support our Pombiliti™ + Opfolda™ commercial launch and third-party professional fees, partially offset by the write-off of cloud computing costs and software licensing fees in the prior year in connection with the strategic deprioritization of our gene therapy portfolio.

Loss on Impairment of Assets. The $5.5 million decrease was primarily in connection with the strategic deprioritization of our gene therapy portfolio in the prior year, which resulted in us recognizing a loss on impairment of assets.

Interest Expense. The $11.3 million increase was due to a higher variable interest rate on debt period over period.

Other (Expense) Income. The $35.8 million variance was primarily related to movement in foreign exchange rates caused by remeasurement of foreign-denominated balances.

Income Tax Benefit. We are subject to income taxes in various jurisdictions. The income tax benefit was primarily due to the recognition of tax benefit in connection with a partial release of a valuation allowance on deferred tax assets resulting from the reclassification of in-process research and development to a definite-lived intangible asset.

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, product revenues, debt issuance, collaborations, and other financing arrangements.

Sources of Liquidity

In November 2022, we entered into a Sales Agreement with The Goldman Sachs & Co. LLC to create an at-the-market equity program ("ATM program"), pursuant to which we may offer to sell shares of our common stock having an aggregate offering gross proceeds of up to $250.0 million. During the three and nine months ended September 30, 2023, we issued and sold an aggregate of 3,002,354 and 5,244,936 shares through our ATM program at a weighted-average public offering price of $12.68 and $12.50 per share, resulting in net proceeds of $36.6 million and $63.1 million, respectively. As of September 30, 2023, an aggregate of $184.4 million worth of shares remain available to be issued and sold under the ATM program.

In October 2023, we entered into the Senior Secured Term Loan due 2029. This transaction resulted in net proceeds of $387.4 million, after deducting fees and estimated expenses. There were no warrants or equity conversion features associated with the Senior Secured Term Loan due 2029. Simultaneously, we also entered into a securities purchase agreement with funds managed by Blackstone, for the private placement of an aggregate of 2,467,104 shares of our common stock, at a purchase price of $12.16 per share. Proceeds from the private placement, net of offering costs, were $29.8 million. We used proceeds from the Senior Secured Term Loan due 2029 and the private placement to prepay the Senior Secured Term Loan due 2026, inclusive of the outstanding principal amount, accrued interest and prepayment premium. The remaining proceeds will be used to fund ongoing operations.

Cash Flow Discussion

As of September 30, 2023, we had cash, cash equivalents, and marketable securities of $280.3 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 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 4. Cash, Cash Equivalents, Marketable Securities, and Restricted Cash," in our Notes to Consolidated Financial Statements.

Net Cash Used in Operating Activities

Net cash used in operations for the nine months ended September 30, 2023 was $72.5 million. The components of net cash used in operations included the net loss for the nine months ended September 30, 2023 of $117.7 million offset by $68.0 million of stock compensation, $25.9 million of other non-cash adjustments, and a net increase in changes in operating assets and liabilities of $48.7 million. The changes in operating assets and liabilities were primarily due to an increase in inventory of $42.2 million and an increase in prepaid expenses and other current assets of $26.0 million, partially offset by an increase in accounts payable and accrued expenses of $41.1 million associated with Pombiliti™ + Opfolda™ launch activities and increases in sales rebates associated with increased commercial sales of Galafold®.

Net cash used in operations for the nine months ended September 30, 2022 was $85.8 million. The components of net cash used in operations included the net loss for the nine months ended September 30, 2022 of $180.7 million offset by $57.9 million of stock compensation, $25.6 million of other non-cash adjustments, and a net increase in changes in operating assets and liabilities of $11.4 million. The changes in operating assets and liabilities were primarily due to an increase in accounts payable and accrued expenses of $25.5 million associated with the strategic deprioritization of our gene therapy portfolio resulting in the non-recurring expense of contractual obligations from which we will no longer receive further economic benefit, as well as tax accruals and sales rebates, 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 $7.4 million due to increased commercial sales of Galafold®.

Net Cash Provided by Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2023 was $122.0 million. Our investing activities have consisted primarily of purchases, sales, and maturities of investments and capital expenditures. Net cash provided by investing activities reflects $180.8 million for the sale and redemption of marketable securities, partially offset by $53.1 million for the purchase of marketable securities and $5.7 million for capital expenditures.

Net cash provided by investing activities for the nine months ended September 30, 2022 was $159.0 million. Our investing activities have consisted primarily of purchases, sales and maturities of investments and capital expenditures. Net cash provided by investing activities reflects $259.9 million for the sale and redemption of marketable securities, partially offset by $99.8 million for the purchase of marketable securities and $1.1 million for capital expenditures.

Net Cash Provided by (Used in) Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2023 was $53.5 million. Net cash provided by financing activities primarily reflects $63.1 million of proceeds from the issuance of shares in connection with the ATM program offering, net of issuance costs, and $7.8 million of proceeds from the exercise of stock options, partially offset by the withholding taxes paid on vested restricted stock units of $16.4 million.

Net cash used in financing activities for the nine months ended September 30, 2022 was $8.0 million. Net cash used in financing activities primarily reflects the withholding taxes paid on vested restricted stock units of $11.1 million, partially offset by $3.2 million of proceeds from the exercise of stock options.

Funding Requirements

We expect to continue to incur significant costs in 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 clinical trials for our drug candidates;
- the cost of manufacturing drug supply for our commercial, clinical and preclinical studies, including the cost of manufacturing Pombiliti™ (also referred to as "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;
- any changes in regulatory standards relating to the review of our product candidates;
- the number and development requirements of other product candidates that we pursue;
- the costs of commercialization activities, including product marketing, sales, and distribution;
- the emergence of competing technologies and other adverse market developments;
- the estimates regarding the potential market opportunity for our products and product candidates;
- our ability to successfully commercialize Galafold® (also referred to as "migalastat HCl");
- our ability to successfully commercialize Pombiliti™ and Opfolda™ (together, also referred to as "AT-GAA") in the E.U., U.K., and U.S., and elsewhere, if regulatory applications are approved;
- our ability to manufacture or supply sufficient clinical or commercial products, including Galafold®, Pombiliti™ and Opfolda™;
- our ability to obtain reimbursement for Galafold®, Pombiliti™ and Opfolda™;
- our ability to satisfy post-marketing commitments or requirements for continued regulatory approval of Galafold®, Pombiliti™ and Opfolda™;
- our ability to obtain market acceptance of Galafold®, Pombiliti™ and Opfolda™;
- 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, including Hatch-Waxman litigation;
- 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 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.

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 for at least the next 12 months. Potential impacts of business development collaborations, pipeline expansion, and investment in manufacturing capabilities could impact our future capital requirements.

Critical Accounting Policies and Significant Judgments

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

There were no significant changes during the nine months ended September 30, 2023 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, 2022.

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

Effective July 1, 2023, we transitioned the reference rate used in our Senior Secured Term Loan due 2026 from LIBOR to Adjusted Term Secured Overnight Financing Rate ("SOFR"), a forward-looking term rate based on SOFR, plus a credit spread adjustment of 0.26%. As a result, our variable-rate debt is now exclusively indexed to Adjusted Term SOFR, including the new Senior Secured Term Loan due 2029 agreement entered on October 2, 2023 (see "—Note 6. Debt" for further details). We continue to believe a hypothetical 100 basis point increase or decrease in the interest rate on our variable-rate debt would result in $1.0 million change in quarterly interest expense as of September 30, 2023.

We used proceeds from the Senior Secured Term Loan due 2029 and the private placement to prepay the Senior Secured Term Loan due 2026, inclusive of the outstanding principal amount, accrued interest and prepayment premium.

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, 2022. As of September 30, 2023, except as discussed above, there have been no material changes to our market risks or to our management of such risks since December 31, 2022.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure 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

In the fourth quarter of 2022, the Company received Paragraph IV Certification Notice Letters from Teva Pharmaceuticals USA, Inc. ("Teva"), Aurobindo Pharma Limited ("Aurobindo"), and Lupin Limited ("Lupin") in connection with Abbreviated New Drug Applications ("ANDA") filed with the FDA requesting approval to market generic Galafold®. In November 2022, the Company filed four lawsuits against Teva, Lupin, and Aurobindo in the U.S. District Court for the District of Delaware for infringement of its Orange Book-listed patents and will vigorously enforce its Galafold® intellectual property rights.

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, 2022.

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 September 30, 2023:

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
July 1, 2023 through July 31, 2023	53,583	$ 13.40	—	—
August 1, 2023 through August 31, 2023	123,214	$ 12.79	—	—
September 1, 2023 through September 30, 2023	24,701	$ 13.07	—	—
Total	201,498	$ 12.99	—	—

[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

Rule 10b5-1 Trading Plans

The following table describes, for the quarterly period covered by this report, each director and officer (as defined in Rule 16a-1(f) under the Exchange Act who has adopted, modified, or terminated a trading plan intended to satisfy the affirmative defense of Rule 10b5-1(c) under the Exchange Act (each plan, a "Rule 10b5-1 Trading Plan"). Each Rule 10b5-1 Trading Plan described below was adopted during an open insider trading window and in accordance with the Company's policies regarding both insider trading and transactions relating to Company securities.

Name (Title)	Action Taken (Date of Action)	Rule 10b5-1 Trading Plan Provides for Purchase/Sale	Duration of the Trading Plan[1]	Aggregate Number of Securities
Bradley Campbell (President and Chief Executive Officer)	Adoption (August 23, 2023)	Sale	December 31, 2024	Indeterminable [2]
Jeffrey Castelli (Chief Development Officer)	Adoption (August 25, 2023)	Sale	May 15, 2024	52,264
David Clark (Chief People Officer)	Adoption (August 25, 2023)	Sale	August 15, 2024	Indeterminable [3]
John F. Crowley (Executive Chairman)	Adoption (September 6, 2023)	Sale	April 15, 2024	Indeterminable [3]
Ellen Rosenberg (Chief Legal Officer and Corporate Secretary)	Adoption (September 8, 2023)	Sale	December 7, 2024	95,000

[1] The dates in this column represent the scheduled expiration date of each director or officer's Rule 10b5-1 Trading Plan. Each Rule 10b5-1 Trading Plan may terminate earlier than the date provided should all transactions contemplated thereunder occur prior to such date.

[2] Mr. Campbell's Rule 10b5-1 Trading Plan provides for the (i) exercise of up to 190,000 stock options and the sale of up to 190,000 underlying shares of common stock and (ii) sale of an indeterminable number of shares of common stock. The shares of common stock in clause (ii) will be obtained from the settlement of Mr. Campbell's 2021 performance restricted stock unit ("PRSU") awards. The number of shares of common stock obtained and available for sale will be subject to the (a) level of achievement of each performance goal contained within the 2021 PRSU awards and (b) shares of common stock withheld to satisfy applicable tax withholding obligations.

[3] The shares of common stock to be sold under this Rule 10b5-1 Trading Plan will be obtained from the settlement of the 2021 PRSU awards and the respective vesting of the 2020, 2021, 2022 and 2023 annual restricted stock unit awards. The number of shares of common stock obtained and available for sale will be subject to the (i) level of achievement of each performance goal contained within the 2021 PRSU awards and (ii) shares of common stock withheld to satisfy applicable tax withholding obligations.

ITEM 6. EXHIBITS

Exhibit Number	Description
10.1	Loan Agreement, dated October 2, 2023 by and among Amicus Therapeutics, Inc., certain subsidiaries of Amicus Therapeutics, Inc. from time to time party thereto as Guarantors, Blackstone Alternative Credit Advisors LP, Blackstone Life Sciences Advisors L.L.C., certain lenders from time to time party thereto and Wilmington Trust, National Association, as Agent for the lenders (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 2, 2023)
10.2	Securities Purchase Agreement, dated October 2, 2023, by and among Amicus Therapeutics, Inc. and the Purchasers identified on the signature pages thereto (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on October 2, 2023)
10.3	Employment Agreement, dated August 21, 2023, by and between Amicus Therapeutics, Inc. and Simon Harford
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: November 8, 2023

By: /s/ Bradley L. Campbell
Bradley L. Campbell
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 8, 2023

By: /s/ Simon Harford
Simon Harford
Chief Financial Officer
(Principal Financial Officer)

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT (this "Agreement"), dated as of August 21, 2023 (the "Effective Date"), between AMICUS THERAPEUTICS, INC., a Delaware corporation having an office at 3675 Market Street, Philadelphia, PA 19104 (the "Company"), and Simon Harford, ("Employee") (together, the "parties").

WHEREAS, the Company wishes to continue to employ Employee, and Employee wishes to continue to be employed by Company, on the terms and conditions set forth herein;

NOW, THEREFORE, in consideration of the mutual covenants contained herein, and for other good and valuable consideration, the sufficiency and receipt whereof is hereby acknowledged, the parties agree as follows:

Section 1. Definitions. Unless otherwise defined herein, the following terms shall have the following respective meanings:

"Accrued Amounts" means, as of the termination of Employee's employment:
(a) the total of any expenses properly incurred by Employee under Section 3.4(b) that have not previously been reimbursed as of the effective date of the termination; (b) the sum of Employee's accrued, but unused, vacation time, if any, as of the effective date of the termination; and (c) any accrued and unpaid Base Salary through and including the effective date of Employee's termination.

"Affiliate" shall mean any other company, directly or indirectly, controlling, controlled by or under common control with the Company.

"Cause" means Employee's: (i) willful or deliberate misconduct that has or could reasonably be expected to have a materially adverse impact on the reputation or business of the Company (or an Affiliate), or that results in gain or personal enrichment of Employee to the detriment of the Company (or an Affiliate); (ii) violation of Company policy including, but not limited to, policies prohibiting harassment and other workplace misconduct, and policies governing corporate compliance; (iii) misappropriation of the funds or assets of the Company (or an Affiliate); (iv) conviction, plea of guilty, admission to facts sufficient for a finding of guilt, or plea of no contest (or nolo contendere) to: (a) any felony, or (b) any misdemeanor involving fraud, theft, dishonesty, wrongful taking of property, embezzlement, bribery, forgery or extortion; (v) material breach of this Agreement; (vi) material breach of the Confidentiality, Non- Disclosure and Non-Competition Agreement attached as Exhibit A; (vii) breach of Employee's duty of loyalty to the Company; (viii) disqualification, bar or suspension by any governmental authority from performing any of the duties contemplated by this Agreement; (ix) material failure to perform Employee's duties or obligations hereunder (other than as a result of being Unable to Work); or (x) willful failure to adhere to or carry out lawful duties or directives of the Company's Chief Executive Officer ("CEO") or Board of Directors ("Board"). Notwithstanding anything to the contrary herein, the Company shall not be deemed to have terminated Employee for Cause for the events described above in subsections (ix) or (x) unless the CEO or Board, as applicable, has determined that such events are amenable to cure and given Employee written notice of the occurrence of the claimed event(s) constituting Cause and Employee has failed to

cure such event(s) within fourteen (14) calendar days after Employee's receipt of such notice (or such other period as may be deemed reasonable by the CEO or Board under the circumstances and communicated to Employee). The other events described above are not subject to an opportunity to cure but the Company may, in its sole discretion, conduct an investigation into those events and provide the employee a full opportunity to participate.

"Change in Control Event" means any of the following: (i) when any person or entity who is not currently a stockholder of the Company (as of the date of this Agreement) becomes the beneficial owner of greater than 50% of the then-outstanding voting power of the Company;
(ii) when a merger or consolidation with another entity occurs that causes the voting securities of the Company outstanding immediately before the transaction to constitute less than a majority of the voting power of the voting securities of the Company or the surviving entity outstanding immediately after the transaction; or (iii) when a sale or disposition of all or substantially all of the Company's assets occurs. Notwithstanding the foregoing, no event shall be deemed to be a Change in Control Event unless such event would also be a Change in Control under Section 409A and the rules and regulations promulgated thereunder (collectively, "Section 409") of the Internal Revenue Code of 1986, as amended (the "Code") or would otherwise be a permitted distribution event under Section 409A.

"Change in Control Severance Benefits" means: (i) payment of an amount equal to one and one-half (1.5) times Employee's then current Base Salary, payable in installments over eighteen (18) months, commencing within sixty (60) calendar days after the resignation or termination (collectively, "termination') of Employee's employment with the Company, in accordance with the Company's customary payroll practices for its senior management personnel; (ii) payment of an amount equal to 100% of the target Bonus for the calendar year in which such termination occurs (such amount being payable in a lump sum), payable within seventy five (75) calendar days following such termination ; (iii) the accelerated vesting of stock options held by Employee immediately prior to such termination ("Options"), such that all Options will become vested as of the date of Employee's termination; (iv) the accelerated vesting of restricted stock grants held by Employee immediately prior to such termination ("Grants"), such that all Grants will become vested as of the date of Employee's termination; (v) the accelerated vesting of performance restricted stock units held by Employee immediately prior to such termination at the applicable performance targets or such greater amounts as determined by the Board of Directors in their sole discretion; and (vi) in the event that Employee is enrolled in any of the Company's group health benefits plans as of the effective date of Employee's termination, then Employee and Employee's eligible dependents, if any, shall remain eligible to continue their participation in such plans for a period of eighteen (18) months after Employee's date of termination, subject to the eligibility and other terms and conditions of such plans, except that the Company will pay the full premiums otherwise payable for such coverage during such 18 month period. Notwithstanding any other provision of this Agreement, Employee's receipt of Change in Control Severance Benefits is conditioned on Employee's execution and delivery to the Company of a separation agreement (that Employee does not revoke) containing a general release, the form and substance of which are acceptable to the Company.

Employee's Initials SH

"Good Reason" means the occurrence of one or both of the following events without Employee's consent: (i) the Company's material diminution of Employee's authority, duties, or responsibilities as set forth in this Agreement; or (ii) the Company's change in the principal geographic location at which Employee provides services to the Company to a location more than thirty (30) miles from Employee's assigned primary office location, unless such relocation is only temporary, for a reasonable period of time, or unless such relocation merely constitutes travel reasonably required in connection with the performance of Employee's duties.
Notwithstanding anything to the contrary herein, Employee shall not be deemed to have resigned for Good Reason unless: (a) Employee had provided to the Company written notice within thirty
(30) calendar days of the occurrence of the claimed event(s) constituting Good Reason, specifying in detail the basis for such Good Reason; (b) the Company fails to cure the Good Reason within thirty (30) calendar days after its receipt of such notice, and (c) Employee terminates employment within sixty (60) calendar days after providing notice to Company of the claimed event(s) constituting Good Reason.

"Severance Benefits" means (i) payment of an amount equal to Employee's then current Base Salary, payable in installments over twelve (12) months, commencing within sixty (60) calendar days of the termination of Employee's employment with the Company, in accordance with the Company's customary payroll practices then in effect for its senior management personnel; (ii) payment of a bonus equal to 100% of the target Bonus for the calendar year in which such termination occurs pro-rated for the number of days actually worked in the year of termination, payable within seventy five (75) calendar days following such termination; (iii) the accelerated vesting of the Options, such that the portion of the Options that was otherwise scheduled to vest during the twelve (12) month period immediately following such termination (had Employee remained employed with the Company for that period) will become vested as of the date of Employee's termination; (iv) the accelerated vesting of RSUs, such that the portion of RSUs that was otherwise scheduled to vest during the twelve (12) month period immediately following such termination (had Employee remained employed with the Company for that period) will become vested as of the date of Employee's termination; (v) the accelerated vesting of PRSUs, such that the portion of PRSUs that was otherwise scheduled to vest during the twelve month period immediately following such termination (had Employee remained employed with the Company for that period) will become vested as of the date of Employee's termination; and (vi)in the event that Employee is enrolled in any of the Company's group health benefits plans as of the effective date of Employee's termination, then Employee and Employee's eligible dependents, if any, shall remain eligible to continue their participation in such plans for a period of twelve (12) months after Employee's date of termination, subject to the eligibility and other terms and conditions of such plans, except that the Company will pay the full premiums otherwise payable for such coverage during such 12 month period. Notwithstanding any other provision of this Agreement, Employee's receipt of Severance Benefits is conditioned on Employee's execution and delivery to the Company of a separation agreement (that Employee does not revoke) containing a general release, the form and substance of which are acceptable to the Company.

"Unable to Work" means the determination by the Company, following an interactive process, that Employee has become physically or mentally incapable of performing Employee's essential job functions, with or without a reasonable accommodation, following any period during which such status would be protected under applicable law.

Employee's Initials SH

Section 2. Employment.

2.1 Duties and Responsibilities. Subject to the terms and conditions of this Agreement, Employee will be employed by the Company as Chief Financial Officer or in such other position as may be mutually agreed upon by the parties. A Job Description setting forth Employee's duties and responsibilities is attached as Exhibit C. Employee accepts such employment and agrees to perform all of the duties and accept all of the responsibilities accompanying such position. Employee agrees to serve the Company faithfully and to the best of Employee's abilities, and to devote all of Employee's business time, skill and attention to such service. Employee is to be based remotely and is expected to work from an Amicus office at a minimum of 2 days per week and as needed for business at the Company's New Jersey, and Philadelphia, Pennsylvania, locations, or such other Company locations as needed including, but not limited to, the Company's international offices.

2.2 Full Time and Attention. Employee shall devote Employee's full business time and best efforts to the performance of Employee's duties and to the furtherance of the Company's interests. During Employee's employment with the Company, Employee may not hold another position of employment, or be retained as a consultant, or engage in any other business activity (whether full-time or part-time, whether or not for compensation), unless the Company gives Employee prior written permission to do so. Notwithstanding anything stated in this provision to the contrary, Employee is permitted to engage in charitable activities, as long as they do not interfere with Employee's employment obligations to the Company.

2.3 Company Policies. During Employee's employment with the Company, Employee will be subject to all applicable employment and other policies of the Company, as outlined in the Amicus Employee Handbook and as otherwise published by the Company in writing.

Section 3. Compensation and Benefits.

3.1 Base Salary. During Employee's employment, the Company shall pay Employee a salary at the gross annual rate of $500,000 (less applicable withholding) or such greater amount as the Board or a committee thereof may from time to time establish pursuant to the terms hereof (the "Base Salary"). Such Base Salary shall *be* reviewed annually and may be increased, but not decreased, by the Board or a committee thereof in its sole discretion. The Base Salary shall be payable in accordance with the Company's customary payroll practices for its senior management personnel.

3.2 Bonus. During Employee's employment, Employee shall be eligible to participate in the Company's bonus programs as may be in effect with respect to senior management personnel. Employee shall be eligible to earn an annual target bonus of 100% of the Base Salary in cash (the "Bonus") such actual amount determined by the Company Compensation Committee in its absolute discretion and at 45% of base salary; provided, however, that notwithstanding anything to the contrary herein or in any bonus program, Employee must be employed by the Company as of December 31 of the applicable calendar year, in order to be eligible to earn a Bonus for such calendar year. Any Bonus payment to which Employee becomes entitled hereunder shall be paid to Employee in a lump sum (less applicable withholding) on or before the 15th day of the third month following the end of the calendar year in which the Bonus was earned.

3.3 Equity. Subject to the terms and conditions of the Company's Amended and Restated 2007 Equity Incentive Plan and such other equity plans as the Company may adopt from time to time including, but not limited to, an Employee Stock Purchase Plan, during Employee's employment with the Company, Employee will be eligible to receive stock options,

Restricted Stock Units and Performance Restricted Stock Units pursuant to any Award Agreement (as that term is defined in the Company's Equity Incentive Plan) between Employee and the Company. Unless otherwise provided in this Agreement, the terms and conditions of the applicable equity plan will govern all equity grants to Employee (including vesting of options and units), including with regard to the impact of the end of Employee's employment on such equity grants.

3.4 Benefits.

(a) Benefit Plans. During Employee's employment, Employee may participate in any benefit plans (including health and medical insurance) as may be in effect with respect to senior management personnel of the Company, including any equity plan, subject to the eligibility and contribution requirements, enrollment criteria and other terms and conditions of such plans. The Company reserves the right to modify, amend and eliminate any such plans, in its sole and absolute discretion.

(b) Reimbursement of Expenses. During Employee's employment, the Company shall pay or promptly reimburse Employee, upon submission of proper invoices or other documentation in accordance with the Company's policies and procedures, for all reasonable out-of-pocket business, entertainment and travel expenses incurred by Employee in the performance of Employee's duties. Any taxable reimbursement of business or other expenses as specified under this Agreement shall be subject to the following conditions: (i) the expenses eligible for reimbursement in one taxable year shall not affect the expenses eligible for reimbursement in any other taxable year; (ii) the reimbursement of an eligible expense shall be made no later than the end of the calendar year after the year in which such expense was incurred; and (iii) the right to reimbursement shall not be subject to liquidation or exchange for another benefit.

(c) Vacation. During Employee's employment, Employee shall be entitled to vacation in accordance with the policies of the Company applicable to senior management personnel as may be in effect from time to time.

(d) Withholding. The Company shall withhold from all amounts payable or benefits accorded to Employee all federal, state and local income, employment and other taxes, as and in such amounts as may be required by applicable law.

Section 4. Duration of Employment. Employee's employment with the Company shall begin on the Effective Date and continue until Employee's employment is terminated by either Employee or the Company. At all times, Employee's employment with the Company shall be "at-will," meaning that either Employee or the Company may terminate the employment at any time, for no reason or any lawful reason.

Section 5. Termination; Severance Benefits.

5.1 Notice of Termination. Any termination of Employee's employment by the Company or by Employee (other than on account of death) shall be communicated to the other party by written notice that indicates the specific termination provision in this Agreement relied upon. Except as otherwise expressly provided in this Agreement or the notice, the termination shall take effect immediately. The parties agree that the notice requirements set forth in this Agreement do not alter the "at will" nature of Employee's employment, as described in Section 4.

5.2 Generally. Upon termination of Employee's employment for any reason, Employee shall be deemed simultaneously to have resigned as a member of the Board, if applicable, and from any other position or office Employee may at the time hold with the Company or any of its Affiliates. Employee agrees to cooperate with the Company by signing

any necessary documents and taking any other steps necessary to effectuate Employee's resignation from the Board, if applicable, and from any other position or office Employee may hold with the Company or any of its Affiliates. In addition, upon termination of Employee's employment for any reason, the Company shall pay Employee the Accrued Amounts. The Accrued Amounts will be paid within the time required by applicable law. The impact of the termination of Employee's employment on the Employee's participation in the Company's health plans is addressed in Section 5.3 and Section 5.4.

5.3 Termination by Employee.

(a) Resignation Independent of a Change in Control Event. If Employee resigns and a Change in Control Event has not occurred in the prior 12 months, then (irrespective of whether the resignation was with or without Good Reason): (i) Employee shall receive no further compensation or remuneration of any kind other than the Accrued Amounts; and (ii) at the end of the month in which the resignation takes effect, Employee shall cease to be covered under or permitted to participate in or receive any of the benefits described in Section 3.4, except that, if Employee is enrolled and participating in the Company's health benefit plans at the time of termination, the Company will allow Employee to continue as a member of those plans at Employee's expense in accordance with the terms of those plans and the Consolidated Omnibus Budget Reconciliation Act (COBRA) for the legally required benefit continuation period.

(b) Good Reason Resignation Within 12 Months of a Change in Control Event. If Employee resigns for Good Reason within twelve (12) months after a Change in Control Event, Employee will be entitled to receive, in addition to the Accrued Amounts, Change in Control Severance Benefits. All payments and benefits under this section, except for the Accrued Amounts, shall: (1) require Employee to execute and return (and not revoke) a separation agreement containing a general release, the form and substance of which are acceptable to the Company; and (2) be subject to Section 5.6 and Section 5.7(b).

5.4 Termination by the Company.

(a) Without Cause Within 12 Months After a Change in Control Event. If the Company terminates Employee's employment without Cause within 12 months after a Change in Control Event, then in lieu of any other payments, rights or benefits under Section 5.4(a). Employee will be entitled to receive Change in Control Severance Benefits in addition to the Accrued Amounts. All payments and benefits under this section, except for the Accrued Amounts, shall: (1) require Employee to execute and return (and not revoke) a separation agreement containing a general release, the form and substance of which are acceptable to the Company; and (2) be subject to Section 5.6 and Section 5.7(b).

(b) Without Cause Not Within 12 Months After a Change in Control Event. If the Company terminates Employee's employment without Cause (other than within 12 months after a Change in Control Event), then Employee will be entitled to receive Severance Benefits in addition to the Accrued Amounts. All payments and benefits under this section, except for the Accrued Amounts, shall: (1) require Employee to execute and return (and not revoke) a separation agreement containing a general release, the form and substance of which are acceptable to the Company; and (2) be subject to Section 5.6 and Section 5.7(b).

(c) For Cause. If the Company terminates Employee's employment for Cause at any time, Employee shall: (i) receive no further compensation or remuneration of any kind (including any Base Salary or Bonus hereunder) other than the Accrued Amounts; and (ii) at the end of the month in which the termination takes effect, cease to be covered under or be permitted to participate in or receive any of the benefits described in Section 3.4, except that, if Employee is enrolled and participating in the Company's health benefit plans at the time of termination, the Company will allow Employee to continue as a member of those plans at Employee's expense in accordance with the terms of those plans and the Consolidated Omnibus Budget Reconciliation Act (COBRA) for the legally required benefit continuation period.

5.5 Termination upon Death or Inability to Work.

(a) Death. Employee's employment shall terminate immediately upon Employee's death. In the event of Employee's death during the course of Employee's employment with the Company, the Company will pay the Employee's estate the Accrued Amounts.

(b) Inability to Work. Except as otherwise provided by applicable law, the Company may terminate Employee's employment in the event Employee is Unable to Work. In the event of Employee's death or termination by the Company due to Employee being Unable to Work, Employee shall receive: (a) the Accrued Amounts, and (b) in the event that Employee is enrolled in any of the Company's group health benefits plans as of the effective date of Employee's termination, then Employee and Employee's eligible dependents, if any, shall remain eligible to continue their participation in such plans for a period of twelve (12) months after Employee's date of termination, subject to the eligibility and other terms and conditions of such plans, except that the Company will pay the full premiums otherwise payable for such coverage during such 12 month period.

5.6 General Release and Compliance Required. Employee's receipt of any right, payment or benefit under Section 5.3(b) or Section 5.4(a) or Section 5.4(b) is subject to and conditioned upon: (a) Employee's execution and delivery to the Company of a separation agreement (that Employee does not revoke) containing a general release, the form and substance of which are acceptable to the Company; and (b) Employee's reaffirmation of and continuing compliance with Employee's contractual and legal obligations to the Company, as expressly set forth in the Confidentiality, Non-Disclosure and Non-Competition Agreement attached as Exhibit A.

5.7 Section 409A.

(a) Purpose. This section is intended to help ensure that compensation paid or delivered to Employee pursuant to this Agreement either is paid in compliance with, or is exempt from, IRC Section 409A. However, the Company does not warrant to Employee that all compensation paid or delivered to Employee for Employee's services will be exempt from, or paid in compliance with, Section 409A.

(b) Amounts Payable On Account of Termination. For the purposes of determining when amounts otherwise payable on account of Employee's termination of employment under this Agreement will be paid, which amounts become due because of Employee's termination of employment, "termination of employment" or words of similar import, as used in this Agreement, shall be construed as the date that Employee first incurs a "separation from service" for purposes of Section 409A on or following termination of employment. Furthermore, if Employee is a "specified employee" of a public company as determined pursuant to Section 409A as of Employee's termination of employment, any amounts payable on account of Employee's termination of employment that constitute deferred compensation within the meaning of Section 409A and that are otherwise payable during the first six months following Employee's termination (or prior to Employee's death after termination) shall be paid to Employee in a cash lump-sum on the earlier of (i) the date of Employee's death; or (ii) the first business day of the seventh calendar month immediately following the month in which Employee's termination occurs.

(c) Series of Payments. Any right to a series of installment payments shall be treated as a right to a series of separate payments.

(d) Interpretative Rules. In applying Section 409A to amounts paid pursuant to this Agreement, any right to a series of installment payments under this Agreement shall be treated as a right to a series of separate payments.

5.8 Participation in Other Severance Plans. Employee agrees and acknowledges that Employee shall not be eligible to participate in or have any right to compensation or benefits pursuant to the Company's Change in Control Severance Plan (or any successor plan thereto) or any other Severance Plan issued by the Company.

5.9 Exclusivity. In the event Employee's employment is terminated for any reason, Employee (and Employee's eligible dependents, if any) shall not be entitled to any payments or benefits from the Company or any of its Affiliates except as specifically set forth in this Section 5.

Section 6. Federal Excise Tax.

6.2 General Rule. Employee's payments and benefits under this Agreement and all other arrangements or programs related thereto shall not, in the aggregate, exceed the maximum amount that may be paid to Employee without triggering golden parachute penalties under Section 280G of the Code, and the provisions related thereto with respect to such payments. If Employee's benefits must be cut back to avoid triggering such penalties, such reduction shall be made in the following order: (i) first, any future cash payments (if any) shall be reduced (if necessary, to zero); (ii) second, any current cash payments shall be reduced (if necessary, to zero); (iii) third, all non-cash payments (other than equity or equity derivative related payments) shall be reduced (if necessary, to zero); and (iv) fourth, all equity or equity derivative payments shall be reduced. If an amount in excess of the limit set forth in this Section is paid to Employee, Employee must repay the excess amount to the Company upon demand, with interest at the rate provided in Section 1274(b)(2)(B) of the Code. Employee and the Company agree to cooperate with each other reasonably in connection with any administrative or judicial proceedings concerning the existence or amount of golden parachute penalties on payments or benefits Employee receives.

6.2 Exception. Section 6.1 shall apply only if it increases the net amount Employee would realize from payments and benefits subject to Section 6.1 after payment of income and excise taxes by Employee on such payments and benefits.

6.3 Determinations. The determination of whether the golden parachute penalties under Section 280G of the Code and the provisions related thereto shall be made by counsel chosen by Employee and reasonably acceptable to the Company. All other determinations needed to apply this Section 6 shall be made in good faith by the Company's independent auditors.

Section 7. Company Computers, Property and Records. Employee agrees to handle all Company property in accordance with the Company's policies and procedures. Employee's authorization to access the Company's computer systems is limited arid use of such systems to compete or prepare to compete with the Company constitutes unauthorized access that is strictly prohibited. All records received or created by Employee in the course of employment related to the Company's business (such as but not limited to, email, notes, files, contact lists, agendas, drawings, maps, specifications, and calendars) are the property of the Company.

Section 8. Resolution of Disputes. Employee and the Company hereby agree that, except for disputes regarding alleged or anticipated violations of the Confidentiality, Non- Disclosure and Non-Competition Agreement attached as Exhibit A, any and all disputes between them shall be resolved solely in accordance with the Mutual Agreement to Arbitrate Disputes on an Individual Basis attached as Exhibit B and, to the greatest extent permitted by law, Employee

and the Company expressly waive their respective right to a trial by jury for any and all such disputes between them.

Section 9. General.

9.1 No Conflict. Employee represents and warrants that Employee has not entered, nor will Employee enter, into any other agreements that restrict Employee's ability to fulfill Employee's obligations under this Agreement.

9.2 Governing Law. This Agreement shall be construed, interpreted and governed by the laws of the state of Employee's assigned primary office location during the last six months of Employee's employment with the Company, without regard to the conflicts of law principles.

9.3 Binding Effect. This Agreement shall extend to and be binding upon Employee, Employee's legal representatives, heirs and distributees and upon the Company, its successors and assigns regardless of any change in the business structure of the Company.

9.4 Assignment. The Company's rights and obligations under this Agreement, including the restrictions in the Confidentiality, Non-Disclosure and Non-Competition Agreement attached as Exhibit A, shall automatically transfer with any sale, transfer or other disposition of all or substantially all of its assets, stock or business. Employee consents to that transfer. Employee may not assign any rights or obligations under this Agreement without the Company's prior written consent.

9.5 Entire Agreement. This Agreement contains the entire agreement of the parties with respect to the subject matter hereof and supersedes all prior agreements, understandings, discussions, negotiations and undertakings, whether written or oral, between the parties with respect thereto, **including all Employee's prior Agreements,** except this Agreement does not supersede the Confidentiality, Non-Disclosure and Non-Competition Agreement attached as Exhibit A or the Mutual Agreement to Arbitrate Disputes on an Individual Basis attached as Exhibit B. Nor does this Agreement supersede any Award Agreement (as that term is defined in the Company's Equity Incentive Plan) between Employee and the Company. No waiver, modification or change of any provision of this Agreement shall be valid unless in writing and signed by both parties.

9.6 Waiver. The waiver of any breach of any duty, term or condition of this Agreement shall not be deemed to constitute a waiver of any preceding or succeeding breach of the same or any other duty, term or condition of this Agreement.

9.7 Severability. If any provision of this Agreement shall be unenforceable in any jurisdiction in accordance with its terms, the provision shall be enforceable to the fullest extent permitted in that jurisdiction and shall continue to be enforceable in accordance with its terms in any other jurisdiction and the validity, legality and enforceability of the remaining provisions contained herein shall not be affected thereby.

9.8 Notices. All notices pursuant to this Agreement shall be in writing and shall be sent by prepaid certified mail, return receipt requested or by recognized air courier service addressed as follows:

(i) If to the Company to:

Amicus Therapeutics, Inc. 3675 Market Street
Philadelphia, PA 19104
c/o CEO or General Counsel

(ii) If to Employee to:[NAME]

at the address identified herein or in Employee's personnel records,

or to such other addresses as may hereinafter be specified by notice in writing by either of the parties and shall be deemed given three (3) business days after the date so mailed or sent.

9.9 Compliance. If reasonably requested in writing, Employee agrees within fifteen (15) business days to provide the Company with an executed IRS Form 4669 (Statement of Payments Received) with respect to any taxable amount paid to Employee by the Company.

9.10 Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original but all of which shall together constitute one and the same agreement.

9.11 Knowing and Voluntary Nature of Agreement. Employee acknowledges and agrees that Employee is executing this Agreement knowingly and voluntarily and without any duress or undue influence by the Company or anyone else. Employee further acknowledges and agrees that Employee has carefully read this Agreement and fully understands it. Employee further agrees that Employee has been provided an opportunity to seek, and has received, the advice of an attorney of Employee's choice (at Employee's expense) before signing this Agreement.

[Signature Page Follows]

Employee's Initials SH

IN WITNESS WHEREOF, the parties have executed this Agreement on the date first above written.

/s/ David Clark
[NAME]
AMICUS THERAPEUTICS, INC.

By: David Clark

Name: David Clark

Title: Chief People Officer

EMPLOYEE

/s/ Simon Harford
SIMON HARFORD

Employee's Initials SH

Attachments to Loan Agreement
Omitted pursuant to Regulation S-K Item *601(a)(5)*

1. Exhibit A – Confidentiality, Non- Disclosure and Non-Competition Agreement

2. Exhibit B – Mutual Agreement to Arbitrate Disputes on an Individual Basis

3. Exhibit C – Job Description

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: November 8, 2023

/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, Simon Harford, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 8, 2023

/s/ Simon Harford
Simon Harford
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 September 30, 2023, fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. 78m or 78o(d)) and that the information contained in such report fairly presents, in all material respects, the financial condition and results of operations of the Company. This written statement is being furnished to the Securities and Exchange Commission as an exhibit to such Form 10-Q. A signed original of this statement has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Date: November 8, 2023 By: /s/ Bradley L. Campbell
Bradley L. Campbell
President and Chief Executive Officer

Date: November 8, 2023 By: /s/ Simon Harford
Simon Harford
Chief Financial Officer