# UNITED STATES
# SECURITIES AND EXCHANGE COMMISSION

**Washington, D.C. 20549**

# FORM 10-Q

**(Mark One)**

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

**For the quarterly period ended June 30, 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) |
| **3675 Market Street, Philadelphia, PA** | **19104** |
| (Address of Principal Executive Offices) | (Zip Code) |

**(215) 921-7600**

(Registrant's Telephone Number, Including Area Code)

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

| Title of each class | Trading Symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common Stock, par value $0.01 per share | FOLD | NASDAQ Global Market |

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

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

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

| | | | |
|---|---|---|---|
| Large accelerated filer | ☒ | Accelerated filer | ☐ |
| Non-accelerated filer | ☐ | Smaller reporting company | ☐ |
| | | Emerging growth company | ☐ |

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

The number of shares outstanding of the registrant's common stock, $0.01 par value per share, as of July 26, 2023 was 287,120,937 shares.

AMICUS THERAPEUTICS, INC.

Form 10-Q for the Quarterly Period Ended June 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 Pompe Enzyme Replacement Therapy ("ERT" or "ATB200" or "cipaglucosidase alfa");
- the future results of preclinical research and subsequent clinical trials for pipeline candidates we may identify from time to time, including our ability to obtain regulatory approvals and commercialize these therapies and obtain market acceptance for such therapies;
- the costs, timing, and outcome of regulatory review of our product candidates, including AT-GAA;
- any changes in regulatory standards relating to the review of our product candidates, including AT-GAA;
- the number and development requirements of other product candidates that we pursue;
- the costs of commercialization activities, including product marketing, sales, and distribution;
- the emergence of competing technologies and other adverse market developments;
- the estimates regarding the potential market opportunity for our product and product candidates, including AT-GAA;
- our ability to successfully commercialize Galafold® (also referred to as "migalastat HCl");
- our ability to successfully commercialize Pombiliti™ and Opfolda™ (also referred to as AT-GAA) in the E.U., and elsewhere, if our regulatory applications for AT-GAA 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®;
- our ability to obtain reimbursement for Pombiliti™ and Opfolda™ in the E.U., and elsewhere, if our regulatory applications for AT-GAA are approved;
- our ability to satisfy post-marketing commitments or requirements for continued regulatory approval of Galafold®;
- our ability to satisfy post-marketing commitments or requirements for continued regulatory approval of Pombiliti™ and Opfolda™ in the E.U., and elsewhere, if our regulatory applications for AT-GAA are approved;
- our ability to obtain market acceptance of Galafold® and, if our regulatory applications are approved, AT-GAA;
- our ability to obtain market acceptance of Pombiliti™ and Opfolda™ in the E.U., and elsewhere, if our regulatory applications for AT-GAA are approved;
- 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 extent to which our business could be adversely impacted by the effects of the novel coronavirus ("COVID-19") outbreak, including actions by us, governments, our customers, our suppliers, or other third parties to control the spread of COVID-19, or by other health epidemics or pandemics;
- the costs associated with, and our ability to comply with, emerging environmental, social and governance standards;
- our ability to accurately forecast revenue, operating expenditures, or other metrics impacting profitability;
- fluctuations in foreign currency exchange rates; and
- changes in accounting standards.

In light of these risks and uncertainties, we may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions, and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in Part I Item 1A — Risk Factors of the Annual Report on Form 10-K for the fiscal year ended December 31, 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)**

| | June 30, 2023 | December 31, 2022 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 211,307 | $ 148,813 |
| Investments in marketable securities | 54,319 | 144,782 |
| Accounts receivable | 63,716 | 66,196 |
| Inventories | 51,381 | 23,816 |
| Prepaid expenses and other current assets | 52,099 | 40,209 |
| Total current assets | 432,822 | 423,816 |
| Operating lease right-of-use assets, net | 28,042 | 29,534 |
| Property and equipment, less accumulated depreciation of $24,060 and $22,281 at June 30, 2023 and December 31, 2022, respectively | 30,238 | 30,778 |
| Intangible assets, less accumulated amortization of $855 and $0 at June 30, 2023 and December 31, 2022, respectively | 22,145 | 23,000 |
| Goodwill | 197,797 | 197,797 |
| Other non-current assets | 19,049 | 19,242 |
| **Total Assets** | $ 730,093 | $ 724,167 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 13,522 | $ 15,413 |
| Accrued expenses and other current liabilities | 124,868 | 93,636 |
| Contingent consideration payable | 13,005 | 21,417 |
| Operating lease liabilities | 7,840 | 8,552 |
| Total current liabilities | 159,235 | 139,018 |
| Long-term debt | 393,350 | 391,990 |
| Operating lease liabilities | 50,976 | 51,578 |
| Deferred reimbursements | 5,906 | 4,656 |
| Deferred income taxes | — | 4,939 |
| Other non-current liabilities | 9,045 | 8,939 |
| Total liabilities | 618,512 | 601,120 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Common stock, $0.01 par value, 500,000,000 shares authorized, 286,992,923 and 281,108,273 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively | 2,856 | 2,815 |
| Additional paid-in capital | 2,733,148 | 2,664,744 |
| Accumulated other comprehensive gain (loss): | | |
| Foreign currency translation adjustment | 4,337 | (11,989) |
| Unrealized loss on available-for-sale securities | (177) | (116) |
| Warrants | 71 | 83 |
| Accumulated deficit | (2,628,654) | (2,532,490) |
| Total stockholders' equity | 111,581 | 123,047 |
| **Total Liabilities and Stockholders' Equity** | $ 730,093 | $ 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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2023** | **2022** | **2023** | **2022** |
| Net product sales | $ 94,503 | $ 80,731 | $ 180,773 | $ 159,446 |
| Cost of goods sold | 9,114 | 8,197 | 16,056 | 15,779 |
| Gross profit | 85,389 | 72,534 | 164,717 | 143,667 |
| Operating expenses: | | | | |
| Research and development | 35,149 | 78,319 | 76,648 | 159,836 |
| Selling, general, and administrative | 65,423 | 53,379 | 139,380 | 111,495 |
| Changes in fair value of contingent consideration payable | 337 | 115 | 588 | (1,073) |
| Loss on impairment of assets | 1,134 | — | 1,134 | 6,616 |
| Depreciation and amortization | 2,206 | 1,334 | 3,463 | 2,745 |
| Total operating expenses | 104,249 | 133,147 | 221,213 | 279,619 |
| Loss from operations | (18,860) | (60,613) | (56,496) | (135,952) |
| Other (expense) income: | | | | |
| Interest income | 1,737 | 356 | 3,936 | 489 |
| Interest expense | (12,492) | (8,257) | (24,336) | (16,404) |
| Other (expense) income | (10,902) | 7,268 | (16,840) | 9,170 |
| Loss before income tax | (40,517) | (61,246) | (93,736) | (142,697) |
| Income tax expense | (2,715) | (911) | (2,428) | (4,720) |
| **Net loss attributable to common stockholders** | $ (43,232) | $ (62,157) | $ (96,164) | $ (147,417) |
| Net loss attributable to common stockholders per common share — basic and diluted | $ (0.15) | $ (0.21) | $ (0.33) | $ (0.51) |
| Weighted-average common shares outstanding — basic and diluted | 292,797,002 | 291,970,562 | 292,071,201 | 288,646,587 |

*See accompanying Notes to Consolidated Financial Statements*

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2023** | **2022** | **2023** | **2022** |
| Net loss | $ (43,232) | $ (62,157) | $ (96,164) | $ (147,417) |
| Other comprehensive gain (loss): | | | | |
| Foreign currency translation adjustment gain (loss) | 10,880 | (16,183) | 16,326 | (21,854) |
| Unrealized gain (loss) on available-for-sale securities | 24 | (29) | (61) | (367) |
| Other comprehensive gain (loss) | 10,904 | (16,212) | 16,265 | (22,221) |
| Comprehensive loss | $ (32,328) | $ (78,369) | $ (79,899) | $ (169,638) |

*See accompanying Notes to Consolidated Financial Statements*

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

**Three Months Ended June 30, 2023**

| | Common Stock | | Additional Paid-In Capital | Warrants | Other Comprehensive Gain (Loss) | Accumulated Deficit | Total Stockholders' Equity |
|---|---|---|---|---|---|---|---|
| | Shares | Amount | | | | | |
| Balance at March 31, 2023 | 283,300,585 | $ 2,820 | $ 2,691,836 | $ 83 | $ (6,744) | $ (2,585,422) | $ 102,573 |
| Stock options exercised, net | 269,109 | 4 | 1,746 | — | — | — | 1,750 |
| Vesting of restricted stock units, net of taxes | 155,776 | — | (1,202) | — | — | — | (1,202) |
| Stock-based compensation | — | — | 16,577 | — | — | — | 16,577 |
| Issuance of shares in connection with at-the-market offering, net of issuance costs | 2,047,353 | 20 | 24,179 | — | — | — | 24,199 |
| Warrants exercised | 1,220,100 | 12 | 12 | (12) | — | — | 12 |
| Unrealized gain on available-for-sale securities | — | — | — | — | 24 | — | 24 |
| Foreign currency translation adjustment | — | — | — | — | 10,880 | — | 10,880 |
| Net loss | — | — | — | — | — | (43,232) | (43,232) |
| Balance at June 30, 2023 | 286,992,923 | $ 2,856 | $ 2,733,148 | $ 71 | $ 4,160 | $ (2,628,654) | $ 111,581 |

**Six Months Ended June 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 | 653,217 | 7 | 4,398 | — | — | — | 4,405 |
| Vesting of restricted stock units, net of taxes | 1,768,751 | | (14,008) | — | — | — | (14,008) |
| Stock-based compensation | — | — | 51,471 | — | — | — | 51,471 |
| Warrants exercised | 1,220,100 | 12 | 12 | (12) | — | — | 12 |
| Issuance of shares in connection with at-the-market offering, net of issuance costs | 2,242,582 | 22 | 26,531 | — | — | — | 26,553 |
| Unrealized loss on available-for-sale securities | — | — | — | — | (61) | — | (61) |
| Foreign currency translation adjustment | — | — | — | — | 16,326 | — | 16,326 |
| Net loss | — | — | — | — | — | (96,164) | (96,164) |
| Balance at June 30, 2023 | 286,992,923 | $ 2,856 | $ 2,733,148 | $ 71 | $ 4,160 | $ (2,628,654) | $ 111,581 |

**Three Months Ended June 30, 2022**

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

**Six Months Ended June 30, 2022**

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

*See accompanying Notes to Consolidated Financial Statements*

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

| | Six Months Ended June 30, | |
|---|---|---|
| | **2023** | **2022** |
| **Operating activities** | | |
| Net loss | $ (96,164) | $ (147,417) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Amortization of debt discount and deferred financing | 1,359 | 1,295 |
| Depreciation and amortization | 3,463 | 2,745 |
| Stock-based compensation | 51,471 | 43,114 |
| Non-cash changes in the fair value of contingent consideration payable | 588 | (1,073) |
| Foreign currency remeasurement loss | 23,904 | 353 |
| Deferred taxes | (4,939) | — |
| Asset impairment charges and other asset write-offs | 2,060 | 12,265 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | 2,705 | (4,424) |
| Inventories | (27,483) | 3,537 |
| Prepaid expenses and other current assets | (12,263) | (4,481) |
| Accounts payable, accrued expenses, and other current liabilities | 31,620 | 22,671 |
| Other non-current assets and liabilities | (2,586) | (2,762) |
| Payment of contingent consideration | (7,937) | — |
| Net cash used in operating activities | $ (34,202) | $ (74,177) |
| **Investing activities** | | |
| Sale and redemption of marketable securities | 126,848 | 184,061 |
| Purchases of marketable securities | (36,448) | (98,330) |
| Capital expenditures | (4,144) | (1,226) |
| Net cash provided by investing activities | $ 86,256 | $ 84,505 |
| **Financing activities** | | |
| Payment of finance leases | (51) | (41) |
| Withholding taxes paid on vested restricted stock units | (14,008) | (9,278) |
| Proceeds from stock options exercised, net | 4,405 | 1,858 |
| Proceeds from warrants exercised, net | 12 | — |
| Proceeds from the issuance of shares in connection with at-the-market offering, net of issuance costs | 26,553 | — |
| Payment of contingent consideration | (1,063) | — |
| Net cash provided by (used in) financing activities | $ 15,848 | $ (7,461) |
| Effect of exchange rate changes on cash, cash equivalents, and restricted cash | $ (6,684) | $ (12,462) |
| **Net increase (decrease) in cash, cash equivalents, and restricted cash at the end of the period** | 61,218 | (9,595) |
| 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** | $ 214,333 | $ 239,861 |
| **Supplemental disclosures of cash flow information** | | |
| Cash paid during the period for interest | $ 23,155 | $ 15,108 |
| Cash paid for taxes | $ 5,978 | $ 710 |
| Capital expenditures unpaid at the end of period | $ 297 | $ 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 Pompe disease that has been approved in the European Union (“E.U.”) and the United Kingdom (“U.K.”), and is under regulatory review 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™ and Opfolda™ (also referred to as AT-GAA, ATB200/AT2221, or cipaglucosidase alfa/miglustat), is a novel, two-component treatment for Pompe disease that was approved by the European Commission ("EC") in June 2023 and the U.K. Medicines and Healthcare products Regulatory Agency ("MHRA") in August 2023. The Company began launch activities for Pombiliti™ and Opfolda™ in Germany and will commence the reimbursement processes with healthcare authorities in other European countries. In October 2022, the U.S. Food and Drug Administration ("FDA") deferred action on the BLA for cipaglucosidase alfa, citing the inability to complete the manufacturing site inspection prior to the PDUFA action date. In the second quarter of 2023, the FDA completed the required pre-approval inspection of the manufacturing site and the review is ongoing.

The Company continues to monitor the novel coronavirus (“COVID-19”) pandemic. The Company's commercial operations have not been significantly impacted by the COVID-19 pandemic and the Company continues to see a gradual improvement in patient identification and Galafold® initiation. The Company has been able to continue to meet required commercial demand for Galafold® as well as supply Pombiliti™ and Opfolda™ commercial launch inventory and its ongoing clinical studies and access programs without interruption. In regard to the Company's regulatory operations, the FDA deferred action on the pending BLA for cipaglucosidase alfa, as a site inspection could not be completed by the PDUFA action date due to COVID-19 related travel restrictions in China. In the second quarter of 2023, the FDA completed the required pre-approval inspection of the manufacturing site. Per FDA guidance relating to pre-approval inspections during the COVID-19 pandemic, receipt of a deferral action indicates no deficiencies have been identified and the application otherwise satisfies the requirements for approval.

The Company had an accumulated deficit of $2.6 billion as of June 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.

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 impacts of the COVID-19 pandemic, business development collaborations, pipeline expansion, and investment in manufacturing capabilities could impact the Company's future capital requirements.

**2. Summary of Significant Accounting Policies**

***Basis of Presentation***

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

The accompanying unaudited Consolidated Financial Statements and related notes should be read in conjunction with the Company's financial statements and related notes as contained in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 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.

Additionally, the Company assessed the impact the COVID-19 pandemic had on its operations and financial results as of June 30, 2023 and through the issuance of these financial statements. The Company’s analysis was informed by the facts and circumstances as they were known to the Company. This assessment considered the impact COVID-19 may have on financial estimates and assumptions that affect the reported amounts of assets and liabilities and revenue and expenses.

***Cash, Cash Equivalents, Marketable Securities, and Restricted Cash***

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

Restricted cash consists primarily of funds held to satisfy the requirements of certain agreements that are restricted in their use and is included in other 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 June 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 June 30, 2023, the Company's allowance for doubtful accounts was $0.1 million.

***Revenue Recognition***

The Company's net product sales consist primarily of sales of Galafold® for the treatment of Fabry disease. Galafold® sales for the three and six months ended June 30, 2023 were $94.3 million and $180.4 million, respectively, and $80.7 million and $159.4 million for the three and six months ended June 30, 2022, respectively. The Company has recorded revenue on sales where Galafold® is available either on a commercial basis or through a reimbursed early access program. Orders for Galafold® are generally received from distributors and pharmacies, with the ultimate payor often a government authority.

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

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| **(in thousands)** | **2023** | **2022** | **2023** | **2022** |
| U.S. | $ 37,128 | $ 27,540 | $ 65,959 | $ 51,718 |
| Ex-U.S. | 57,375 | 53,191 | 114,814 | 107,728 |
| Total net product sales | $ 94,503 | $ 80,731 | $ 180,773 | $ 159,446 |

***Inventories and Cost of Goods Sold***

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

***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 six months ended June 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 June 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 six months ended June 30, 2023 was $0.8 million and $0.9 million, respectively. Total estimated amortization for the finite-lived intangible assets is estimated to be $2.5 million for the year ended December 31, 2023 and $3.3 million for the next four years thereafter.

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

As of June 30, 2023, the Company held $211.3 million in cash and cash equivalents and $54.3 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 gain (loss) in the Company's Consolidated Statements of Comprehensive Loss. If a decline in the fair value of a marketable security below the Company's cost basis is determined to be other-than-temporary or if an available-for-sale debt security's fair value is determined to be less than the amortized cost and the Company intends or is more than likely to sell the security before recovery and it is not considered a credit loss such security is written down to its estimated fair value as a new cost basis and the amount of the write-down is included in earnings as an impairment charge. If the unrealized loss of an available-for-sale debt security is determined to be a result of credit loss, the Company would recognize an allowance and the corresponding credit loss would be included in earnings.

The Company regularly invests excess operating cash in deposits with major financial institutions 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 June 30, 2023 | | | |
|---|---|---|---|---|
| (in thousands) | Cost | Gross Unrealized Gain | Gross Unrealized Loss | Fair Value |
| Cash and cash equivalents | $ 211,307 | $ — | $ — | $ 211,307 |
| Commercial paper | 44,022 | 10 | (1) | 44,031 |
| U.S. government agency bonds | 9,875 | 12 | — | 9,887 |
| Money market | 350 | — | — | 350 |
| Certificates of deposit | 51 | — | — | 51 |
| | $ 265,605 | $ 22 | $ (1) | $ 265,626 |
| Included in cash and cash equivalents | $ 211,307 | $ — | $ — | $ 211,307 |
| Included in marketable securities | 54,298 | 22 | (1) | 54,319 |
| Total cash, cash equivalents, and marketable securities | $ 265,605 | $ 22 | $ (1) | $ 265,626 |

| | 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 six months ended June 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 June 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 gain (loss). The fair value of these marketable securities in unrealized loss positions was $3.0 million as of June 30, 2023. The Company had no securities in an unrealized loss position as of 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 June 30, | |
|---|---|---|
| (in thousands) | 2023 | 2022 |
| Cash and cash equivalents | $ 211,307 | $ 235,639 |
| Restricted cash | 3,026 | 4,222 |
| Cash, cash equivalents, and restricted cash shown in the Consolidated Statements of Cash Flows | $ 214,333 | $ 239,861 |

## 5. Inventories

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

| (in thousands) | June 30, 2023 | December 31, 2022 |
|---|---|---|
| Raw materials | $ 36,379 | $ 10,054 |
| Work-in-process | 7,327 | 9,615 |
| Finished goods | 7,675 | 4,147 |
| Total inventories | $ 51,381 | $ 23,816 |

The Company's reserve for inventory was $1.0 million and $0.4 million as of June 30, 2023 and December 31, 2022, respectively.

## 6. Debt

The Company's debt consists of the following:

| (in thousands) | June 30, 2023 | December 31, 2022 |
|---|---|---|
| **Senior Secured Term Loan due 2026:** | | |
| Principal | $ 400,000 | $ 400,00 |
| Less: debt discount [1] | (3,795) | (4,57 |
| Less: deferred financing [1] | (2,855) | (3,43 |
| Net carrying value of Long-term debt | $ 393,350 | $ 391,99 |

[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 using the effective interest rate method.

***Interest Expense***

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| (in thousands) | 2023 | 2022 | 2023 | 2022 |
| Contractual interest expense | $ 11,789 | $ 7,589 | $ 23,019 | $ 15,08 |
| Amortization of debt discount | $ 395 | $ 375 | $ 776 | $ 73 |
| Amortization of deferred financing | $ 297 | $ 283 | $ 583 | $ 55 |

## 7. Stockholder's Equity

During the three and six months ended June 30, 2023, the Company issued and sold an aggregate of 2,047,353 and 2,242,582 shares, respectively, through its at-the-market equity program ("ATM program") at weighted-average public offering prices of $12.21 and $12.25 per share, resulting in net proceeds of $24.2 million and $26.6 million, respectively. As of June 30, 2023, an aggregate of $222.5 million worth of shares remain available to be issued and sold under the ATM program.

**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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2023 | 2022 | 2023 | 2022 |
| Expected stock price volatility | 59.2 % | 61.3 % | 59.3 % | 62.2 % |
| Risk free interest rate | 3.8 % | 3.0 % | 3.9 % | 1.6 % |
| 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 six months ended June 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 | 5,194 | $ 11.97 | | |
| Exercised | (655) | $ 6.73 | | |
| Forfeited | (160) | $ 11.36 | | |
| Expired | (35) | $ 13.99 | | |
| Options outstanding, June 30, 2023 | 23,408 | $ 11.58 | 6.9 | $ 41 |
| Vested and unvested expected to vest, June 30, 2023 | 21,510 | $ 11.52 | 6.7 | $ 39 |
| Exercisable at June 30, 2023 | 13,061 | $ 11.02 | 5.3 | $ 32 |

As of June 30, 2023, the total unrecognized compensation cost related to non-vested stock options granted was $43.4 million and is expected to be recognized over a weighted average period of three years.

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

RSUs awarded under the Plan are generally subject to graded vesting and are contingent on an employee's continued service. RSUs are generally subject to forfeiture if employment terminates prior to the release of vesting restrictions. The Company expenses the cost of the RSUs, which is determined to be the fair market value of the shares of common stock underlying the RSUs at the date of grant, ratably over the period during which the vesting restrictions lapse. A summary of non-vested RSU activity under the Plan for the six months ended June 30, 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 | 3,967 | $ 13.06 | | |
| Vested | (2,752) | $ 12.12 | | |
| Forfeited | (567) | $ 9.86 | | |
| Non-vested units as of June 30, 2023 | 10,365 | $ 13.53 | 2.3 | $ 130 |

As of June 30, 2023, there was $68.5 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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| (in thousands) | 2023 | 2022 | 2023 | 2022 |
| Research and development expense | $ 4,117 | $ 4,379 | $ 12,607 | $ 13,7 |
| Selling, general, and administrative expense | 12,460 | 8,084 | 38,864 | 29,3 |
| Total equity compensation expense | $ 16,577 | $ 12,463 | $ 51,471 | $ 43,1 |

## 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 June 30, 2023 are identified in the following tables:

| (in thousands) | Level 2 | Total |
|---|---|---|
| ***Assets:*** | | |
| Commercial paper | $ 44,031 | $ 44,03 |
| U.S. government agency bonds | 9,887 | 9,88 |
| Money market | 7,133 | 7,13 |
| | $ 61,051 | $ 61,05 |

| (in thousands) | Level 2 | Level 3 | Total |
|---|---|---|---|
| ***Liabilities:*** | | | |
| Contingent consideration payable | $ — | $ 13,005 | $ 13,005 |
| Deferred compensation plan liability | 6,783 | — | 6,783 |
| | $ 6,783 | $ 13,005 | $ 19,788 |

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.

The Company did not have any Level 3 assets as of June 30, 2023 or December 31, 2022.

***Cash, Money Market Funds, and Marketable Securities***

The Company classifies its cash within the fair value hierarchy as Level 1 as these assets are valued using quoted prices in an active market for identical assets at the measurement date. The Company considers its investments in marketable securities as available-for-sale and classifies these assets and the money market funds within the fair value hierarchy as Level 2 primarily utilizing broker quotes in a non-active market for valuation of these securities.

***Contingent Consideration Payable***

The contingent consideration payable resulted from the acquisition of Callidus Biopharma, Inc. ("Callidus") in November 2013. The most recent valuation was determined using a probability weighted discounted cash flow valuation approach. Gains and losses are included in the Company's Consolidated Statements of Operations.

The contingent consideration payable for Callidus has been classified as a Level 3 recurring liability as its valuation requires substantial judgment and estimation of factors that are not currently observable in the market. If different assumptions

were used for the various inputs to the valuation approach, the estimated fair value could be significantly higher or lower than the fair value the Company determined.

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

| Contingent Consideration Liability | Fair Value as of June 30, 2023 | Valuation Technique | Unobservable Input | Range |
|---|---|---|---|---|
| | (in thousands) | | | |
| | | | Discount rate | 11.7% |
| Clinical and regulatory milestones | $ 13,005 | Probability weighted discounted cash flow | Probability of achievement of milestones | 88% |
| | | | Projected year of payments | 2023 |

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

The Company reached a regulatory milestone in March 2023 associated with the EC granting approval for Pombiliti™, related to the contingent consideration of Callidus for the ATB200 Pompe disease program. The satisfaction of this milestone resulted in a milestone payment of $9.0 million.

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| (in thousands) | 2023 | 2022 | 2023 | 2022 |
| Balance, beginning of the period | $ 12,668 | $ 19,151 | $ 21,417 | $ 20,339 |
| Changes in fair value during the period, included in the Consolidated Statements of Operations | 337 | 115 | 588 | (1,073) |
| Milestone payment in cash | — | — | (9,000) | — |
| Balance, end of the period [1] | $ 13,005 | $ 19,266 | $ 13,005 | $ 19,266 |

[1] As certain milestones are expected to be reached within the next twelve months, the June 30, 2023 balance was recorded as a current liability in the Company's Consolidated Balance Sheets.

**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 June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| **(in thousands, except per share amounts)** | **2023** | **2022** | **2023** | **2022** |
| Numerator: | | | | |
| Net loss attributable to common stockholders | $ (43,232) | $ (62,157) | $ (96,164) | $ (147,417) |
| Denominator: | | | | |
| Weighted average common shares outstanding — basic and diluted | 292,797,002 | 291,970,562 | 292,071,201 | 288,646,587 |

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 June 30, | |
|---|---|---|
| **(in thousands)** | **2023** | **2022** |
| Options to purchase common stock | 23,408 | 19,28 |
| Unvested restricted stock units | 10,365 | 10,16 |
| Total number of potentially issuable shares | 33,773 | 29,44 |

## 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 Pompe disease that has been approved in the European Union ("E.U.") and the United Kingdom ("U.K."), and is under regulatory review 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™ and Opfolda™ (also referred to as AT-GAA, ATB200/AT2221, or cipaglucosidase alfa/miglustat), is a novel, two-component treatment for Pompe disease that was approved by the European Commission ("EC") in June 2023 and the U.K. Medicines and Healthcare products Regulatory Agency ("MHRA") in August 2023. We began launch activities for Pombiliti™ and Opfolda™ in Germany and will commence the reimbursement processes with healthcare authorities in other European countries. In October 2022, the U.S. Food and Drug Administration ("FDA") deferred action on the BLA for cipaglucosidase alfa, citing the inability to complete the manufacturing site inspection prior to the PDUFA action date. In the second quarter of 2023, the FDA completed the required pre-approval inspection of the manufacturing site and the review is ongoing.

### 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.

We continue to monitor the novel coronavirus ("COVID-19") pandemic. Our commercial operations have not been significantly impacted by the COVID-19 pandemic and we continue to see a gradual improvement in patient identification and Galafold® initiation. We have been able to continue to meet required commercial demand for Galafold® as well as supply Pombiliti™ and Opfolda™ commercial launch inventory and our ongoing clinical studies and access programs without interruption. In regard to our regulatory operations, the FDA deferred action on the pending BLA for cipaglucosidase alfa, as a site inspection could not be completed by the PDUFA action date due to COVID-19 related travel restrictions in China. In the second quarter of 2023, the FDA completed the required pre-approval inspection of the manufacturing site. Per FDA guidance relating to pre-approval inspections during the COVID-19 pandemic, receipt of a deferral action indicates no deficiencies have been identified and the application otherwise satisfies the requirements for approval.

Highlights of our progress include:

- *Commercial and regulatory success in Fabry disease.* For the six months ended June 30, 2023, Galafold® revenue was $180.4 million of consolidated revenue, which represented an increase of $21.0 million compared to the same period in the prior year. We continue to see strong commercial momentum and expansion into additional geographies. In countries where we have been operating the longest, we see an increasing proportion of previously untreated patients come onto Galafold® 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™ and Opfolda™ were approved by the EC in June 2023 and MHRA in August 2023. The regulatory reviews in the U.S. remain ongoing. Additionally, multiple expanded access mechanisms are in place around the globe, including in the U.S., U.K., Japan, and others.
- *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 June 30, 2023 was $265.6 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 impacts of the COVID-19 pandemic, business development collaborations, pipeline expansion, and investment in manufacturing capabilities could impact our future capital requirements.

**Our Commercial Product and Product Candidates**

***Galafold® (migalastat HCl) for Fabry Disease***

Our oral precision medicine Galafold® was granted accelerated approval by the FDA in August 2018 under the brand name Galafold® for the treatment of adults with a confirmed diagnosis of Fabry disease and an amenable galactosidase alpha gene ("GLA") variant based on in vitro assay data. The FDA has approved Galafold® for 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 53 Orange Book listed patents, including 9 composition-of-matter patents, of which 37 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 have an academic research collaboration agreement to explore next generation pharmacological chaperones for Fabry disease.

***Novel ERT for Pompe Disease***

We are leveraging our biologics capabilities to develop AT-GAA, a novel treatment paradigm for Pompe disease. AT-GAA consists of a uniquely engineered rhGAA enzyme, ATB200, or cipaglucosidase alfa, with an optimized carbohydrate structure to enhance lysosomal uptake, administered in combination with AT2221, or miglustat, that functions as an enzyme stabilizer. Miglustat binds to and stabilizes ATB200 preventing inactivation of rhGAA in circulation to improve the uptake of active enzyme in key disease-relevant tissues, resulting in increased clearance of accumulated substrate, ("glycogen"). Miglustat is not an active ingredient that contributes directly to glycogen reduction.

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

In October 2022 and February 2023, we reported positive long-term data from our ongoing phase 1/2 clinical study and Phase 3 open-label extension study, respectively. Phase 1/2 and 3 study participants treated with AT-GAA for up to 48 months and up to 2 years, respectively, demonstrated persistent and durable effects on six-minute walk test distance and measures of motor function and muscle strength, stability, or increase in forced vital capacity, and reductions in biomarkers of muscle damage and disease substrate.

Pombiliti™ and Opfolda™ were approved by the EC in June 2023 and MHRA in August 2023. We began launch activities for Pombiliti™ and Opfolda™ in Germany and will commence reimbursement processes with healthcare authorities in other European countries.

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

***Next Generation for Pompe Disease***

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.

***Additional Development and Next Generation Programs***

We are researching potential therapies for CDKL5 deficiency disorder ("CDD"). We are collaborating with the LouLou Foundation to assess the natural history of the disease to identify endpoints for potential use in future studies. We also have a number of additional gene therapies in clinical and preclinical development, including potential gene therapies in multiple forms of Batten disease.

***Strategic Alliances and Arrangements***

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

**Consolidated Results of Operations**

***Three Months Ended June 30, 2023 compared to June 30, 2022***

The following table provides selected financial information for the Company:

| | Three Months Ended June 30, | | |
|---|---|---|---|
| **(in thousands)** | **2023** | **2022** | **Change** |
| Net product sales | $ 94,503 | $ 80,731 | $ 13,772 |
| Cost of goods sold | 9,114 | 8,197 | 917 |
| Cost of goods sold as a percentage of net product sales | 9.6 % | 10.2 % | (0.6) |
| Operating expenses: | | | |
| Research and development | 35,149 | 78,319 | (43,170) |
| Selling, general, and administrative | 65,423 | 53,379 | 12,044 |
| Changes in fair value of contingent consideration payable | 337 | 115 | 222 |
| Loss on impairment of assets | 1,134 | — | 1,134 |
| Depreciation and amortization | 2,206 | 1,334 | 872 |
| Other (expense) income: | | | |
| Interest income | 1,737 | 356 | 1,381 |
| Interest expense | (12,492) | (8,257) | (4,235) |
| Other (expense) income | (10,902) | 7,268 | (18,170) |
| Income tax expense | (2,715) | (911) | (1,804) |
| Net loss attributable to common stockholders | $ (43,232) | $ (62,157) | $ 18,925 |

*Net Product Sales.* Net product sales increased $13.8 million during the three months ended June 30, 2023 compared to the same period in the prior year. The increase was primarily due to continued growth in the U.S., Europe and Japan markets.

*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 June 30, | |
|---|---|---|
| ***Projects*** | **2023** | **2022** |
| Third party direct project expenses | | |
| Galafold® (Fabry Disease) | $ 3,822 | $ 3,419 |
| AT-GAA (Pompe Disease) | 13,117 | 21,585 |
| Gene therapy programs | 520 | 27,225 |
| Pre-clinical and other programs | 345 | — |
| Total third-party direct project expenses | 17,804 | 52,229 |
| Other project costs | | |
| Personnel costs | 13,662 | 18,152 |
| Other costs | 3,683 | 7,938 |
| Total other project costs | 17,345 | 26,090 |
| Total research and development costs | $ 35,149 | $ 78,319 |

The $43.2 million decrease in research and development costs was primarily driven by the strategic prioritization 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 costs decreased in connection with the reallocation of resources to support our anticipated AT-GAA commercial launch and continued growth of Galafold®.

*Selling, General, and Administrative Expense.* Selling, general, and administrative expense increased $12.0 million, primarily driven by personnel costs in connection with the reallocation of resources to support AT-GAA commercial launch activities and third-party professional fees, partially offset by the write-off of cloud computing costs and software licensing fees in the prior period in connection with the strategic prioritization of our gene therapy portfolio.

*Interest Expense.* The $4.2 million variance was due to a higher variable interest rate on debt period over period.

*Other (Expense) Income.* The $18.2 million variance was primarily related to foreign exchange losses caused by remeasurement of foreign-denominated balances.

**Consolidated Results of Operations**

***Six Months Ended June 30, 2023 compared to June 30, 2022***

The following table provides selected financial information for the Company:

| | Six Months Ended June 30, | | |
|---|---|---|---|
| **(in thousands)** | **2023** | **2022** | **Change** |
| Net product sales | $ 180,773 | $ 159,446 | $ 21,327 |
| Cost of goods sold | 16,056 | 15,779 | 277 |
| Cost of goods sold as a percentage of net product sales | 8.9 % | 9.9 % | (1.0 |
| Operating expenses: | | | |
| Research and development | 76,648 | 159,836 | (83,188 |
| Selling, general, and administrative | 139,380 | 111,495 | 27,885 |
| Changes in fair value of contingent consideration payable | 588 | (1,073) | 1,661 |
| Loss on impairment of assets | 1,134 | 6,616 | (5,482 |
| Depreciation and amortization | 3,463 | 2,745 | 718 |
| Other (expense) income: | | | |
| Interest income | 3,936 | 489 | 3,447 |
| Interest expense | (24,336) | (16,404) | (7,932 |
| Other (expense) income | (16,840) | 9,170 | (26,010 |
| Income tax expense | (2,428) | (4,720) | 2,292 |
| Net loss attributable to common stockholders | $ (96,164) | $ (147,417) | $ 51,253 |

*Net Product Sales.* Net product sales increased $21.3 million during the six months ended June 30, 2023 compared to the same period in the prior year. The increase was primarily due to continued growth in the U.S., Europe and Japan markets, partially offset by the $4.1 million unfavorable 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. Cost of goods sold as a percentage of net product sales decreased 1.0% primarily due to the increased proportion of sales in countries not subject to royalties.

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

| (in thousands) | Six Months Ended June 30, | |
|---|---|---|
| ***Projects*** | **2023** | **2022** |
| Third party direct project expenses | | |
| Galafold® (Fabry Disease) | $ 6,466 | $ 7,039 |
| AT-GAA (Pompe Disease) | 28,893 | 48,563 |
| Gene therapy programs | 755 | 44,917 |
| Pre-clinical and other programs | 710 | 93 |
| Total third-party direct project expenses | 36,824 | 100,612 |
| Other project costs | | |
| Personnel costs | 31,914 | 43,827 |
| Other costs | 7,910 | 15,397 |
| Total other project costs | 39,824 | 59,224 |
| Total research and development costs | $ 76,648 | $ 159,836 |

The $83.2 million decrease in research and development costs was primarily driven by the strategic prioritization 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 costs decreased in connection with the reallocation of resources to support our anticipated AT-GAA commercial launch and continued growth of Galafold®.

*Selling, General, and Administrative Expense.* Selling, general, and administrative expense increased $27.9 million, primarily driven by personnel costs in connection with the reallocation of resources to support our anticipated AT-GAA 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 prioritization of our gene therapy portfolio.

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

*Interest Expense.* The $7.9 million variance was due to a higher variable interest rate on debt period over period.

*Other (Expense) Income.* The $26.0 million variance was primarily related to foreign exchange losses caused by remeasurement of foreign-denominated balances.

**Liquidity and Capital Resources**

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

***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 six months ended June 30, 2023, we issued and sold an aggregate of 2,047,353 and 2,242,582 shares through our ATM program at a weighted-average public offering price of $12.21 and $12.25 per share, resulting in net proceeds of $24.2 million and $26.6 million, respectively. As of June 30, 2023, an aggregate of $222.5 million worth of shares remain available to be issued and sold under the ATM program.

***Cash Flow Discussion***

As of June 30, 2023, we had cash, cash equivalents, and marketable securities of $265.6 million. We invest cash in excess of our immediate requirements in regard to liquidity and capital preservation in a variety of interest-bearing instruments, including obligations of U.S. government agencies and money market accounts. Wherever possible, we seek to minimize the potential effects of concentration and degrees of risk. Although we maintain cash balances with financial institutions in excess of insured limits, we do not anticipate any losses with respect to such cash balances. For more details on the cash, cash equivalents, and marketable securities, refer to "— Note 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 six months ended June 30, 2023 was $34.2 million. The components of net cash used in operations included the net loss for the six months ended June 30, 2023 of $96.2 million offset by $51.5 million of stock compensation, $26.4 million of other non-cash adjustments, and a net increase in changes in operating assets and liabilities of $15.9 million. The changes in operating assets and liabilities were primarily due to an increase in inventory of $27.5 million and an increase in prepaid expenses and other current assets of $12.3 million, partially offset by an increase in accounts payable and accrued expenses of $31.6 million associated with Pombiliti™ and Opfolda™ launch activities and increases in sales rebates associated with increased commercial sales of Galafold®.

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

***Net Cash Provided by Investing Activities***

Net cash provided by investing activities for the six months ended June 30, 2023 was $86.3 million. Our investing activities have consisted primarily of purchases, sales, and maturities of investments and capital expenditures. Net cash provided by investing activities reflects $126.8 million for the sale and redemption of marketable securities, partially offset by $36.4 million for the purchase of marketable securities and $4.1 million for capital expenditures.

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

***Net Cash Provided by (Used in) Financing Activities***

Net cash provided by financing activities for the six months ended June 30, 2023 was $15.8 million. Net cash provided by financing activities primarily reflects $26.6 million of proceeds from the issuance of shares in connection with the ATM program offering, net of issuance costs, and $4.4 million of proceeds from the exercise of stock options, partially offset by the withholding taxes paid on vested restricted stock units of $14.0 million.

Net cash used in financing activities for the six months ended June 30, 2022 was $7.5 million. Net cash used in financing activities primarily reflects the withholding taxes paid on vested restricted stock units of $9.3 million, partially offset by $1.9 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 Pompe Enzyme Replacement Therapy ("ERT" or "ATB200" or "cipaglucosidase alfa");
- the future results of preclinical research and subsequent clinical trials for pipeline candidates we may identify from time to time, including our ability to obtain regulatory approvals and commercialize these therapies and obtain market acceptance for such therapies;
- the costs, timing, and outcome of regulatory review of our product candidates, including AT-GAA;
- any changes in regulatory standards relating to the review of our product candidates, including AT-GAA;
- the number and development requirements of other product candidates that we pursue;
- the costs of commercialization activities, including product marketing, sales, and distribution;
- the emergence of competing technologies and other adverse market developments;
- the estimates regarding the potential market opportunity for our product and product candidates, including AT-GAA;
- our ability to successfully commercialize Galafold® (also referred to as "migalastat HCl");
- our ability to successfully commercialize Pombiliti™ and Opfolda™ (also referred to as AT-GAA) in the E.U., and elsewhere, if our regulatory applications for AT-GAA 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®;
- our ability to obtain reimbursement for Pombiliti™ and Opfolda™ in the E.U., and elsewhere, if our regulatory applications for AT-GAA are approved;
- our ability to satisfy post-marketing commitments or requirements for continued regulatory approval of Galafold®;
- our ability to satisfy post-marketing commitments or requirements for continued regulatory approval of Pombiliti™ and Opfolda™ in the E.U., and elsewhere, if our regulatory applications for AT-GAA are approved;
- our ability to obtain market acceptance of Galafold®;
- our ability to obtain market acceptance of Pombiliti™ and Opfolda™ in the E.U., and elsewhere, if our regulatory applications for AT-GAA are approved;
- 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 extent to which our business could be adversely impacted by the effects of the novel coronavirus ("COVID-19") outbreak, including actions by us, governments, our customers, our suppliers, or other third parties to control the spread of COVID-19, or by other health epidemics or pandemics;
- the costs associated with, and our ability to comply with, emerging environmental, social and governance standards;

- our ability to accurately forecast revenue, operating expenditures, or other metrics impacting profitability;
- fluctuations in foreign currency exchange rates; and
- changes in accounting standards.

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 the COVID-19 pandemic, business development collaborations, pipeline expansion, and investment in manufacturing capabilities could impact our future capital requirements.

**Financial Uncertainties Related to Potential Future Payments**

***Milestone Payments / Royalties***

*Callidus* - In connection with our acquisition of Callidus Biopharma, Inc. ("Callidus"), we may be obligated to make additional payments to the former stockholders of Callidus upon the achievement of certain clinical milestones of up to $35 million and regulatory milestones of up to $80 million set forth in the merger agreement, provided that the aggregate merger consideration shall not exceed $130 million. As of June 30, 2023, $20 million and $59 million remain outstanding, respectively. Refer to “— Note 9. Assets and Liabilities Measured at Fair Value,” to the Consolidated Financial Statements.

*Celenex* - In connection with our acquisition of Celenex, Inc. ("Celenex"), we may be obligated to pay up to an additional $10 million in connection with the achievement of certain development milestones, $220 million in connection with the achievement of certain regulatory approval milestones across multiple programs and up to $75 million in tiered sales milestone payments. Celenex has an exclusive license agreement with Nationwide Children’s Hospital ("Nationwide Children’s"). Under this license agreement, Nationwide Children’s is eligible to receive development and sales-based milestones of up to $7.8 million for each product.

*University of Pennsylvania* - In connection with our license agreement with the University of Pennsylvania ("Penn"), Penn is eligible to receive up to an aggregate of $86.5 million for the achievement of certain milestones and royalty payments with respect to licensed products for each indication. Royalty payments are based on net sales of licensed products on a licensed product-by-licensed product and country-by-country basis.

*GlaxoSmithKline* - In connection with our collaboration agreement with GlaxoSmithKline ("GSK"), pursuant to which we obtained global rights to develop and commercialize Galafold® as a monotherapy and in combination with ERT for Fabry disease, GSK is eligible to receive post-approval and sales-based milestones up to $40 million, as well as tiered royalties in the mid-teens in eight major markets outside the U.S.

**Critical Accounting Policies and Significant Judgments**

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

There were no significant changes during the six months ended June 30, 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

The Financial Conduct Authority has announced the intent to phase out the use of LIBOR by June 30, 2023. In May 2023, the Company entered into an amendment (the “Second Amendment”) to the Senior Secured Term Loan due 2026. Pursuant to the terms of the Second Amendment, effective with the interest period beginning July 1, 2023, LIBOR was replaced with Adjusted Term Secured Overnight Financing Rate ("SOFR"), a forward-looking term rate based on SOFR, plus a credit spread adjustment of 0.26%. All other terms of the Senior Secured Term Loan due 2026 were unchanged by the Second Amendment.

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 June 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 June 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 |
|---|---|---|---|---|
| April 1, 2023 through April 30, 2023 | 11,858 | $ 11.45 | — | — |
| May 1, 2023 through May 31, 2023 | 20,679 | $ 11.26 | — | — |
| June 1, 2023 through June 30, 2023 | 8,198 | $ 12.96 | — | — |
| Total | 40,735 | $ 11.66 | — | — |

[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**

On May 17, 2023, Daphne Quimi, the Company's Chief Financial Officer, entered into a Rule 10b5-1 trading plan. Ms. Quimi's trading plan provides for the potential sale of up to 26,232 shares of the Company's common stock, between August 16, 2023 and December 29, 2023. This trading plan was entered into during an open insider trading window and is intended to satisfy the affirmative defense of Rule 105b-1(c) under the Exchange Act and the Company's policies regarding transactions in the Company's securities.

**Bylaws Amendment**

On August 7, 2023, the Company’s Board of Directors approved the Second Amended and Restated Bylaws of the Company (the “Amended Bylaws”), effective immediately upon adoption, with such amendments including, among other things, updates to the advance notice provisions to address the adoption by the SEC of “universal proxy” rules and updates to conform certain provisions with the Delaware General Corporation Law. The Amended Bylaws also contain various other conforming, technical and non-substantive changes.

With respect to stockholder nominees to the Company’s Board of Directors, the Amended Bylaws provide, among other things, (i) that stockholders must comply with the SEC’s newly adopted Rule 14a-19 under the Exchange Act, (ii) that no stockholder may solicit proxies in support of a director nominee other than the Board of Directors’ nominees unless such stockholder has complied with Rule 14a-19 under the Exchange Act, including applicable notice and solicitation requirements, (iii) that, if any stockholder provides notice of intent to solicit proxies pursuant to Rule 14a-19 under the Exchange Act, such stockholder must provide upon request by the Company, no later than five business days prior to the applicable meeting, evidence that such stockholder has met the requirements of Rule 14a-19(a)(3) and Rule 14a-19(b) under the Exchange Act, and (iv) that the Company may disregard any proxies or votes solicited for a stockholder’s nominee(s) if such stockholder does not comply with the requirements of Rule 14a-19(a)(2) and Rule 14a-19(a)(3) under the Exchange Act.

The foregoing summary of the Amended Bylaws is qualified in its entirety by reference to the full text of the Amended Bylaws, which are filed as Exhibit 3.2 to this Quarterly Report on Form 10-Q and incorporated herein by reference.

**ITEM 6. EXHIBITS**

| Exhibit Number | Description |
|---|---|
| 3.1 | Certificate of Amendment to the Company's Amended and Restated Certificate of Incorporation, dated June 8, 2023 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on June 13, 2023) |
| 3.2 | Second Amended and Restated By-Laws of the Registrant |
| 10.1 | Amendment No. 2 to Loan Agreement, dated as of July 17, 2020, by and among Amicus Therapeutics International Holding Ltd, as Borrower, Amicus Therapeutics, Inc. as Parent and a Guarantor, certain subsidiaries of Parent as additional Guarantors, and Hayfin Services LLP as Agent for certain 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 May 12, 2023) |
| ++10.2 | Supply and Manufacturing Services Agreement, dated as of March 31, 2023, by and among the Company, WuXi Biologics (Hong Kong) Limited, WuXi Biologics Ireland Limited and WuXi Biologics Germany GmbH |
| 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) |

++ Subject to confidential treatment request.

**SIGNATURES**

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

AMICUS THERAPEUTICS, INC.

Date: August 8, 2023

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

Date: August 8, 2023

By: /s/ Daphne Quimi
Daphne Quimi
Chief Financial Officer
(Principal Financial Officer)

**Exhibit 3.2**

**AMICUS THERAPEUTICS, INC.**

**SECOND AMENDED AND RESTATED BY-LAWS**

## Article I. — General.

**1.1. Offices.** The registered office of Amicus Therapeutics, Inc. (the "Company") shall be in the City of Wilmington, County of New Castle, State of Delaware. The Company may also have offices at such other places both within and without the State of Delaware as the board of directors of the Company (the "Board of Directors") may from time to time determine or the business of the Company may require.

**1.2. Seal.** The seal, if any, of the Company shall be in the form of a circle and shall have inscribed thereon the name of the Company, the year of its organization and the words "Corporate Seal, Delaware."

**1.3. Fiscal Year.** The fiscal year of the Company shall be the period from January 1 through December 31.

## Article II. — Stockholders.

**2.1. Place of Meetings.** Each meeting of the stockholders shall be held upon notice as hereinafter provided, at such place, including virtually, as the Board of Directors shall have determined and as shall be stated in such notice.

**2.2. Annual Meeting.** The annual meeting of the stockholders shall be held each year on such date and at such time as the Board of Directors may determine. At each annual meeting the stockholders entitled to vote shall elect such members of the Board of Directors as are eligible for election, and they may transact such other corporate business as may properly be brought before the meeting. At the annual meeting any business may be transacted, irrespective of whether the notice calling such meeting shall have contained a reference thereto, except where notice is required by law, the Company's certificate of incorporation (as amended from time to time, the "Certificate of Incorporation"), or these by-laws.

**2.3. Quorum.** At all meetings of the stockholders the holders of a majority of the stock issued and outstanding and entitled to vote thereat, present in person or represented by proxy, shall constitute a quorum requisite for the transaction of business except as otherwise provided by law, the Company's Certificate of Incorporation, or these by-laws. Whether or not there is such a quorum at any meeting, the chairman of the meeting or the stockholders entitled to vote thereat, present in person or by proxy, by a majority vote, may adjourn the meeting from time to time without notice other than announcement at the meeting. If the adjournment is for more than thirty (30) days, or if after the adjournment a new record date is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting. At such adjourned meeting, at which the requisite amount of voting stock shall be represented, any business may be transacted that might have been transacted if the meeting had been held as originally called. The stockholders present in person or by proxy at a duly called meeting at which a quorum is present may continue to transact business until adjournment, notwithstanding the withdrawal of enough stockholders to leave less than a quorum.

**2.4. Right to Vote; Proxies.** Subject to the provisions of the Company's Certificate of Incorporation, each holder of a share or shares of capital stock of the Company having the right to vote at any meeting shall be entitled to one vote for each such share of stock held by such holder. Any stockholder entitled to vote at any meeting of stockholders may vote either in person or by proxy, but no proxy that is dated more than three years prior to the meeting at which it is offered shall confer the right to vote thereat unless the proxy provides that it shall be effective for a longer period. The authorization of a person to act as proxy may be documented, signed, and delivered in accordance with Section 116 of the General Corporation Law of the State of Delaware, as it may be amended from time to time (the "DGCL") provided that such authorization shall set forth, or be delivered with, information enabling the Company to determine the identity of the stockholder granting such authorization. A proxy shall be irrevocable if it states that it is irrevocable and if, and only as long as, it is coupled with an interest sufficient in law to support an irrevocable power. A stockholder may revoke any proxy that is not irrevocable by attending the meeting and voting in person or by delivering to the Secretary of the Company a revocation of the proxy or a new proxy bearing a later date. Any stockholder soliciting proxies from other stockholders must use a proxy card color other than white, which shall be reserved for the exclusive use by the Board of Directors.

**2.5. Voting.** At all meetings of stockholders, except as otherwise expressly provided for by statute, the Company's Certificate of Incorporation or these by-laws, (i) in all matters other than the election of directors, the affirmative vote of a majority of shares present in person or represented by proxy at the meeting and entitled to vote on such matter shall be the act of the stockholders and (ii) directors shall be elected by a plurality of the votes of the shares present in person or represented by proxy at the meeting and entitled to vote on the election of directors.

**2.6. Notice of Annual Meetings.** Written notice of the annual meeting of the stockholders shall be mailed to each stockholder entitled to vote thereat at such address as appears on the stock books of the Company at least ten (10) days (and not more than sixty (60) days) prior to the meeting. The Board of Directors may postpone any annual meeting of the stockholders at its discretion, even after notice thereof has been mailed. It shall be the duty of every stockholder to furnish to the Secretary of the Company or to the transfer agent for the Company, if any, of the class of stock owned by him and his post-office address, and to notify the Secretary of the Company of any change therein. Without limiting the manner by which notices of meetings otherwise may be given effectively to stockholders, any such notice may be given by electronic transmission in accordance with applicable law. Notice need not be given to any stockholder who submits a written waiver of notice signed by him before or after the time stated therein. Attendance of a stockholder at a meeting of stockholders shall constitute a waiver of notice of such meeting, except when the stockholder attends the meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Any stockholder so waiving notice of the meeting shall be bound by the proceedings of the meeting in all respects as if due notice thereof had been given. Neither the business to be transacted at, nor the purpose of, any regular meeting of the stockholders need be specified in any written waiver of notice.

**2.7. Stockholders' List.** A complete list of the stockholders entitled to vote at any meeting of stockholders (*provided, however,* if the record date for determining the stockholders entitled to vote is less than ten (10) days before the date of the meeting, the list shall reflect the stockholders entitled to vote as of the tenth ($10^{th}$) day before the meeting date), arranged in alphabetical order and showing the address of each stockholder, and the number of shares registered in the name of each stockholder, shall be prepared by the Secretary and shall be open to the examination of any stockholder, for any purpose germane to the meeting for a period of at least ten (10) days ending on the day before the meeting date (i) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting, or (ii) during ordinary business hours, at the principal place of business of the Company. Except as provided by applicable law, the stock ledger of the Company shall be the only evidence as to who are the stockholders entitled to examine the stock ledger and the list of stockholders or to vote in person or by proxy at any meeting of stockholders.

**2.8. Special Meetings.** Special meetings of the stockholders for any purpose or purposes, unless otherwise provided by statute, may be called only by the Chairman of the Board of Directors, the President, or a majority of the Board of Directors. Any such person or persons may postpone any special meeting of the stockholders at its or their discretion, even after notice thereof has been mailed.

**2.9. Notice of Special Meetings.** Written notice of a special meeting of stockholders, stating the time and place and object thereof shall be mailed, postage prepaid, not less than ten (10) nor more than sixty (60) days before such meeting, to each stockholder entitled to vote thereat, at such address as appears on the books of the Company. No business may be transacted at such meeting except that referred to in said notice, or in a supplemental notice given also in compliance with the provisions hereof, or such other business as may be germane or supplementary to that stated in said notice or notices. Without limiting the manner by which notices of special meetings otherwise may be given effectively to stockholders, any such notice may be given by electronic transmission in accordance with applicable law. Notice need not be given to any stockholder who submits a written waiver of notice signed by him before or after the time stated therein. Attendance of a stockholder at a meeting of stockholders shall constitute a waiver of notice of such meeting, except when the stockholder attends the meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Any stockholder so waiving notice of a special meeting shall be bound by the proceedings of the special meeting in all respects as if due notice thereof had been given. Neither the business to be transacted at, nor the purpose of, any special meeting of the stockholders need be specified in any written waiver of notice.

**2.10. Inspectors.**

Section 231 of the DGCL with respect to inspectors of election and voting procedures shall apply.

**2.11. Advance Notice of Stockholder Nominations and Proposals.**

(a) Nominations of persons for election to the Board of Directors and the proposal of other business to be considered by the stockholders may be made at an annual meeting of stockholders only (A) pursuant to the Company's notice of meeting (or any supplement thereto), (B) by or at the direction of the Board of Directors or (C) by a stockholder who (i) is a stockholder of record of the Company who is entitled to vote at the meeting at the time the notice provided for in this Section 2.11 is received by the Secretary, (ii) complies with the notice procedures set forth in this Section 2.11 and, with respect to nominations of persons for election to the Board of Directors, (iii) complies with the requirements of Regulation 14A under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), including, without limitation, the requirements of Rule 14a-19 (as such rule and regulation may be amended from time to time by the Securities and Exchange Commission ("SEC") including any SEC staff interpretations relating thereto).

(b) For nominations or other business to be properly brought before an annual meeting by a stockholder pursuant to Section 2.11(a), the stockholder must first have given timely written notice thereof to the Secretary of the Company and any such proposed business other than the nominations of persons for election to the Board of Directors must

constitute a proper matter for stockholder action. To be timely, a notice of nominations or other business to be brought before an annual meeting of stockholders must be delivered to the Secretary: (x) not less than 90 nor more than 120 days prior to the first anniversary of the date of the preceding year's annual meeting if such meeting is to be held on a day which is not more than 30 days before or more than 60 days after such anniversary; and (y) with respect to any other annual meeting of stockholders, including in the event that no annual meeting was held in the previous year, not earlier than 120 days prior to such annual meeting and not later than the later of (i) 90 days prior to the annual meeting or (ii) 10 days following the date on which public announcement of the date of such annual meeting is first made by the Company. In no event shall the public announcement of an adjournment or postponement of an annual meeting commence a new time period, or extend any time period, for the giving of a stockholder's notice as described above. Such notice must contain: (A) as to each person whom the stockholder proposes to nominate for election as a director, all information relating to such person that is required to be disclosed in solicitations of proxies for election of directors in an election contest, or is otherwise required in each case pursuant to Regulation 14A under the Exchange Act, regardless of the application of the Exchange Act to such nomination, and such person's written consent to being named in the proxy statement as a nominee and to serving as such a director if elected; (B) as to any other business that the stockholder proposes to bring before the meeting, a brief description of the business desired to be brought before the meeting, the text of the proposal or business (including the text of any resolutions proposed for consideration and in the event that such business includes a proposal to amend these by-laws, the language of the proposed amendment), the reasons for conducting such business at the meeting and any material interest in such business of such stockholder and of the beneficial owner, if any, on whose behalf the proposal is made; and (C) as to the stockholder giving the notice and the beneficial owner, if any, on whose behalf the nomination or proposal is made (1) the name and address of such stockholder, as they appear on the Company's books, and of such beneficial owner, (2) the class and number of shares of capital stock of the Company that are owned beneficially and of record by such stockholder and such beneficial owner as well as any derivative or synthetic instrument, convertible security, put, option, stock appreciation right, swap or similar contract, agreement, arrangement or understanding the value of or return on which is based on or linked to the value of or return on any of shares of capital stock of the Company, (3) any proxy (other than a revocable proxy given in response to a solicitation statement filed pursuant to, and in accordance with, Section 14(a) of the Exchange Act), voting trust, voting agreement or similar contract, arrangement, agreement or understanding pursuant to which the stockholder or beneficial owner on whose behalf the nomination or proposal is being made has a right to vote or direct the voting of any shares of the Company's capital stock, (4) a representation that the stockholder is a holder of record of capital stock of the Company entitled to vote at such meeting and intends to appear in person or by proxy at the meeting to propose such business or nomination, and (5) a representation whether the stockholder or the beneficial owner, if any, intends or is part of a group that intends (a) to deliver a proxy statement and/or form of proxy to holders of at least the percentage of the Company's outstanding capital stock required to approve or adopt the proposal or elect the nominee and/or (b) otherwise to solicit proxies from stockholders in support of such proposal or nomination. In addition, to be timely, a stockholder's notice shall further be updated and supplemented, if necessary, (1) as of the voting record date for the meeting and (2) as of the date that is ten (10) days prior to the meeting or any adjournment or postponement thereof, and such update and supplement shall be delivered to the Secretary at the principal office of the Company. With respect to any proposal of business, the notice requirements of this Section 2.11 shall be deemed satisfied by a stockholder if the stockholder has notified the Company of such stockholder's intention to present a proposal at an annual meeting in compliance with Rule 14a-8 (or any successor thereof) promulgated under the Exchange Act and such stockholder's proposal will be included in a proxy statement that will be prepared by the Company to solicit proxies for such annual meeting. The Company may require any proposed nominee to furnish such other information as it may reasonably require to determine the eligibility of such proposed nominee to serve as a director of the Company. In addition to the requirements set forth in this Section 2.11(b), unless otherwise required by law, (i) no stockholder shall solicit proxies in support of director nominees other than the Company's nominees unless such stockholder has complied with Rule 14a-19 promulgated under the Exchange Act in connection with the solicitation of such proxies in all respects, including but not limited to the minimum solicitation and notice requirements. If any stockholder (1) provides notice pursuant to Rule 14a-19(b) promulgated under the Exchange Act and (2) subsequently fails to comply with the requirements of Rules 14a-19(a)(2) and Rule 14a-19(a)(3) promulgated under the Exchange Act, then the Company shall disregard any proxies or votes solicited for the stockholder's candidates. Upon request by the Company, if any stockholder provides notice pursuant to Rule14a-19(b) promulgated under the Exchange Act, such stockholder shall deliver to the Company, no later than five (5) business days prior to the applicable meeting, reasonable evidence that it has met the requirements of Rule 14a-19(a)(3) and 14a-19(b).

(c) The only business that shall be conducted at a special meeting of stockholders shall be the business that shall have been brought before the meeting pursuant to the Company's notice of meeting. Nominations of persons for election to the Board of Directors may be made at a special meeting of stockholders called by the Board of Directors at which directors are to be elected pursuant to the Company's notice of meeting (i) by or at the direction of the Board of Directors or (ii) provided that the Board of Directors has determined that directors shall be elected at such meeting, by any stockholder of the Company who (x) is a stockholder of record at the time the notice provided for in this Section 2.11 is delivered to the Secretary, (y) is entitled to vote both at the meeting and upon such election, and (z) complies with the notice procedures set forth in this Section 2.11.

In the event the Company calls a special meeting of stockholders for the purpose of electing one or more directors to the Board of Directors, any such stockholder entitled to vote in such election of directors may nominate a person or persons (as the case may be) for election to such position(s) as specified in the Company's notice of meeting, if such stockholder delivers a stockholder's notice that complies with the requirements of this Section 2.11 applicable to such nomination to the Secretary at the principal executive offices of the Company not earlier than the close of business on the 90th day prior to such special meeting and not later than the close of business on the later of: (x) the 60th day prior to such special meeting; or (y) the tenth (10th) day following the date on which public announcement of the date of such meeting is first made by the Company. In no event shall the public announcement of an adjournment or postponement of a special meeting commence a new time period, or extend any notice time period.

## Article III. — Directors.

**3.1. Number of Directors.**

1. Except as otherwise provided by law, the Company's Certificate of Incorporation, or these by-laws, the property and business of the Company shall be managed by or under the direction of the Board of Directors. Directors need not be stockholders, residents of Delaware or citizens of the United States. The use of the phrase "whole board" herein refers to the total number of directors which the Company would have if there were no vacancies.

2. The number of directors constituting the full Board of Directors shall be as determined by the Board of Directors from time to time. The Board of Directors shall be divided into three classes of directors, such classes to be as nearly equal in number of directors as practicable as determined by the Board of Directors, having staggered three-year terms of office, the term of office of the directors of the first such class to expire as of the first annual meeting of the Company's stockholders following the closing of the initial public offering of the Company's common stock, those of the second class to expire as of the second annual meeting of the Company's stockholders following such closing, and those of the third class as of the third annual meeting of the Company's stockholders following such closing, such that at each annual meeting of stockholders after such closing, nominees will stand for election to succeed those directors whose terms are to expire as of such meeting. Members of the Board of Directors shall hold office until the annual meeting of stockholders at which their respective successors are elected and qualified or until their earlier death, incapacity, resignation, or removal. Except as the DGCL or the Company's Certificate of Incorporation may otherwise require, in the interim between annual meetings of stockholders or special meetings of stockholders called for the election of directors and/or for the removal of one or more directors and for the filling of any vacancy in that connection, any vacancies in the Board of Directors, including unfilled vacancies resulting from the removal of directors for cause, may be filled by the vote of a majority of the remaining directors then in office, although less than a quorum, or by the sole remaining director.

(c) If the office of any director becomes vacant by reason of death, resignation, disqualification, removal, failure to elect, or otherwise, the remaining directors, although more or less than a quorum, by a majority vote of such remaining directors may elect a successor or successors who shall hold office for the unexpired term.

**3.2. Resignation.** Any director of the Company may resign at any time by giving written notice to the Chairman of the Board, the President, or the Secretary of the Company. Such resignation shall take effect at the later time specified therein, at the time of receipt if no later time is specified therein and at the time of acceptance if the effectiveness of such resignation is conditioned upon its acceptance. Unless otherwise specified therein, the acceptance of such resignation shall not be necessary to make it effective.

**3.3. Removal.** Except as may otherwise be provided by the DGCL or the Company's Certificate of Incorporation, any director or the entire Board of Directors may be removed only for cause and only by the vote of the holders of a majority of the shares of the Company's stock entitled to vote for the election of directors.

**3.4. Place of Meetings and Books.** The Board of Directors may hold their meetings and keep the books of the Company outside the State of Delaware, at such places as they may from time to time determine.

**3.5. General Powers.** In addition to the powers and authority expressly conferred upon them by these by-laws, the Board of Directors may exercise all such powers of the Company and do all such lawful acts and things as are not by statute or by the Company's Certificate of Incorporation or by these by-laws directed or required to be exercised or done by the stockholders.

**3.6. Other Committees.** The Board of Directors may designate one or more committees, by resolution or resolutions passed by a majority of the whole board; such committee or committees shall consist of one or more directors of the Company, and to the extent provided in the resolution or resolutions designating them, shall have and may exercise specific powers of the Board of Directors in the management of the business and affairs of the Company to the extent permitted by statute and shall have power to authorize the seal of the Company to be affixed to all papers that may require it. Such committee or committees shall have such name or names as may be determined from time to time by resolution adopted by the Board of Directors.

**3.7. Powers Denied to Committees.** Committees of the Board of Directors shall not, in any event, have any power or authority to amend the Company's Certificate of Incorporation (except that a committee may, to the extent

authorized in the resolution or resolutions providing for the issuance of shares adopted by the Board of Directors as provided in Section 151(a) of the DGCL, fix the designations and any of the preferences or rights of such shares relating to dividends, redemption, dissolution, any distribution of assets of the Company or the conversion into, or the exchange of such shares for, shares of any other class or classes or any other series of the same or any other class or classes of stock of the Company or fix the number of shares of any series of stock or authorize the increase or decrease of the shares of any series), adopt an agreement of merger or consolidation, recommend to the stockholders the sale, lease, or exchange of all or substantially all of the Company's property and assets, recommend to the stockholders a dissolution of the Company or a revocation of a dissolution, or to amend these by-laws. Further, no committee of the Board of Directors shall have the power or authority to declare a dividend, to authorize the issuance of stock, or to adopt a certificate of ownership and merger pursuant to Section 253 of the DGCL, unless the resolution or resolutions designating such committee expressly so provides.

**3.8. Substitute Committee Member.** In the absence or on the disqualification of a member of a committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not he or they constitute a quorum, may unanimously appoint another member of the Board of Directors to act at the meeting in the place of such absent or disqualified member. Any committee shall keep regular minutes of its proceedings and report the same to the Board of Directors as may be required by the Board of Directors.

**3.9. Compensation of Directors.** The Board of Directors shall have the power to fix the compensation of directors and members of committees of the Board of Directors. The directors may be paid their expenses, if any, of attendance at each meeting of the Board of Directors and may be paid a fixed sum for attendance at each meeting of the Board of Directors or a stated salary as director. No such payment shall preclude any director from serving the Company in any other capacity and receiving compensation therefore. Members of special or standing committees may be allowed like compensation for attending committee meetings.

**3.10. Regular Meetings.** No notice shall be required for regular meetings of the Board of Directors for which the time and place, including virtually, have been fixed.

**3.11. Special Meetings.** Special meetings of the board may be called by the Chairman of the Board, if any, Lead Independent Director of the Board, if any, or the President, on two (2) days' notice to each director, or such shorter period of time before the meeting as will nonetheless be sufficient for the convenient assembly of the directors so notified; special meetings shall be called by the Secretary of the Company in like manner and on like notice, on the written request of three or more directors. Notice need not be given to any director who submits a written waiver of notice signed by him before or after the time stated therein. Attendance of any director at a meeting shall constitute a waiver of notice of such meeting, except when such director attends a meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any special meeting of the directors need be specified in any notice, and unless indicated in the notice thereof, any and all business may be transacted at a special meeting.

**3.12. Quorum.** At all meetings of the Board of Directors, a majority of the whole board shall be necessary and sufficient to constitute a quorum for the transaction of business, and the act of a majority of the directors present at any meeting at which there is a quorum shall be the act of the Board of Directors, except as may be otherwise specifically permitted or provided by statute, or by the Company's Certificate of Incorporation, or by these by-laws. If at any meeting of the Board of Directors there shall be less than a quorum present, a majority of those present may adjourn the meeting from time to time until a quorum is obtained, and no further notice thereof need be given other than by announcement at said meeting that shall be so adjourned.

**3.13. Telephonic Participation in Meetings.** Members of the Board of Directors or any committee designated by the Board of Directors may participate in a meeting of the Board of Directors or committee by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear one another and be heard, and participation in a meeting pursuant to this section shall constitute presence in person at such meeting.

**3.14. Action by Consent.** Unless otherwise restricted by the Company's Certificate of Incorporation or these by-laws, any action required or permitted to be taken at any meeting of the Board of Directors or of any committee thereof may be taken without a meeting if all directors or members of such committee, as the case may be, consent thereto in writing or by electronic transmission, and any consent may be documented, signed, and delivered in any manner permitted by Section 116 of the DGCL. After an action is taken, such written consent or consents relating thereto shall be filed with the minutes of proceedings of the Board of Directors or committee in accordance with applicable law.

## Article IV. — Officers.

**4.1. Positions and Election.** The officers of the Company shall be chosen by the Board of Directors. There shall be a President, a Secretary, and a Treasurer ("Required Officers"), and there may be a Chairman of the Board of Directors, one or more Vice Presidents, one or more Assistant Secretaries, and one or more Assistant Treasurers, as the Board of Directors may elect. Any number of offices may be held by the same person, except that the offices of President and Secretary shall not be held by the same person simultaneously. No officer need be a director.

**4.2. Time of Election.** The Required Officers shall be chosen by the Board of Directors at its first meeting after each annual meeting of stockholders.

**4.3. Additional Officers.** The Board of Directors may appoint such other officers and agents as it shall deem necessary, who shall hold their offices for such terms and shall exercise such powers and perform such duties as shall be determined from time to time by the Board of Directors. The Board of Directors may, from time to time, authorize any officer to appoint and remove subordinate officers and to prescribe the powers and duties thereof.

**4.4. Terms of Office.** Each officer of the Company shall hold office until his successor is chosen and qualified, or until his earlier death, resignation or removal. Any officer elected or appointed by the Board of Directors may be removed at any time by the Board of Directors.

**4.5. Compensation of Officers.** The Board of Directors shall have power to fix the compensation of all officers of the Company. It may authorize any officer, upon whom the power of appointing subordinate officers may have been conferred, to fix the compensation of such subordinate officers.

**4.6. Chairman of the Board.** The Chairman of the Board of Directors shall preside at all meetings of the stockholders and directors and shall have such other duties as may be assigned to him from time to time by the Board of Directors.

**4.7. President.** Unless the Board of Directors otherwise determines, the President shall be the chief executive officer and head of the Company. If there is not a Chairman of the Board, the President shall preside at all meetings of directors and stockholders. Under the supervision of the Board of Directors, the President shall have the general control and management of the Company's business and affairs, subject, however, to the right of the Board of Directors to confer any specific power, except such as may be by statute exclusively conferred on the President, upon any other officer or officers of the Company. The President shall perform and do all acts and things incident to the position of President and such other duties as may be assigned to him from time to time by the Board of Directors.

**4.8. Vice Presidents.** The Vice Presidents shall perform such duties of the President on behalf of the Company as may be respectively assigned to them from time to time by the Board of Directors or by the President. The Board of Directors may designate one of the Vice Presidents as the Executive Vice President, and in the absence or inability of the President to act, such Executive Vice President shall have and possess all of the powers and discharge all of the duties of the President, subject to the control of the Board of Directors.

**4.9. Treasurer.** The Treasurer shall have the care and custody of all the funds and securities of the Company that may come into his hands as Treasurer, and the power and authority to endorse checks, drafts and other instruments for the payment of money for deposit or collection when necessary or proper and to deposit the same to the credit of the Company in such bank or banks or depository as the Board of Directors, or the officers or agents to whom the Board of Directors may delegate such authority, may designate, and he may endorse all commercial documents requiring endorsements for or on behalf of the Company. The Treasurer may sign all receipts and vouchers for the payments made to the Company. The Treasurer shall render an account of his transactions to the Board of Directors as often as the Board of Directors or the committee shall require the same. The Treasurer shall enter regularly in the books to be kept by the Treasurer for that purpose full and adequate account of all moneys received and paid by him on account of the Company. The Treasurer shall perform all acts incident to the position of Treasurer, subject to the control of the Board of Directors. He shall when requested, pursuant to vote of the Board of Directors, give a bond to the Company conditioned for the faithful performance of his duties, the expense of which bond shall be borne by the Company.

**4.10. Secretary.** The Secretary shall keep the minutes of all meetings of the Board of Directors and of the stockholders; he shall attend to the giving and serving of all notices of the Company. Except as otherwise ordered by the Board of Directors, the Secretary shall attest the seal of the Company upon all contracts and instruments executed under such seal and shall affix the seal of the Company thereto and to all certificates of shares of capital stock of the Company. The Secretary shall have charge of the stock certificate book, transfer book and stock ledger, and such other books and papers as the Board of Directors may direct. The Secretary shall, in general, perform all the duties of Secretary, subject to the control of the Board of Directors.

**4.11. Assistant Secretary.** The Board of Directors or any two of the officers of the Company acting jointly may appoint or remove one or more Assistant Secretaries of the Company. Any Assistant Secretary upon his appointment shall perform such duties of the Secretary, and also any and all such other duties as the Board of Directors or the President or the Executive Vice President or the Treasurer or the Secretary may designate.

**4.12. Assistant Treasurer.** The Board of Directors or any two of the officers of the Company acting jointly may appoint or remove one or more Assistant Treasurers of the Company. Any Assistant Treasurer upon his appointment shall perform such duties of the Treasurer, and also any and all such other duties as the Board of Directors or the President or the Executive Vice President or the Treasurer or the Secretary may designate.

## Article V. — Stock.

**5.1. Stock.** The stock of the Company shall be represented by certificates as described in this Article 5, provided that the Company may issue uncertificated stock. Notwithstanding the foregoing, every holder of stock already represented by certificates, and upon request every holder of uncertificated stock, shall be entitled to a certificate or certificates of stock of the Company in such form as the Board of Directors may from time to time prescribe. The certificates of stock of the Company shall be numbered and shall be entered in the books of the Company as they are issued. They shall certify the holder's name and number and class of shares and shall be signed by, or in the name of, the Company by any two authorized officers of the Company. If such certificate is countersigned (l) by a transfer agent other than the Company or its employee, or, (2) by a registrar other than the Company or its employee, the signature of the officers of the Company and the corporate seal may be facsimiles. In case any officer or officers who shall have signed, or whose facsimile signature or signatures shall have been used on, any such certificate or certificates shall cease to be such officer or officers of the Company, whether because of death, resignation or otherwise, before such certificate or certificates shall have been delivered by the Company, such certificate or certificates may nevertheless be adopted by the Company and be issued and delivered as though the person or persons who signed such certificate or certificates or whose facsimile signature shall have been used thereon had not ceased to be such officer or officers of the Company.

**5.2. Fractional Share Interests.** The Company may, but shall not be required to, issue fractions of a share. If the Company does not issue fractions of a share, it shall (i) arrange for the disposition of fractional interests by those entitled thereto, (ii) pay in cash the fair value of fractions of a share as of the time when those entitled to receive such fractions are determined, or (iii) issue scrip or warrants in registered or bearer form that shall entitle the holder to receive a certificate for a full share upon the surrender of such scrip or warrants aggregating a full share. A certificate for a fractional share shall, but scrip or warrants shall not unless otherwise provided therein, entitle the holder to exercise voting rights, to receive dividends thereon, and to participate in any of the assets of the Company in the event of liquidation. The Board of Directors may cause scrip or warrants to be issued subject to the conditions that they shall become void if not exchanged for certificates representing full shares before a specified date, or subject to the conditions that the shares for which scrip or warrants are exchangeable may be sold by the Company and the proceeds thereof distributed to the holders of scrip or warrants, or subject to any other conditions that the Board of Directors may impose.

**5.3. Transfers of Stock.** Subject to any transfer restrictions then in force, the shares of stock of the Company shall be transferable only upon its books by the holders thereof in person or by their duly authorized attorneys or legal representatives and upon such transfer the old certificates shall be surrendered to the Company by the delivery thereof to the person in charge of the stock and transfer books and ledgers or to such other person as the directors may designate by whom they shall be canceled and new certificates shall thereupon be issued. The Company shall be entitled to treat the holder of record of any share or shares of stock as the holder in fact thereof and accordingly shall not be bound to recognize any equitable or other claim to or interest in such share on the part of any other person whether or not it shall have express or other notice thereof save as expressly provided by the laws of Delaware.

**5.4. Record Date.** For the purpose of determining the stockholders entitled to notice of or to vote at any meeting of stockholders or any adjournment thereof, the Board of Directors may fix, in advance, a record date, that shall not be more than sixty (60) days nor less than ten (10) days before the date of such meeting. For the purpose of determining the stockholders entitled to receive payment of any dividend or other distribution or the allotment of any rights, or entitled to exercise any rights in respect of any change, conversion, or exchange of stock or for the purpose of any other lawful action, the Board of Directors may fix, in advance, a record date, that shall not be more than sixty (60) days prior to any other action. If no such record date is fixed by the Board of Directors, the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held; the record date for determining stockholders for any other purpose shall be at the close of business on the day on which the Board of Directors adopts the resolution relating thereto. A determination of stockholders of record entitled to notice of or to vote at any meeting of stockholders shall apply to any adjournment of the meeting; provided, however, that the Board of Directors may fix a new record date for the adjourned meeting. **5.5. Transfer Agent and Registrar.** The Board of Directors may appoint one or more transfer agents or transfer clerks and one or more registrars and may require all certificates of stock to bear the signature or signatures of any of them.

**5.6. Dividends.**

1. Power to Declare. Dividends upon the capital stock of the Company, subject to the provisions of the Company's Certificate of Incorporation, if any, may be declared by the Board of Directors at any regular or special meeting, pursuant to law. Dividends may be paid in cash, in property, or in shares of the capital stock, subject to the provisions of the Company's Certificate of Incorporation and the laws of Delaware.

2. Reserves. Before payment of any dividend, there may be set aside out of any funds of the Company available for dividends such sum or sums as the directors from time to time, in their absolute discretion, think proper as a reserve or reserves to meet contingencies, or for equalizing dividends, or for repairing or maintaining any property of the Company, or for such other purpose as the directors shall think conducive to the interest of the Company, and the directors may modify or abolish any such reserve in the manner in which it was created.

**5.7. Lost, Stolen, or Destroyed Certificates.** No certificates for shares of stock of the Company shall be issued in place of any certificate alleged to have been lost, stolen, or destroyed, except upon production of such evidence of the loss, theft, or destruction and upon indemnification of the Company and its agents to such extent and in such manner as the Board of Directors may from time to time prescribe.

**5.8. Inspection of Books.** The stockholders of the Company, by a majority vote at any meeting of stockholders duly called, or in case the stockholders shall fail to act, the Board of Directors shall have power from time to time to determine whether and to what extent and at what times and places and under what conditions and regulations the accounts and books of the Company (other than the stock ledger) or any of them, shall be open to inspection of stockholders; and no stockholder shall have any right to inspect any account or book or document of the Company except as conferred by statute or authorized by the Board of Directors or by a resolution of the stockholders.

## Article VI. — Miscellaneous Management Provisions.

**6.1. Checks, Drafts, and Notes.** All checks, drafts, or orders for the payment of money, and all notes and acceptances of the Company shall be signed by such officer or officers, or such agent or agents, as the Board of Directors may designate.

**6.2. Notices.**

1. Notices to directors may, and notices to stockholders shall, be in writing and delivered personally or mailed to the directors or stockholders at their addresses appearing on the books of the Company. Notice by mail shall be deemed to be given when the notice is deposited in the U.S. mail, postage prepaid. Notice to directors may also be given orally by telephone, in person or by electronic transmission in accordance with applicable law.

2. Whenever any notice is required to be given under the provisions of any applicable statute or of the Company's Certificate of Incorporation or of these by-laws, a written waiver of notice, signed by the person or persons entitled to said notice, whether before or after the time stated therein or the meeting or action to which such notice relates, shall be deemed equivalent to notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting except when the person attends a meeting for the express purpose of objecting, at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened.

**6.3. Conflict of Interest.** No contract or transaction between the Company and one or more of its directors or officers, or between the Company and any other corporation, partnership, association, or other organization in which one or more of its directors or officers are directors or officers, or have a financial interest, shall be void or voidable solely for this reason, or solely because the director or officer is present at or participates in the meeting of the Board of Directors of or committee thereof that authorized the contract or transaction, or solely because his, her or their votes are counted for such purpose, if: (i) the material facts as to his relationship or interest and as to the contract or transaction are disclosed or are known to the Board of Directors or the committee and the Board of Directors or committee in good faith authorizes the contract or transaction by the affirmative vote of a majority of the disinterested directors, even though the disinterested directors be less than a quorum; or (ii) the material facts as to his or her relationship or interest and as to the contract or transaction are disclosed or are known to the stockholders of the Company entitled to vote thereon, and the contract or transaction as specifically approved in good faith by vote of such stockholders; or (iii) the contract or transaction is fair as to the Company as of the time it is authorized, approved, or ratified, by the Board of Directors, a committee or the stockholders. Common or interested directors may be counted in determining the presence of a quorum at a meeting of the Board of Directors or of a committee that authorizes the contract or transaction.

**6.4. Voting of Securities owned by the Company.** Subject always to the specific directions of the Board of Directors, (i) any shares or other securities issued by any other corporation and owned or controlled by the Company may be voted in person at any meeting of security holders of such other corporation by the President of the Company if he is present at such meeting, or in his absence by the Treasurer of the Company if he is present at such meeting, and (ii) whenever, in the judgment of the President, it is desirable for the Company to execute a proxy or written consent in respect to any shares or other securities issued by any other corporation and owned by the Company, such proxy or consent shall be executed in the name of the Company by the President, without the necessity of any authorization by the Board of Directors, affixation of corporate seal or countersignature or

attestation by another officer, provided that if the President is unable to execute such proxy or consent by reason of sickness, absence from the United States or other similar cause, the Treasurer may execute such proxy or consent. Any person or persons designated in the manner above stated as the proxy or proxies of the Company shall have full right, power and authority to vote the shares or other securities issued by such other corporation and owned by the Company the same as such shares or other securities might be voted by the Company.

## Article VII. — Indemnification.

**7.1. Right to Indemnification.** Each person who was or is made a party or is threatened to be made a party to or is otherwise involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative (a "Proceeding"), by reason of being or having been a director or officer of the Company or serving or having served at the request of the Company as a director, trustee, officer, employee or agent of another corporation or of a partnership, joint venture, trust or other enterprise, including service with respect to an employee benefit plan (an "Indemnitee"), whether the basis of such proceeding is alleged action or failure to act in an official capacity as a director, trustee, officer, employee or agent or in any other capacity while serving as a director, trustee, officer, employee or agent, shall be indemnified and held harmless by the Company to the fullest extent authorized by the DGCL, as the same exists or may hereafter be amended (but, in the case of any such amendment, only to the extent that such amendment permits the Company to provide broader indemnification rights than permitted prior thereto) (as used in this Article 7, the "Delaware Law"), against all expense, liability and loss (including attorneys' fees, judgments, fines, ERISA excise taxes or penalties and amounts paid in settlement) reasonably incurred or suffered by such Indemnitee in connection therewith and such indemnification shall continue as to an Indemnitee who has ceased to be a director, trustee, officer, employee, or agent and shall inure to the benefit of the Indemnitee's heirs, executors, and administrators; provided, however, that, except as provided in Section 7.2 hereof with respect to Proceedings to enforce rights to indemnification, the Company shall indemnify any such Indemnitee in connection with a Proceeding (or part thereof) initiated by such Indemnitee only if such Proceeding (or part thereof) was authorized by the Board of Directors of the Company. The right to indemnification conferred in this Article 7 shall be a contract right and shall include the right to be paid by the Company the expenses (including attorneys' fees) actually and reasonably incurred in defending any such Proceeding in advance of its final disposition (an "Advancement of Expenses"); provided, however, that, if the Delaware Law so requires, an Advancement of Expenses incurred by an Indemnitee shall be made only upon delivery to the Company of an undertaking (an "Undertaking"), by or on behalf of such Indemnitee, to repay all amounts so advanced if it shall ultimately be determined by final judicial decision from which there is no further right to appeal (a "Final Adjudication") that such Indemnitee is not entitled to be indemnified for such expenses under this Article 7 or otherwise.

**7.2. Right of Indemnitee to Bring Suit.** If a claim under Section 7.1 hereof is not paid in full by the Company within 60 days after a written claim has been received by the Company, except in the case of a claim for an Advancement of Expenses, in which case the applicable period shall be 20 days, the Indemnitee may at any time thereafter bring suit against the Company to recover the unpaid amount of the claim. If successful in whole or in part in any such suit, or in a suit brought by the Company to recover an Advancement of Expenses pursuant to the terms of an Undertaking, the Indemnitee shall be entitled to be paid also the expense of prosecuting or defending such suit. In any suit brought by the Indemnitee to enforce a right to indemnification hereunder (but not in a suit brought by the Indemnitee to enforce a right to an Advancement of Expenses) it shall be a defense that the Indemnitee has not met the applicable standard of conduct set forth in the Delaware Law. In addition, any suit by the Company to recover an Advancement of Expenses pursuant to the terms of an Undertaking the Company shall be entitled to recover such expenses upon a Final Adjudication that, the Indemnitee has not met the applicable standard of conduct set forth in the Delaware Law. Neither the failure of the Company (including its Board of Directors, independent legal counsel, or its stockholders) to have made a determination prior to the commencement of such suit that indemnification of the Indemnitee is proper in the circumstances because the Indemnitee has met the applicable standard of conduct set forth in the Delaware Law, nor an actual determination by the Company (including its Board of Directors, independent legal counsel, or its stockholders) that the Indemnitee has not met such applicable standard of conduct, shall create a presumption that the Indemnitee has not met the applicable standard of conduct or, in the case of such a suit brought by the Indemnitee, be a defense to such suit. In any suit brought by the Indemnitee to enforce a right to indemnification or to an Advancement of Expenses hereunder, or by the Company to recover an Advancement of Expenses pursuant to the terms of an Undertaking, the burden of proving that the Indemnitee is not entitled to be indemnified, or to such Advancement of Expenses, under this Article 7 or otherwise shall be on the Company.

**7.3. Non-Exclusivity of Rights.** The rights to indemnification and to the Advancement of Expenses conferred in this Article 7 shall not be exclusive of any other right that any person may have or hereafter acquire under any statute, the Company's Certificate of Incorporation, these by-laws, agreement, vote of stockholders or disinterested directors or otherwise both as to action in their official capacity and as to action in another capacity while holding office. The Company is specifically authorized to enter into individual contracts with any or all of its directors, officers, employees or agents respecting indemnification and advances, to the fullest extent not prohibited by the DGCL.

**7.4. Insurance.** The Company may purchase and maintain insurance, at its expense, on behalf of any person who is or was a director, officer, employee or agent of the Company, or is or was serving at the request of the Company as a director, officer, employee, or agent of another corporation, partnership, joint venture, trust or other enterprise against any expense, liability or loss, whether or not the Company would have the power to indemnify such person against such expense, liability or loss under this Article 7 or under the Delaware Law.

**7.5. Indemnification of Employees and Agents of the Company.** The Company may, to the extent authorized from time to time by the Board of Directors, grant rights to indemnification, and to the Advancement of Expenses, to any employee or agent of the Company to the fullest extent of the provisions of this Article 7 with respect to the indemnification and Advancement of Expenses of directors and officers of the Company.

## Article VIII. — Amendments.

**8.1. Amendments**. Subject always to any limitations imposed by the Company's Certificate of Incorporation, these by-laws may be altered, amended, or repealed, or new by-laws may be adopted, only by (i) the affirmative vote of the holders of at least a majority of the outstanding voting stock of the Company, provided that the affirmative vote of the holders of at least 67% of the outstanding voting stock of the Company shall be required for any such alteration, amendment, repeal, or adoption that would affect or be inconsistent with the provisions of Sections 2.11, 3.1, 3.3 and this Section 8.1 (in each case, in addition to any separate class vote that may be required pursuant to the terms of any then outstanding preferred stock of the Company), or (ii) by resolution of the Board of Directors duly adopted by not less than a majority of the directors then constituting the full Board of Directors.

**Exhibit 10.2**

**PORTIONS HEREIN IDENTIFIED BY [***] HAVE BEEN EXCLUDED FROM THIS EXHIBIT BECAUSE THE EXCLUDED INFORMATION IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.**

# Supply and Manufacturing Services Agreement

Between

Amicus Therapeutics, Inc.
3675 Market Street
Philadelphia, PA 19104

and

WuXi Biologics (Hong Kong) Limited
Flat/RM826, 8/F Ocean Centre Harbour City,
5 Canton Road TST, Hong Kong

WuXi Biologics Ireland Limited
Mullagharlin, Dundalk, Co Louth
A91 X56F, Ireland

and

WuXi Biologics Germany GmbH
Chempark Leverkusen
Building D 201, Tor 133
51368 Leverkusen Germany

CONFIDENTIAL

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This Supply and Manufacturing Services Agreement ("Agreement") is entered into on March 31, 2023 ("Effective Date") between Amicus Therapeutics, Inc. having a place of business at 3675 Market Street, Philadelphia, PA 19104 ("AMICUS"); and WuXi Biologics (Hong Kong) Limited having a place of business at Flat/RM826, 8/F Ocean Centre Harbour City, 5 Canton Road TST, Hong Kong, WuXi Biologics Ireland Limited Mullagharlin, Dundalk, Co Louth A91 X56F, Ireland and WuXi Biologics Germany GmbH, Chempark Leverkusen, Building D 201, Tor 133, 51368 Leverkusen Germany (collectively "WUXI BIOLOGICS") (referred to herein individually as a "Party" and collectively as the "Parties").

WHEREAS, the Parties entered into a Manufacturing and Supply Agreement on December 5, 2018 where WUXI BIOLOGICS manufactured and supplied to AMICUS, AMICUS' proprietary biological drug substance and finished drug product;

WHEREAS, the Parties or the Affiliates have entered into a Master Services Agreement and any amendments thereto having an effective date of July 14, 2014 for development services and duly amended thereafter; and

WHEREAS, the Parties now wish to continue their relationship by terminating the Manufacturing and Supply Agreement as of the Effective Date of this Agreement and have the placement of any new orders, services and supplies be governed under this Agreement.

NOW, THEREFORE, in consideration of the foregoing and the mutual covenants and promises set forth herein and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the parties agree as follows:

1. Definitions

1.1 "Active Pharmaceutical Ingredient" ("API") means the active pharmaceutical ingredient or drug substance, designated herein as ATB200 made according to the Specifications.

1.2 "Adverse Regulatory Development" means [***].

1.3 "Affiliate" means any individual, corporation, limited liability company, partnership, joint venture, association or other legal entity ("Person") who, directly or indirectly through one or more intermediaries, Controls, is Controlled by, or is under common Control with any other Person. "Control" means (a) the direct or indirect legal or beneficial ownership of more than fifty percent (50%) of (i) the ownership interests in a Person or (ii) the outstanding voting rights in a Person or (b) the power to otherwise direct the business activities of a Person.

1.4 "Applicable Laws" means all laws, regulations, regulatory guidance and industry standards applicable to the manufacture, storage, distribution and sale of Product or components, including API, thereof in any territory.

1.5 "Batch" [***] undergoing the number of IMAC cycles designated in a Firm Order or a specific quantity of Units of Product produced from a single Run.

1.6 "Batch Certificate" or "Certified Batch" means that (i) each Batch of API or Product has undergone a full qualitative and quantitative analysis of API and other relevant constituents to ensure that the quality of the API and Product complies with the requirements of the marketing authorization of the importing country (ii) the Batch Certificate must attest that the Batch meets the specifications and has been manufactured in accordance with the marketing authorization of the importing country, detailing the specifications of the API / Product, the analytical methods referenced, the analytical

results obtained, and containing a statement that the batch processing, packaging and quality control records were reviewed and found in conformity with GMP and (iii) a completed Batch Disposition Sheet that is approved by AMICUS, which approval will not be unreasonably withheld, delayed, or conditioned, and for which an example is set forth in Appendix G. Batch Disposition Sheet.

1.7 “Binding Quarter” means Binding API Quarter and Binding Product Quarter as set forth in Sections 3.1.1 and 3.2.1, respectively.

1.8 “Bill of Materials or “BOM” means an itemized list of RmRC components for an API Batch, including batch quantities and raw material unit costs. An illustrative BOM template is provided in Appendix D. Bill of Materials.

1.9 “Business Day” means a day on which banking institutions in New York City, New York are open for business.

1.10 “Cell Line” means the [***], and which have been purchased by AMICUS for expression of the API.

1.11 “Consumable” means all bags, liners and other single use or regularly replaced materials that are required to perform the Manufacturing Process (excluding Raw Materials and Resins).

1.12 “Commercially Reasonable Efforts” as applied to each Party’s obligations hereunder, shall mean diligent and consistent application of those efforts and resources commonly associated with the customary business practice and standards in the pharmaceutical manufacturing industry and incurring a financial detriment to the extent, or spending only what would be, reasonable in relation to the benefit obtained by the other Party while considering the financial circumstances of the Party incurring the detriment.

1.13 “Facility” means WUXI BIOLOGICS’ testing, manufacturing, packaging and warehousing GMP facilities (including relevant equipment) as set forth in Appendix H.

1.14 "GMP" or “cGMP” means all current Good Manufacturing Practices as required by Applicable Law related to the manufacture, testing, processing, packaging and distribution of pharmaceutical products.

1.15 “Intellectual Property” means patents, trademarks, service marks, design rights, copyrights, including applications for any of the foregoing, all rights in know-how, trade or business names and other rights or forms of protection of a similar nature or having equivalent or similar effect to any of these which may subsist anywhere in the world whether registerable or not. For the purposes of this definition, know-how shall mean any current and future scientific, technical, or commercial information, results and data of any type whatsoever, in any tangible and intangible form, that is not in the public domain or otherwise publicly known, including, without limitation, discoveries, inventions, trade secrets, databases, practices, protocols, regulatory filings, methods, processes, techniques, biological and other materials, reagents, specifications, formulations, formulae, data (including pharmacological, biological, chemical, toxicological and clinical information, analytical, quality control and stability data, studies and procedures), manufacturing process and development information, results and data, whether or not patentable.

1.16 “Latent Defect” means a non-conformity of a Batch from the Specifications not reasonably ascertainable upon inspection at Delivery.

1.17 “Manufacturing Documentation” means all records describing or related to the Manufacturing Process, other than those embodied in the Master Production Record.

1.18 “Manufacturing Process” means process for manufacturing the API or Product.

1.19 “Master Cell Bank” means AMICUS’ reference deposit or collection of vials of Modified Cells, from which the Working Cell Bank is derived.

1.20 “Master Production Record” (“MPR”) means the document, proposed by WUXI BIOLOGICS and approved by AMICUS, that defines the manufacturing methods, test methods, specifications, materials, and other procedures, directions and controls associated with the manufacture and testing of the API or Product; and shall further include or incorporate by reference, without limitation, Materials Specifications, in process and final sampling standards, equipment and instrumentation specifications, standard operating procedures, including, without limitation, those for in-process quality control testing, packaging and aliquoting procedures.

1.21 “Materials Specification” (“MS”) means a document detailing the specifications for each Raw Material, Resin or Consumable, each as mutually approved by the Parties.

1.22 “Modified Cells” means any and all modifications, derivatives, components or progeny of the Cell Line utilizing or incorporating AMICUS’ technology that express API.

1.23 “MSA” means Master Services Agreement and any amendments thereto between the Parties or its Affiliates having an effective date of July 14, 2014.

1.24 “Person” means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government, or any agency or political subdivision thereof.

1.25 “Price” means the price charged by WUXI BIOLOGICS in U.S. Dollars to Deliver to AMICUS a Batch of API or Unit of Product which equals [***].

1.26 “Price Discount” means the discount to the Price [***].

1.27 “Price Premium” means the increase to the Price [***].

1.28 “Product” or “Drug Product” means the API formulated as a finished dosage form according to the Specifications.

1.29 “Quality Agreement” means the agreement described in Section 2.7.

1.30 “Quality Failure” means [***].

1.31 “Raw Materials” means all ingredients, intermediates, solvents, cell culture (growth) media and other components of the API or Product required to perform the Manufacturing Process (excluding API and any Consumables and Resins).

1.32 “Reference Materials” means API or Product that is generated from a Run that meets Specifications and stored in a controlled manner to be used as a standard for analytical testing purposes.

1.33 “Regulatory Authority” includes the Food and Drug Administration (“FDA”) in the United States, the Pharmaceuticals and Medical Devices Agency (“PMDA”) in Japan, the European Medicines Agency (“EMA”) in the European Union, Health Canada, the Therapeutic Goods Administration (“TGA”) in Australia and their counterparts in all other territories involved in regulating any aspect of the development, manufacture, in-country testing, labeling, packaging, marketing approval, sale, distribution, shipment and/or use of the API and Product.

1.34 “Regulatory Filings” means any or all filings and applications submitted to Regulatory Authorities for the purpose of registering the Manufacturing Process and the Product as required by Applicable Law.

1.35 [***]

1.36 “Resin” means all chromatographic media intended to purify the API described in the Master Production Record.

1.37 “RmRC” means Raw Materials, Resins and Consumables.

1.38 “RmRC Unit Costs” equals the price paid by WUXI BIOLOGICS, [***].

1.39 “Rolling Forecast” means Rolling API Forecast and Rolling Product Forecast as set forth in Section 3.1and 3.2, respectively.

1.40 “Run” means one complete operation at the WUXI BIOLOGICS Facility of the Manufacturing Process to make API or Product according to the Master Production Record.

1.41 “Service Fee” equals [***].

1.42 “Short Batch” means a Batch of API but one undergoing less than the number of IMAC cycles designated in a Firm Order but in no case less than [***]. References to Batch herein also apply to Short Batches unless specifically differentiated.

1.43 “Specifications” means the manufacturing processes, specifications, yields, timelines, acceptance criteria, test procedures, packaging, storage conditions and delivery of GMP API and GMP Product according to Sections 2 and 3, Appendix A. API and Product Specifications, Materials Specifications, Batch Certificates, Rolling Forecasts, Regulatory Filings, the Quality Agreement, Applicable Laws and as otherwise set forth in this Agreement.

1.44 “Storage Guidelines” means procedures for packaging, preserving, monitoring and storing any and all AMICUS property, including the RmRC, Cell Line, Master Cell Bank, Working Cell Bank, API and Product as set forth in the Specifications.

1.45 “Subcontractor” means any Third Party that WUXI BIOLOGICS contracts with to perform any of its obligations under this Agreement after having received signed written consent from AMICUS, which consent shall not be unreasonably withheld, delayed, or conditioned.

1.46 “Third Party” means any Person other than a Party or any of its Affiliates.

1.47 “Unit” means one vial of the Product comprising an amount of API measured in milligrams as further described in the Specifications.

1.48 [***].

1.49 “Vial Thaw” means thawing of Modified Cells from a Working Cell Bank in order to commence a Run for API.

1.50 “Working Cell Bank” means serially sub-cultivated cells derived from the Master Cell Bank and used to establish seed cultures of the Modified Cells upon commencement of the Manufacturing Process.

2. Supply

2.1 Commitment to Supply. AMICUS retains WUXI BIOLOGICS on a non-exclusive basis to supply API and/or Product according to its Rolling Forecasts and WUXI

BIOLOGICS shall use Commercially Reasonable Efforts to supply said API and Product solely to AMICUS.

2.2 Facilities. WUXI BIOLOGICS will maintain all equipment, RmRC and staff necessary to manufacture API and Product at the Facility and will not change the location of Facility or use any additional facility without AMICUS' written approval, which will not be unreasonably withheld, delayed, or conditioned.

2.3 Ownership and Control of Cell Line, Modified Cells and Cell Banks. Title to Cell Line, Modified Cells, Master Cell Bank, and Working Cell Bank shall at all times remain solely with AMICUS and (i) shall not be included in WUXI BIOLOGICS' sales inventory but may be included in its inventory for purposes of tracking performance under this Agreement (ii) shall not be represented by WUXI BIOLOGICS as WUXI BIOLOGICS' collateral (iii) shall not be pledged or mortgaged by WUXI BIOLOGICS and (iv) shall not permit any lien, encumbrance or other cloud on title ("Liens") to be attached thereto, other than those granted by AMICUS. WUXI BIOLOGICS shall notify AMICUS of any WUXI BIOLOGICS' Liens within three (3) Business Days after WUXI BIOLOGICS of learning of such and shall have them removed or terminated within ten (10) days thereafter. If a WUXI BIOLGOICS' Lien is not removed or terminated within such period, AMICUS may take such action as it determines to remove or terminate such WUXI BIOLGOICS' Lien at WUXI BIOLOGICS' expense.

2.3.1. WUXI BIOLOGICS shall treat the Cell Line, Master Cell Bank, and Working Cell Bank as AMICUS' Confidential Information and shall not use them for any purpose except to fulfill its obligations under this Agreement.

2.3.2. WUXI BIOLOGICS shall not transfer the Cell Line, Master Cell Bank, or Working Cell Bank to any Third Party without prior written authorization from AMICUS.

2.3.3. WUXI BIOLOGICS shall use Commercially Reasonable Efforts to secure all Cell Lines, Master Cell Banks, or Working Cell Banks at Facility in accordance with the Storage Guidelines.

2.3.4. WUXI BIOLOGICS shall, to the extent possible, label the Cell Line, Modified Cells, Master Cell Bank, and Working Cell Bank (or the vessels containing any of such materials) as the property of AMICUS.

2.3.5. Upon AMICUS' written request (and expense), WUXI BIOLOGICS shall return all or specified portions of the Cell Line, Master Cell Bank, or Working Cell Bank to AMICUS or its designee.

2.4 Ownership and Control of RmRC, API and Product. Subject to Sections 2.5.1 and 4.5, Title to RmRC, API and Product shall transfer to AMICUS upon invoicing by WUXI BIOLOGICS and thereafter shall not be (i) included in WUXI BIOLOGICS's inventory (ii) represented by WUXI BIOLOGICS as WUXI BIOLOGICS' collateral (iii) pledged or mortgaged by WUXI BIOLOGICS (iv) permitted by WUXI BIOLOGICS to be attached by its creditors and (v) retained by WUXI BIOLOGICS in any manner including as represented on shipping and export documents.

2.5 RmRC. WUXI BIOLOGICS shall (i) procure all RmRC required to manufacture API and Product and (ii) be responsible for ensuring that RmRC conforms to the Materials Specifications.

2.5.1. Upon 90 days' written notice to WUXI BIOLOGICS, AMICUS may (at its cost) elect to procure and deliver to WUXI BIOLOGICS some or all of the RmRC required to manufacture API and Product provided that any existing supplies of RmRC procured by WUXI BIOLOGICS shall first be utilized in manufacturing API and Product.

2.6 Risk of Loss and Insurance. Notwithstanding AMICUS' ownership of title pursuant to Sections 2.3 and 2.4, WUXI BIOLOGICS shall bear all risk of loss or damage to RmRC, and AMICUS shall purchase sufficient insurance not less than the Price to cover all API and Product stored in WUXI BIOLOGICS' facilities to cover all risk of loss or damage until Delivery.

2.7 Quality Agreement. Representatives of the Parties' quality assurance departments shall meet to develop and approve a Quality Agreement by the later of (1) ninety (90) days from the Effective Date or (2) prior to the placement of the first Firm Order under Section 3.3. The Quality Agreement shall be subject to and be without prejudice to this Agreement and shall complement the terms of this Agreement on matters relating to quality of the Product; provided however, that if there is a direct conflict between the terms of the Quality Agreement and this Agreement that pertain directly to the quality of the Product, the Quality Agreement shall prevail over this Agreement, provided however that they shall be no less favorable to Amicus than those herein. The Quality Agreement may be modified from time to time by mutual written agreement. Once executed by both Parties, the Quality Agreement shall be incorporated into and made part of this Agreement by this reference.

2.8 Retention of Samples. WUXI BIOLOGICS shall retain and record reserve samples of all Raw Materials, samples generated during production of Batches and Batch Samples as set forth in the Materials Specifications, a record of standard operating procedures, a Master Production Record, or as otherwise agreed in writing with AMICUS.

2.9 Designated Vendors and Subcontractors

2.9.1. Approval of Designated Vendors. If AMICUS elects to require WUXI BIOLOGICS to (i) procure RmRC from Third Parties designated and approved by AMICUS in writing (the "Designated Vendors"), or (ii) subcontract a portion of the Services to Third Parties designated and approved by AMICUS in writing (the "Designated Subcontractors"), which Third Parties in each case of (i) and (ii) are not then under contract with WUXI BIOLOGICS, AMICUS shall so advise WUXI BIOLOGICS in writing, and WUXI BIOLOGICS shall use commercially reasonable efforts to establish supply arrangements or subcontracting arrangements with such Designated Vendors or Designated Subcontractors (which supply arrangements or subcontracting arrangements shall comply with the terms of this Agreement, the Quality Agreement and any other related agreements) and the terms and conditions of such supply shall be subject to the approval of AMICUS.

2.9.2. Notification. WUXI BIOLOGICS shall promptly advise AMICUS if it encounters or is advised of (i) RmRC supply problems, including written notice of material delays and/or delivery of non-conforming RmRC from AMICUS' Designated

Vendors, or (ii) problems with the services subcontracted to AMICUS' Designated Subcontractors; and (except to the extent RmRC or subcontracted services are provided by AMICUS) WUXI BIOLOGICS shall use Commercially Reasonable Efforts to reduce and eliminate any supply or subcontracting problems from such Designated Vendors or Designated Subcontractors (and AMICUS shall provide WUXI BIOLOGICS with reasonable assistance in connection therewith). For clarity, WUXI BIOLOGICS will not be responsible for any delays caused by AMICUS' Designated Vendors or Designated Subcontractors, and may reasonably request that AMICUS select a different Designated Vendor or Designated Subcontractor after repeated problems with any such Designated Vendor or Designated Subcontractor.

2.9.3. Certification and Audit. AMICUS shall audit and certify the Designated Vendors and Designated Subcontractors on an annual basis, in accordance with the Quality Agreement and provide WUXI BIOLOGICS with such documentation upon request.

2.10 Notice of Nonconformity, Acceptance and Rejection. For a period of [***] after the Delivery of a Batch (or, in the case of Latent Defects, [***] of the Latent Defect), AMICUS shall have the right to reject any Batch it reasonably believes is non-conforming to the Specifications upon written notice to WUXI BIOLOGICS, such notice to include the reason(s) for the rejection and to be accompanied with any supporting documentation or other evidence. Within [***] thereafter, WUXI BIOLOGICS shall respond to AMICUS in writing whether it agrees with AMICUS' notice of non-conformity. After the applicable time periods set forth in this Section, all Product(s) will be deemed accepted by AMICUS and materially compliant with all required Material Specifications, the Quality Agreement, cGMP, and Applicable Laws.

2.10.1. If a Short Batch meets the Specifications in every other regard except for the number of IMAC cycles, it shall not be deemed non-conforming but shall constitute a Supply Delay for the amount of API equal to the difference between the amount ordered in a Firm Order and the amount Delivered on-time in the Short Batch.

2.10.2. A Batch running less than [***] IMAC cycles shall be deemed non-conforming.

2.11 Disputes over Conformity. If WUXI BIOLOGICS disputes a notice of non-conformity, the Parties' quality assurance representatives shall make a good faith attempt to resolve the dispute.

2.11.1. Third Party Evaluation. If the dispute is not resolved within 45 (forty-five) Business Days, a sample of the non-conforming Batch and another sample that both Parties stipulate is conforming will be evaluated against the Specifications by a mutually agreeable Third Party laboratory whose results shall be final and binding on the Parties. The cost of this evaluation shall be borne by the Party whose position on conformity was controverted by the Third Party evaluation, provided that, if the non-conformity was due to a defect in materials provided by or on behalf of AMICUS (*e.g.*, defective cell lines) not reasonably ascertainable by WUXI BIOLOGICS in advance, then AMICUS shall pay for the evaluation and the non-conforming Batch. The Parties hereby designate [***] to be the Third

Party laboratory since they have validated the analytical methods for API and Product.

2.11.2. Cost of Disposal. WUXI BIOLOGICS shall bear the cost of returning to AMICUS or disposing of any such non-conforming Batch (at AMICUS' election).

2.11.3. Non-Conforming API Batch. Subject to Section 2.11.7, if a Batch of API is found to be non-conforming under Sections 2.10, 2.11 or 2.11.1, then WUXI BIOLOGICS shall, at AMICUS' election, either (i) use best efforts following the determination of non-conformity, to commence a Run as soon as possible and in no case later than [***], subject to capacity and raw material availability to replace such non-conforming Batch with a conforming Batch ("Replacement API Batch") at no additional cost to AMICUS or (ii) refund the Price paid for such non-conforming Batch.

2.11.4. Non-Conforming Replacement API Batch. Subject to Section 2.11.7, if a Replacement API Batch is also found to be non-conforming under Sections 2.11 or 2.11.1, AMICUS may elect to (i) require WUXI BIOLOGICS to (a) promptly refund the Price paid for such non-conforming Batch and (b) use best efforts following the determination of non-conformity, to commence a Run as soon as possible and in no case later than 180 days, subject to capacity and raw material availability to replace such non-conforming Replacement API Batch with a conforming second Replacement API Batch at no additional cost to AMICUS.

2.11.5. Non-Conforming Product Batch. Subject to Section 2.11.7, if a Batch of Product is found to be non-conforming under Sections 2.10, 2.11 or 2.11.1, then WUXI BIOLOGICS shall, at AMICUS' election, (i) use best efforts following the determination of non-conformity, to commence a Run as soon as possible and in no case later than 120 days subject to capacity and raw material availability to replace such non-conforming Batch with a conforming Batch ("Replacement Product Batch") at no additional cost to AMICUS other than paying WUXI BIOLOGICS 50% of the Price of replacement API (manufactured by WUXI BIOLOGICS) to be used in the Replacement Product Batch or (ii) refund to AMICUS the Price paid for such non-conforming Batch of Product.

2.11.6. Non-Conforming Replacement Product Batch. Subject to Section 2.11.7, if a Replacement Product Batch of Product is also found to be non-conforming under Sections 2.10, 2.11 or 2.11.1, AMICUS may elect to (i) require WUXI BIOLOGICS to (a) promptly refund the Price paid for such non-conforming Batch and (b) use best efforts following the determination of non-conformity, to commence a Run as soon as possible and in no case later than 120 days, subject to capacity and raw material availability to replace such non-conforming Replacement Product Batch with a conforming second Replacement Product Batch at no additional cost to AMICUS.

2.11.7. Non-Conforming Batches due to AMICUS Process Changes. If a post-PPQ, commercial Batch is found to be non-conforming solely due to a change in the process requested by AMICUS that was not first validated in a separate development batch, then AMICUS will be liable for paying for such non-conforming Batch. If AMICUS requests WUXI BIOLOGICS to replace such non-conforming Batch under these circumstances, WUXI BIOLOGICS shall replace

such non-conforming Batch and AMICUS will pay the Price for the new Batch delivered by WUXI BIOLOGICS in replacement of such non-conforming Batch. AMICUS will be also responsible for collecting or disposing the non-conforming Batch, at its own expense.

2.11.8. Acceptance of Conformity. AMICUS' payment of the Price for any Batch shall not constitute acceptance of Batch conformity to Specifications and shall also not constitute a waiver of any of its rights under this Agreement.

2.12 Recalls. WUXI BIOLOGICS shall cooperate with AMICUS in implementing in any recall of Product required by a Regulatory Authority or elected by AMICUS. If such recall is initiated because of (i) non-conforming Product (provided that the non-conformity was not due to a defect in materials provided by or on behalf of AMICUS, *e.g.*, cell lines, that were not reasonably detected by WUXI BIOLOGICS in advance) or (ii) WUXI BIOLOGICS' negligence or willful misconduct, WUXI BIOLOGICS shall promptly reimburse AMICUS the Price paid by AMICUS for the recalled Product and all other related costs and AMICUS may seek any other available remedies. In all other scenarios, AMICUS shall bear any and all costs associated with the recall of such Product.

2.13 Change in Specifications. AMICUS may elect to amend the Specifications even if they are not required by a change in Applicable Law, the Regulatory Authority, or to protect patient safety; provided however, that AMICUS shall bear any costs and expenses solely attributable to such amendments, including but not limited to the costs of, any filings or other actions WUXI BIOLOGICS must take with the Regulatory Authority as a result thereof. WUXI BIOLOGICS shall use Commercially Reasonable Efforts to promptly implement such change.

2.13.1. If amendments to the Specifications are required by the Regulatory Authority, change in Applicable Law or to protect patient safety, AMICUS shall bear all costs and expenses associated therewith including filings with the Regulatory Authority necessitated by the change. WUXI BIOLOGICS shall use Commercially Reasonable Efforts to promptly implement such change.

2.13.2. WUXI BIOLOGICS shall not amend the Specifications without AMICUS' prior written authorization. AMICUS shall bear all costs and expenses associated therewith, including but not limited to the costs of, any filings or other actions AMICUS must take with the Regulatory Authority necessitated by the change.

2.14 Waste Material. Each Party shall promptly notify the other of any health hazards or potential health hazards of which it is or becomes aware of concerning exposure to or handling of the Raw Materials, API, Consumables, Resins, Product, or their waste products. At WUXI BIOLOGICS' expense, WUXI BIOLOGICS or a designated Subcontractor shall handle, label, package, store, transport and dispose of all waste generated from the performance of its obligations under this Agreement and in strict compliance with Applicable Laws.

2.15 Delivery by WUXI BIOLOGICS**.** WUXI BIOLOGICS shall deliver (at its cost) API and/or Product to AMICUS' designated carrier FCA (Free Carrier), at Facility in the designated cities applicable to each Facility set forth in Appendix H Facilities (Incoterms® 2020). WUXI BIOLOGICS shall (at it**s** cost) package API and/or Product for transportation by AMICUS' designated carrier according to Specifications

and shall include the following with each shipment: (i) WUXI BIOLOGICS lot and batch numbers, (ii) the quantity of API and/or Product (iii) a bill of lading (iv) Batch Certificate(s) and (v) other documents as required by the Quality Agreement or Applicable Law (collectively "Delivery or Deliver").

2.16 Delivery by AMICUS. All materials to be provided by AMICUS to WUXI BIOLOGICS will be delivered DDP (site designated by WUXI BIOLOGICS) (Incoterms 2020), including but not limited to Cell Line, Master Cell Bank, Working Cell Bank or any other materials provided by AMICUS. For the avoidance of doubt, DDP (site designated by WUXI BIOLOGICS) means AMICUS is responsible for delivery to and unloading at the site designated by WUXI BIOLOGICS and pays all costs including import duties and taxes.

2.17 Engineering and PPQ Batches and Development Services. Any engineering Batches, Process Performance Qualification ("PPQ") Batches or miscellaneous services required to enable the future manufacture of a Batch of API/Product suitable for commercial sale shall be the subject of separately negotiated "Work Orders" issued hereunder. As the term "commercial Batches" is used herein, it does not include PPQ Batches or engineering Batches though PPQ batches may be used for commercial purposes.

3. Forecasts and Orders

3.1 Rolling API Forecasts. An initial [***] rolling quarterly forecast of the quantity and size of API Batches AMICUS desires WUXI BIOLOGICS to Deliver API is provided in Appendix B. API Rolling Forecasts shall be updated by AMICUS in writing by the first three (3) Business Days of the beginning of each calendar quarter (January 1st, April 1st, July 1st or October 1st) ("Rolling API Forecasts") and WUXI BIOLOGICS shall promptly acknowledge receipt thereof. API Batches included in this initial API Rolling Forecast shall be governed under this Agreement and considered as having conformed to API lead time requirements as set forth in Section 3.3.4.

3.1.1 Binding Quarterly API Forecasts. The quantity of the first [***] calendar quarters [***] of each Rolling API Forecast shall be binding on both Parties ("Binding First Quarterly API Forecast" or each of said quarters constituting a "Binding API Quarter") such that AMICUS shall be bound to purchase said quantities from WUXI BIOLOGICS, and WUXI BIOLOGICS shall be bound to supply and sell said quantities to AMICUS.

3.1.2 Non-Binding Quarterly API Forecasts. The quantity of the last [***] calendar quarters [***] of each Rolling API Forecast shall not be binding on either Party ("Non-Binding Quarterly API Forecast" or each of said quarters constituting a "Non-Binding API Quarter") but shall be made in good faith by AMICUS and shall be used in good faith by WUXI BIOLOGICS to achieve Capacity (as defined below in Section 3.6).

3.2 Rolling Product Forecasts. An initial [***] forecast of the amount of API (in weight) AMICUS desires WUXI BIOLOGICS to manufacture into Product and Deliver to AMICUS is provided in Appendix C shall be updated by AMICUS in writing by the first three (3) Business Days of the beginning each calendar quarter (January 1st, April 1st, July 1st or October 1st) ("Rolling Product Forecasts") and WUXI BIOLOGICS

shall promptly acknowledge receipt thereof. Product Batches included in this initial Product Rolling Forecast shall be governed under this Agreement and considered as having conformed to Product lead time requirements as set forth in Section 3.3.5.

3.2.1. Binding Quarterly Product Forecasts. The quantity of the first [***] calendar quarters [***] of each Rolling Product Forecast shall be binding on both Parties ("Binding First Quarterly Product Forecast" or each of said quarters constituting a "Binding Product Quarter") such that AMICUS shall be bound to purchase said quantity from WUXI BIOLOGICS, and WUXI BIOLOGICS shall be bound to supply and sell said quantity to AMICUS.

3.2.2. Non-Binding Quarterly Product Forecasts. The quantity of the last [***] calendar quarters [***] of each Rolling Product Forecast shall not be binding on either Party ("Non-Binding Quarterly Product Forecast" or each of said quarters constituting a "Non-Binding Product Quarter") but shall be made in good faith by AMICUS and shall be used in good faith by WUXI BIOLOGICS to achieve Capacity.

3.3 Firm Orders. AMICUS shall issue to WUXI BIOLOGICS a firm purchase order ("Firm Order") for the forecasted quantity of API or Product for a Binding Quarter as set forth below:

3.3.1. Submission Date. AMICUS shall submit each Firm Order in advance of the Delivery Lead Times set forth in sections 3.3.4 and 3.3.5.

3.3.2. Confirmation and Acceptance of Firm Orders. WUXI BIOLOGICS shall confirm receipt of the Firm Order within two (2) Business Days which shall be deemed to be accepted if in accordance with the Binding Forecasts.

3.3.3. Confirmation of RmRC. Within ten (10) Business Days of receiving a Firm Order, WUXI BIOLOGICS shall provide written confirmation to AMICUS that it has ordered sufficient RmRC to manufacture and Deliver API/Product by the Delivery Date set forth in Section 3.3.6.

3.3.4. API Delivery Lead-Time. Subject to Section 3.1, if a Firm Order is for API, it must be submitted to WUXI BIOLOGICS at least [***] days in advance of the Delivery Date.

3.3.5. Product Delivery Lead-Time. Subject to Section 3.2, if a Firm Order is for Product, it must be submitted to WUXI BIOLOGICS at least [***] days in advance of the Delivery Date.

3.3.6. Delivery Date. Subject to Sections 3.3.4 and 3.3.5, WUXI BIOLOGICS shall Deliver API or Product to AMICUS by the date designated in the corresponding Firm Order ("Delivery Date").

3.3.7. Scope of Authorization. The issuance of a Firm Order shall constitute (i) AMICUS' authorization for WUXI BIOLOGICS to manufacture API and/or Product without which WUXI BIOLOGICS shall not manufacture API or Product (ii) AMICUS' agreement to purchase API and/or Product specified therein from WUXI BIOLOGICS and (iii) WUXI BIOLOGICS' agreement to sell said API and/or Product solely to AMICUS under the terms of this Agreement and in consideration for the Price set forth in Section 4.

3.3.8. Surplus Orders. If AMICUS revises a Firm Order to equal a quantity of API or Product greater than that forecasted within its respective Binding Quarter but not by more than [***] ("Surplus Order") and AMICUS submits to WUXI BIOLOGICS said Surplus Order [***], WUXI BIOLOGICS shall use Commercially Reasonable Efforts to Deliver the surplus quantity by the date set forth in said Surplus Order, provided that AMICUS shall reimburse all reasonable costs actually incurred by WUXI BIOLOGICS in the event it satisfies said Surplus Order.

3.3.9. Excess Orders. If AMICUS revises a Firm Order to equal a quantity of API or Product greater than that forecasted by more than [***] ("Excess Order"), WUXI BIOLOGICS shall [***].

3.3.10. Compensating Orders. Notwithstanding Sections 3.3.8 and 3.3.9, if a Firm Order is made to compensate for a Supply Delay or Supply Failure ("Compensating Order"), WUXI BIOLOGICS shall [***] commence a Run as soon as possible for the additional quantity by the date set forth in said Firm Order/Compensating Order and in no case later than [***].

3.3.11. Controlling Terms. If a purchase order, invoice, acknowledgment form or other such document exchanged by AMICUS and WUXI BIOLOGICS contains any provisions additional or contrary to the provisions of this Agreement, they shall have no force or effect and the terms of this Agreement shall control.

3.4 Accounting of RmRC and Bill of Materials. An initial BOM shall be populated by WUXI BIOLOGICS 30 days prior to the placement of the first Firm Order according to the template provided in Appendix D. Thereafter, the BOM shall be reviewed within PRM meetings quarterly and be supported by auditable documentation from WUXI BIOLOGICS' suppliers.

3.4.1. AMICUS shall have the right to conduct (or have conducted on its behalf), [***], a physical or virtual audit of all documentation relating to the purchase and usage of RmRC in the production of Batches.

3.4.2. Additionally, within the first 10 days of a calendar quarter, WUXI BIOLOGICS must provide a gap analysis report showing the variance between the projected total RmRC costs and actual total RmRC costs on the Batches produced in the previous quarter.

3.5 Target API Yields. The Target API Yield is the agreed upon amount of API (measured in kilograms to 2 decimal places and represented as a range) that is to be produced in any one Batch ("Target API Yield").

3.5.1. Target API Yield for the Facility [***] through [***] is set forth in Appendix F [***].

3.5.2. A separate Target API Yield shall be established for each remaining Facility (including [***] onwards) by the JSC on an annual basis, provided however, that the Target API Yield should be no less than [***] of API.

3.5.3. The Target API Yield for the other Facilities will be determined by averaging the yields of the first [***] commercial Batches of API manufactured under this Agreement having yields greater than or equal to [***] kg of API and less than or equal to [***] kg of API.

3.5.4. The Parties will use best efforts to improve API yields and achieve or surpass the Target API Yield.

3.5.5. After the Target API Yield has been determined, it will be used to calculate the Price Discounts and Price Premiums (if any) described in Section 4.2 [***].

3.5.6. The Target API Yield at each Facility will be reviewed [***] by the JSC to determine if the Target API Yield should be increased.

3.6 Capacity. WUXI BIOLOGICS shall use Commercially Reasonable Efforts to provide the capacity to supply API and Product according to Rolling Forecasts based on the Target API Yield and provide exclusive capacity as applicable pursuant to Section 3.7 ("Capacity"). If WUXI BIOLOGICS becomes aware that it may encounter difficulty meeting any Rolling Forecast, it shall immediately notify AMICUS in writing, providing details of the expected shortfall and cause(s) thereof.

3.7 Exclusive Capacity / Suite Reservation. WUXI BIOLOGICS shall reserve the MFG 6.2 Facility to exclusively manufacture API for AMICUS and not for the use of any other customer in exchange for an annual "Suite Reservation Fee" [***] "Exclusive Use Period" as set forth below:

3.7.1. Commencing on the Effective Date, WUXI BIOLOGICS shall prepare and qualify MFG 6.2 to satisfy all Applicable Laws for the manufacture of API.

3.7.2. MFG 6.2 shall be in the same building as MFG 6.1 and shall be fitted with comparable equipment to manufacture API according to the Specifications.

3.7.3. After AMICUS has determined that MFG 6.2 satisfies all Applicable Laws for the manufacture of API (consent not to be unreasonably withheld), WUXI BIOLOGICS shall commence engineering Batches in MFG 6.2 which shall be exclusively used for AMICUS and no other customers during the period specified in Appendix J.

3.7.4. After AMICUS has determined that the engineering Batches were satisfactorily completed (consent not to be unreasonably withheld), WUXI BIOLOGICS shall commence [***] PPQ Batches in MFG 6.2 which shall be exclusively used for AMICUS and no other customers during the [***] period specified in Appendix J. After AMICUS has determined that the engineering Batches were satisfactorily completed, AMICUS will be bound to proceed with Sections 3.7.5- 3.7.16, [***].

3.7.5. After AMICUS has determined that the PPQ Batches were successful and produced a Target API Yield not less than [***] (consent not to be unreasonably withheld), WUXI BIOLOGICS shall invoice AMICUS [***].

3.7.6. In the following first full Exclusive Use Period of [***], as set forth in Appendix J (and contingent upon the satisfaction of the PPQ requirements set forth in Section 3.7.5), WUXI BIOLOGICS shall commence the manufacture of API Batches ordered/forecasted by AMICUS in its Binding Forecasts and Firm Orders for MFG 6.2 according to Section 3.7.11 which shall be exclusively used for AMICUS and no other customers.

3.7.7. The Suite Reservation Fee of [***] for that Exclusive Use Period shall satisfy the Service Fees for manufacturing [***].

3.7.8. The Suite Reservation Fee shall be invoiced [***] and no earlier than Delivery of each Batch, [***].

3.7.9. [***].

3.7.10. [***].

3.7.11. [***].

3.7.12. For the first Exclusive Use Period, the Firm Orders which AMICUS submits in accordance with Section 3.7.11 will be contingent upon the satisfaction of Sections 3.7.1 - 3.7.5, [***].

3.7.13. If [***] the activities for that Phase are not completed to AMICUS' satisfaction (consent not to be unreasonably withheld), then AMICUS may [***].

3.7.14. Additionally, AMICUS may elect to discontinue any further obligations under this Section 3.7. by [***].

3.7.15. [***] are subject to the provisions in this Section 3.7.

3.7.16. Except as specifically set forth in this Section 3.7 and Appendix J, the Batches referred to in this Section 3.7 are also subject [***].

3.8 Supply Delays. If API or Product is not Delivered within [***] of the time permitted under Section 3.3.6 it shall constitute a "Supply Delay" unless it is due to a Force Majeure Event.

3.9 Supply Failure. If API or Product [***], it shall constitute a "Supply Failure".

4. Price and Payments

4.1 Price. WUXI BIOLOGICS shall sell and Deliver one-hundred percent (100%) of API and Product it manufactures to AMICUS, and AMICUS shall purchase the API and Product from WUXI BIOLOGICS based on Firm Orders for the Price set forth in Appendix E.

4.2 Price Discounts and Premiums. [***].

4.2.1. Price Discounts and Premiums will be specific to each Facility to align with the Target API Yields of each Facility.

4.2.2. API yields will be measured for each commercial Batch made during consecutive [***] ("Evaluation Period") commencing at a time determined by the JSC.

4.2.3. [***].

4.2.4. [***].

4.2.5. [***].

4.2.6. [***].

4.2.7. [***].

4.2.8. [***]. The QBR shall report Price Discounts and Price Premiums to the JSC for final approval.

4.3 [***].

4.4 Invoicing. WUXI BIOLOGICS shall invoice AMICUS for Batches of API and Units of Product at the Price specified in Appendix E Price and for any Price Premiums due pursuant to Section 4.2, upon the earlier of the issuance of a Batch Certificate to AMICUS or Delivery. AMICUS shall pay invoices the later of (i) forty-five (45) days of receipt of the invoice or (ii) Delivery, if undisputed. To ensure prompt payment, invoices should be submitted by electronic mail to [***].

4.5 Payment Terms. The Parties shall make all payments required under this Agreement by wire transfer in United States dollars to a bank account designated in writing by the other Party. All dollar ($) amounts specified in this Agreement are United States dollar (USD) amounts. [***].

4.6 Taxes and VAT. AMICUS shall be responsible for all sales, use, value added, excise and similar taxes imposed by any government or governmental agency with respect to AMICUS' purchase of any Product under this Agreement, except as noted below.

4.6.1. The Parties acknowledge and agree that the Price in the invoices is exclusive of Value Added Tax ("VAT") and that, if applicable, VAT will be added to such amounts. In such instance, WUXI BIOLOGICS will give or cause to be given to AMICUS such assistance as may reasonably be necessary to enable AMICUS to (i) claim exemption therefrom (ii) credit therefor and WUXI BIOLOGICS (i) will use diligent efforts to recover all amounts paid for such taxes from the applicable authorities and (ii) in each case will furnish AMICUS with proper evidence of the taxes paid on its behalf.

4.6.2. WUXI BIOLOGICS will only invoice AMICUS for VAT and other similar goods and services taxes that WUXI BIOLOGICS has paid on AMICUS' behalf and for which WUXI BIOLOGICS, despite using diligent efforts, is unable to receive reimbursement from the applicable taxing authorities.

4.6.3. All amounts paid by WUXI BIOLOGICS for such taxes that are subsequently recovered by WUXI BIOLOGICS will, at AMICUS' option, be refunded to AMICUS or credited against Price until such amounts have been fully credited.

4.6.4. If WUXI BIOLOGICS performs Services and a goods and services tax such as VAT is levied on pass-through costs made by WUXI BIOLOGICS on AMICUS' behalf, WUXI BIOLOGICS will initially pay such taxes on behalf of AMICUS and will use diligent efforts to recover all amounts paid for such taxes from the applicable authorities.

4.6.5. WUXI BIOLOGICS shall be responsible for income taxes resulting from payment received from AMICUS under this Agreement.

4.7 Cancellation Fees. Subject to Section 4.8, if AMICUS notifies WUXI BIOLOGICS to manufacture less than the quantity designated in a Binding Quarter or a Firm Order ("Forecast Shortfall"), AMICUS shall [***].

4.8 Cancellation Fee Requirements. [***]:

4.9.1. [***];

4.9.2. [***];

4.9.3. [***];

4.9.4. [***];

4.9.5. [***];

4.9.6. [***];

4.9.7. [***];

4.9.8. [***];

4.9.9. [***];

4.9.10. [***]; and

4.9.11. [***].

4.9 Payment of Cancellation Fees. WUXI BIOLOGICS may invoice AMICUS for any API Cancellation Fee [***].

4.1.1 [***].

4.10 Offset for Supply Delay. [***].

4.11 Per Vial Product Pricing. [***].

5. Performance and Relationship Management

5.1 A Performance and Relationship Management ("PRM") model utilizing a series of PRM committees will monitor performance under the terms of this Agreement.

5.2 The PRM committees are listed in descending order of authority in Appendix I. with the "JSC" ("Joint Steering Committee") having the highest authority, subject to Section 11.1 shall agree to formal charters for the JSC and QBR.

5.3 Each PRM committee is tasked to monitor various aspects of performance under this Agreement as set forth in Appendix I including an obligation to measure and report the Key Performance Indicators therein.

5.4 PRM committees shall have suitable managerial and/or technical staff to discuss and consider the items on the agenda and make written record of all meeting minutes and mutually agreed upon decisions.

5.5 PRM committees shall be able to review the BOM pursuant to Section 3.4.

5.6 No PRM committee shall have the power to amend, modify or waive compliance with this Agreement. PRM meeting minutes, regardless of whether signed by senior representatives of both Parties, shall not be deemed to amend, modify or waive compliance with this Agreement.

6. Confidentiality and Intellectual Property

6.1 Confidential Information. Each Party agrees to keep in confidence and not to disclose to any Third Party, or use for any purpose, except pursuant to, and in order to carry out, the terms and objectives of this Agreement, any Confidential Information of the other disclosing Party. "Confidential Information" with respect to AMICUS shall mean all trade secrets or confidential or proprietary information of AMICUS designated as such in writing, whether by letter or by the use of an appropriate stamp or legend, prior to or at the time any such trade secret or confidential or proprietary information is disclosed to WUXI BIOLOGICS. Confidential Information herein shall also include the Amicus' Confidential Information generated under the MSA. Confidential Information shall mean, with respect to WUXI BIOLOGICS, any and all information (in whatever form, tangible or intangible) relating to WUXI BIOLOGICS' or its Affiliates' methodology, testing processes, packaging and manufacturing techniques, data collection and data management techniques designated as such in writing, whether by letter or by the use of an appropriate stamp or legend, prior to or at the time any such trade secret or confidential or proprietary information is disclosed to AMICUS and which is of a confidential nature.

6.1.1 Notwithstanding the foregoing, information which is orally or visually disclosed to a Party or is disclosed in writing without an appropriate letter, stamp or legend,

shall constitute Confidential Information if its confidential nature is reasonably apparent from the circumstances of disclosure, context and subject matter, despite the absence of an identifying stamp or legend.

6.1.2 The restrictions on the disclosure and use of Confidential Information set forth shall not apply to any Confidential Information that: (1) was known by a receiving Party prior to the disclosure by the other Party hereunder (as evidenced by the receiving Party's written records or other competent evidence) and not also subject to confidentiality between the Parties under a previous agreement; (2) is or becomes part of the public domain through no fault of the receiving Party; (3) is disclosed to receiving Party by a Third Party having a legal right to make such disclosure without violating any confidentiality or non-use obligation that such Third Party has; or (4) is independently developed by receiving Party personnel who did not have access to the Confidential Information (as evidenced by receiving Party's written records or other competent evidence).

6.1.3 In addition to the exceptions above, if a receiving Party is required to disclose Confidential Information of the disclosing Party by regulation, law or legal process, receiving Party shall provide prior notice of such intended disclosure to disclosing Party, if possible, under the circumstances and shall disclose only such Confidential Information as is required to be disclosed.

6.1.4 Neither anything contained herein nor the delivery of any disclosing Party's Confidential Information to receiving Party shall be deemed to grant receiving Party any right or licenses under any patents or patent applications or to any know-how, technology or inventions of disclosing Party, except (i) as otherwise stated in this Agreement; or (ii) to enable each Party to perform its obligations under this Agreement.

6.1.5 The terms of this Agreement shall be considered Confidential Information hereunder.

6.2 Cell Line and Modified Cells. [***]:

6.2.1. [***];

6.2.2. [***];

6.2.3. [***];

6.2.4. [***]; and

6.2.5. [***].

6.3 Data Ownership and Intellectual Property. Any Intellectual Property (i) derived from or related to AMICUS' Confidential Information; (ii) derived from any other information related to the API or Product (or Biosimilar or Interchangeable thereof); or (iii) related to or arising out of WUXI BIOLOGICS' performance under this Agreement (other than as described in Section 5.3.1), including but not limited to artwork, advertising and packaging information necessary to package Product, chemical, biological and physical properties of API, and Product and analytical methods that pertain specifically thereto, chirality, purity, particle size, particle shape, particle aggregation, crystalline and amorphous forms and optical characteristics of the API and the works, information and improvements in Section 6.3.2; howsoever gained or obtained by WUXI BIOLOGICS except not if provided by a Third Party under no

obligation to AMICUS (collectively referred to herein as "AMICUS Intellectual Property"), shall be immediately communicated and delivered to AMICUS, and shall be the exclusive property of, and all right, title and interest shall be owned by AMICUS. WUXI BIOLOGICS hereby grants to AMICUS all right, title and interest in and to such Intellectual Property, as well as any patents or other intellectual property rights relating thereto, and WUXI BIOLOGICS agrees to execute such documents and take such actions as AMICUS may reasonably request to vest more fully in AMICUS all such rights.

6.3.1. Subject to Sections 6.3 and 6.3.2, the Intellectual Property related exclusively to procedures, processes and manufacturing know-how that may be invented by WUXI BIOLOGICS in the course of performing its obligations under this Agreement but which relate to manufacturing operations generally and not to API or Product (or Biosimilar or Interchangeable thereof) and the relevant Intellectual Property rights shall belong to WUXI BIOLOGICS ("WUXI BIOLOGICS Intellectual Property"); provided however, that WUXI BIOLOGICS shall grant and hereby does grant to AMICUS a worldwide, royalty-free, perpetual, fully paid-up, non-exclusive license to WUXI BIOLOGICS Intellectual Property to enable AMICUS or its Affiliates to develop and commercialize API and Product, including without limitation, the right to use information required for submission to Regulatory Authorities.

6.3.2. The Intellectual Property related exclusively to procedures, processes, analytical characterization and manufacturing of API and Product shall belong solely to AMICUS pursuant to Section 6.3. All artwork, advertising and packaging information necessary to package Product is and shall remain the exclusive property of AMICUS, and AMICUS shall be solely responsible for the content thereof. Such artwork, advertising and packaging information or any reproduction thereof may only be used by WUXI BIOLOGICS to perform its obligations under this Agreement. All such copyrightable works shall constitute work-for-hire for purposes of the United States copyright laws, and constitute AMICUS Intellectual Property. WUXI BIOLOGICS hereby acknowledges that it does not have, and shall not acquire any interest in any of AMICUS' trademarks or trade names and agrees not to use any AMICUS' trade names or trademarks except as specifically authorized in writing both as to the names or marks which may be used and as to the manner and prominence of use.

6.3.3. AMICUS hereby grants to WUXI BIOLOGICS a fully paid, non-exclusive, non-sublicensable, non-transferable license under any and all AMICUS Intellectual Property that is necessary for WUXI BIOLOGICS to perform its obligations during the term of this Agreement.

6.4 Return of Confidential Information. WUXI BIOLOGICS agrees that upon termination or expiration of this Agreement or, at the request of AMICUS, it shall (and shall cause its directors, officers, employees, agents, representatives and advisors to) return to AMICUS all parts of the Confidential Material provided by AMICUS and return or destroy any copies thereof made by WUXI BIOLOGICS, its directors, officers, employees, agents or representatives.

6.5 Records. WUXI BIOLOGICS will keep complete and accurate records (including without limitation Manufacturing Documentation, MPR, MS, reports, accounts, data, and records of all information and results obtained from performing under this Agreement) of all work done by it under this Agreement, in form and substance as specified in the Quality Agreement and this Agreement (collectively, the "Records"). While in the possession or control of WUXI BIOLOGICS, Records will be available at reasonable times for inspection, examination and copying by the Regulatory Authority (if required by Applicable Law) and AMICUS. WUXI BIOLOGICS will ensure that all Records of its performance under this Agreement will be retained and archived in accordance with cGMP and Applicable Law, but in no case for less than a period of five (5) years following completion of performance under this Agreement.

6.6 Employee, Consultant and Advisor Obligations. Each Party agrees that it and its Affiliates shall provide or permit access to Confidential Information received from the other Party and such Party's Affiliates and representatives only to the receiving Party's employees, consultants and advisors and to the employees, consultants and advisors of the receiving Party's Affiliates who, in such Party's reasonable judgment have a need to know such Confidential Information to assist the receiving Party with the activities contemplated by this Agreement and who are subject to obligations of confidentiality and non-use with respect to such Confidential Information similar to the obligations of confidentiality and non-use of the receiving Party pursuant to Section 6.1; provided, however, that WUXI BIOLOGICS and AMICUS shall each remain responsible for any failure by its Affiliates, and its and its Affiliates' respective employees, consultants and advisors, to treat such Confidential Information as required under Section 6.1 (as if such Affiliates, employees, consultants and advisors were Parties directly bound by the requirements of Section 6.1).

6.7 Publicity. Neither Party shall issue a press release or other public announcement relating to this Agreement or its subject matter without the prior written approval of the other Party.

6.8 Injunctive Relief. Each Party agrees and acknowledges that its disclosure of Confidential Information or other breach of Section 6 of this Agreement may cause irreparable harm to other Party, and therefore that any such breach or threatened breach may entitle such Party to seek injunctive relief, in addition to any other legal remedies available in a court of competent jurisdiction.

6.9 Material Breach. Both Parties agrees that breach of this and any of the confidentiality provisions of this Agreement shall constitute a material breach of this Agreement, and both Parties shall immediately take all necessary measures to mitigate and cure such breach. Both Parties shall have the right to audit and inspect the other Party for conformance to Section 6.

6.10 Data Privacy. In the event that either Party processes any personal data (including personal data of personnel of either Party) in the course of fulfillment of their obligations under this Agreement, each Party shall do so in full compliance of Applicable Laws on data privacy. WUXI BIOLOGICS hereby consents to its personal data being transferred to, and processed outside China by any AMICUS group company, business partner, supplier or sub-contractor, provided that such group

company, business partner, supplier or sub-contractor offers an equivalent level of protection as that offered by AMICUS under its data privacy policies and procedures.

7. Compliance, Ethics And Transparency

7.1 Both Parties represent and warrant that they will perform their obligations under this Agreement in compliance with all Applicable Laws and shall procure and maintain all necessary authorizations, permits and licenses required for the performance contemplated under this Agreement.

7.2 The Parties represent and covenant further that in connection with this Agreement, they, their Affiliates, their directors, their employees, their officers, and anyone acting on their behalf, unless permitted under the Applicable Laws, shall not directly or through Third Parties pay, promise to pay, authorize a payment, give, promise to give, or authorize the giving of anything of value or any benefit to any Public Official for purposes of (i) influencing any act or decision of such Public Official in his official capacity, (ii) inducing such Public Official to do or omit to do any act in violation of the lawful duty of such individual; (iii) securing any improper advantage; or (iv) inducing such Public Official to use its influence to affect or influence any act or decision of the government with respect to any activities undertaken relating to this Agreement.

7.2.1. "Public Official" means any of the following: (i) official (elected, appointed, or career) or employee of a federal, national, state, provincial, local, or municipal government or any department, agency, or subdivision thereof (incl. the Social Security Institution); (ii) officer or employee of a government-owned or controlled enterprise, company, or organization; (iii) Officer or employee of a public international organization (e.g., UN, World Bank, EU, WTO); (iv) individual acting for or representing a government or any of the organizations referred to above, even if he/she is not an employee of such government or organization; (v) individual who is considered to be a government official under applicable local law; (vi) candidate for public office; and (vii) an officer or individual who holds a position in a political party.

7.3 Each Party shall comply with the provisions of the UK Bribery Act 2010, the US Foreign Corrupt Practices Act 1997, and any laws intended to implement to OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, each as amended from time to time ("Anti-Bribery Requirements"). WUXI BIOLOGICS shall comply with AMICUS' anti-bribery, anti-corruption and ethics policies as updated from time to time by AMICUS and notified to WUXI BIOLOGICS ("Anti-Bribery Policies"). WUXI BIOLOGICS shall appoint an appropriate representative of WUXI BIOLOGICS to receive training from AMICUS on such policies at a time and place convenient to both Parties. In addition, WUXI BIOLOGICS shall maintain in place throughout the term of this Agreement its own policies and procedures to ensure compliance with the Anti-Bribery Requirements and the Anti-Bribery Policies, will enforce them where appropriate and will promptly report to AMICUS any request or demand for any undue or suspicious financial or other advantage of any kind received by WUXI BIOLOGICS in connection with the performance of this Agreement.

7.4 WUXI BIOLOGICS shall immediately notify AMICUS in writing if a public official becomes an officer or employee of WUXI BIOLOGICS or acquires a direct or indirect interest in WUXI BIOLOGICS, and WUXI BIOLOGICS warrants that it has no such public officials as direct or indirect owners, officers or employees at the Effective Date; and

7.5 Upon request by a Party, the other Party shall certify in writing signed by an officer of such other Party, compliance with this Section 7. The other Party shall also provide such supporting evidence of compliance as the requesting Party may reasonably request.

7.6 Each Party shall have the right to conduct audits of the other Party and the other Party shall provide access to any facilities, employees and records as may be reasonably required by the Party conducting the audit for the purpose of verifying the other Party's compliance with the terms of Sections 2 through 7 from time to time. Compliance audits will be conducted not more than once per year on reasonable notice and during normal working hours.

7.7 WUXI BIOLOGICS shall ensure that all of its agents, sub-contractors and affiliates who perform services in connection with this Agreement do so only on the basis of a written contract which imposes on and secures from such persons' terms equivalent to those imposed on WUXI BIOLOGICS in this Section 7 ("the Ethical Terms"). WUXI BIOLOGICS shall be responsible for the observance and performance by such persons of the Ethical Terms, and shall be directly liable to AMICUS for any breach by such persons of any of these terms.

8. Representations, Warranties and Covenants

8.1 Representations of Authority. WUXI BIOLOGICS and AMICUS each represents and warrants to the other Party that, as of the Effective Date, it has full right, power and authority to enter into this Agreement and to perform its respective obligations under this Agreement.

8.2 No Conflict. WUXI BIOLOGICS and AMICUS each represents and warrants to the other Party that the execution and delivery of this Agreement by such Party and the performance of such Party's obligations hereunder (1) do not conflict with or violate any requirement of Applicable Law existing as of the Effective Date applicable to such Party and (2) do not conflict with, violate, breach or constitute a default under any contractual obligations of such Party or any of its Affiliates existing as of the Effective Date.

8.3 Enforceability. WUXI BIOLOGICS and AMICUS each represents and warrants to the other Party that, as of the Effective Date, this Agreement is a legal and valid obligation binding upon it and is enforceable against it in accordance with its terms.

8.4 Additional Representations Warranties and Covenants of WUXI BIOLOGICS. WUXI BIOLOGICS further represents, warrants and covenants that, at the time of delivery to AMICUS, the API and Product manufactured under this Agreement will have been manufactured in accordance with all material requirements of cGMP and all other Applicable Law, the Quality Agreement, and Specifications. WUXI BIOLOGICS represents and warrants that WUXI BIOLOGICS and its employees, Affiliates, contractors, and agents have never been debarred or convicted of a crime for which a

person can be debarred under Applicable Law. WUXI BIOLOGICS further represents and warrants that it has the requisite skills and experience to perform the obligations under this Agreement.

8.5 Environmental and Sustainability

8.5.1. Program Existence. WUXI BIOLOGICS represents and warrants that it has a bona fide environmental and/or sustainability program, or substantially similar equivalent (the, "Program"), as of the Effective Date.

8.5.2. Reporting. WUXI BIOLOGICS agrees to provide quarterly (i.e., every three (3) calendar months) updates at the JSC and written updates every 6 months to AMICUS on the status and effectiveness of the Program. Such updates shall include, at a minimum, (i) any material developments to the Program, (ii) any metrics required by local, state or federal rules, regulations or laws, and (iii) a copy of any report generated by the Program relating specifically to AMICUS.

8.5.3. Notice. WUXI BIOLOGICS agrees to notify AMICUS immediately, but in no event more than five (5) Business Days after becoming aware of, any materially adverse development to WUXI BIOLOGICS' Program. Should such adverse event result in a deviation from, or discontinuation of, WUXI BIOLOGICS' Program, WUXI BIOLOGICS shall work with AMICUS in good faith to find an acceptable alternative approach that meets AMICUS' internal Program criteria. WUXI BIOLOGICS further agrees and acknowledges that AMICUS has entered into this Agreement on the basis of, in part, the viability of and agreement with WUXI BIOLOGICS' Program and any failure to maintain such Program in a form acceptable to AMICUS shall be escalated to the JSC for resolution.

8.5.4. Compliance. WUXI BIOLOGICS shall use its best efforts to comply with the terms and conditions of Section 8.5 and assist AMICUS in providing any and all information required by local, state or federal rules, regulations or laws in effect as of the Effective Date or promulgated during the term of this Agreement. Any failure by WUXI BIOLOGICS to comply with this Section 8.5.4 shall permit AMICUS to terminate this Agreement immediately and report WUXI BIOLOGICS' non-compliance to the relevant governmental agency or authority.

8.6 Additional Representations Warranties and Covenants of AMICUS. AMICUS further represents, warrants and covenants to WUXI BIOLOGICS that AMICUS shall adhere to all Applicable Laws relating to the handling, storage, use, disposal, sale, advertising and marketing of all Product while such Product is in AMICUS' possession and/or control.

8.7 Additional Representations Warranties and Covenants. This Section incorporates by reference other representations and warranties made by the Parties as may be evident throughout this Agreement.

8.8 Limited Applicability. The representations and warranties of a Party set forth in this Agreement are intended for the sole and exclusive benefit of the Parties hereto, and may not be relied upon by any Third Party other than permitted successors or assigns.

8.9 Limitation. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH HEREIN, THE PARTIES MAKE NO REPRESENTATION NOR EXTEND ANY WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, TO EACH OTHER, AND HEREBY

DISCLAIM ALL IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT WITH RESPECT TO THE API AND PRODUCT SUPPLIED HEREUNDER.

9. Indemnification

9.1 General Indemnification by WUXI BIOLOGICS. WUXI BIOLOGICS shall defend, indemnify and hold harmless AMICUS, its Affiliates and their respective directors, officers, employees and agents (collectively, the "AMICUS Indemnified Parties"), from, against and in respect of any and all actions, liabilities, losses, costs (including costs of investigation, defense and enforcement of this Agreement), damages, fines, penalties, government orders, taxes, expenses or amounts paid in settlement (in each case, including reasonable attorneys' and experts' fees and expenses), involving a claim or action of a Third Party or governmental authority (collectively, "Losses"), incurred or suffered by the AMICUS Indemnified Parties or any of them as a result of, arising out of or directly or indirectly relating to: (i) any breach of Agreement by WUXI BIOLOGICS; or (ii) the gross negligence, intentional misconduct or violation of law of or by any of WUXI BIOLOGICS, its Affiliates and their respective directors, officers, employees and agents, except, in each case, to the extent caused by the gross negligence, willful misconduct or violation of law of or by AMICUS or any of the other AMICUS Indemnified Parties.

9.2 General Indemnification by AMICUS. AMICUS shall defend, indemnify and hold harmless WUXI BIOLOGICS, its Affiliates and their respective directors, officers, employees and agents (collectively, the "WUXI BIOLOGICS Indemnified Parties"), from, against and in respect of any and all Losses incurred or suffered by the WUXI BIOLOGICS Indemnified Parties or any of them as a result of, arising out of or directly or indirectly relating to: (i) any breach of this Agreement by AMICUS; or (ii) the gross negligence, intentional misconduct or violation of law by or of AMICUS, its Affiliates and their respective directors, officers, employees and agents, except, in each case, to the extent caused by the gross negligence, willful misconduct or violation of law of or by any of WUXI BIOLOGICS or any of the other WUXI BIOLOGICS Indemnified Parties.

9.3 Product Liability Indemnification. Notwithstanding Sections 9.1 and 9.2, AMICUS shall indemnify and hold harmless the WUXI BIOLOGICS Indemnified Parties from, against and in respect of any and all Losses involving a Third Party products liability claim or action incurred or suffered by the WUXI BIOLOGICS Indemnified Parties or any of them directly relating to conforming Product supplied hereunder by WUXI BIOLOGICS to AMICUS.

9.4 Claims for Indemnification. A Person entitled to indemnification under Section 9 (an "Indemnified Party") shall give prompt written notification to the Person from whom indemnification is sought (the "Indemnifying Party") of the commencement of any action, suit or proceeding relating to a Third Party claim for which indemnification may be sought or, if earlier, upon the assertion of any such claim by a Third Party (it being understood and agreed, however, that the failure by an Indemnified Party to give notice of a Third Party claim as provided in this Section 9 shall not relieve the Indemnifying Party of its indemnification obligation under this Agreement except and

only to the extent that such Indemnifying Party is actually prejudiced as a result of such failure to give notice).

9.4.1. Within ten (10) Business Days after delivery of such notification, the Indemnifying Party may, upon written notice thereof to the Indemnified Party, assume control of the defense of such action, suit, proceeding or claim with counsel reasonably satisfactory to the Indemnified Party. If the Indemnifying Party does not assume control of such defense, the Indemnified Party shall control such defense.

9.4.2. The Party not controlling such defense may participate therein at its own expense; provided, however, that if the Indemnifying Party assumes control of such defense and the Indemnified Party reasonably concludes, based on advice from counsel, that the Indemnifying Party and the Indemnified Party have conflicting interests with respect to such action, suit, proceeding or claim, the Indemnifying Party shall be responsible for the reasonable fees and expenses of counsel to the Indemnified Party solely in connection therewith; provided further, however, that in no event shall the Indemnifying Party be responsible for the fees and expenses of more than one counsel in any one jurisdiction for all Indemnified Parties.

9.4.3. The Party controlling such defense shall keep the other Party advised of the status of such action, suit, proceeding or claim and the defense thereof and shall consider in good faith recommendations made by the other Party with respect thereto.

9.4.4. The Indemnified Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the Indemnifying Party, which shall not be unreasonably withheld or delayed. The Indemnifying Party shall not agree to any settlement of such action, suit, proceeding or claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the Indemnified Party from all liability with respect thereto or that imposes any liability or obligation on the Indemnified Party, without the prior written consent of the Indemnified Party.

9.5 Limitation of Liability. Except for [***] any breach of Sections 6 and 10, in no event shall the liability under this Agreement [***].

9.6 Insurance. Each Party shall maintain at its own cost full and sufficient Third Party, public and product liability, and product recall insurance, which may be by means of self- insurance, to cover its actual and potential liabilities hereunder and shall provide to the other a certificate of such insurance (or equivalent) upon request.

9.7 EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES (INCLUDING WITHOUT LIMITATION, DAMAGES RESULTING FROM LOSS OF USE, LOSS OF PROFITS, INTERRUPTION OR LOSS OF BUSINESS, LOST GOODWILL, LOST REVENUE AND LOST OPPORTUNITY) ARISING OUT OF ANY OF THE TERMS OR CONDITIONS OF THIS AGREEMENT OR WITH RESPECT TO ITS PERFORMANCE HEREUNDER; PROVIDED, HOWEVER, THAT THE FOREGOING SHALL NOT BE CONSTRUED TO PRECLUDE RECOVERY IN RESPECT OF ANY LOSS DIRECTLY INCURRED OR SUFFERED FROM THIRD PARTY CLAIMS.

9.8 Except with respect to (i) WUXI BIOLOGICS' confidentiality obligations under Section 6, (ii) WUXI BIOLOGICS' indemnification obligations under Section 9.1 (iii) any cases involving willful misconduct, gross negligence or personal injury or death, in no event shall WUXI BIOLOGICS' liability [***] exceed [***].

10. Term and Termination

10.1 Term. This Agreement shall become effective as of the Effective Date and, unless earlier terminated under Section 10, shall continue for five (5) years ("Initial Term") and shall automatically renew for successive terms of two (2) years ("Renewal Term") unless AMICUS provides WUXI BIOLOGICS at least twelve (12) months prior notice of its intent not to renew (collectively "Term"). For the avoidance of doubt, the issuance of a notice of non-renewal shall not relieve WUXI Biologics of its obligation to Deliver Binding Orders submitted prior to the expiration of the Term nor Amicus of its obligation to pay for Batches Delivered under Binding Orders submitted prior to the expiration of the Term nor prejudice any other accrued obligation or right.

10.2 Termination by WUXI BIOLOGICS. WUXI BIOLOGICS shall have the right to terminate this Agreement upon written notice to AMICUS if AMICUS breaches any material obligation hereunder and such default is not cured within [***] after receipt of written notice to AMICUS specifying such default.

10.3 Termination by AMICUS. If WUXI BIOLOGICS defaults under or fails to comply with any of its material obligations contained in this Agreement and (i) if such default is not curable, AMICUS shall have the right to terminate this Agreement upon written notice to WUXI BIOLOGICS, or (ii) if such default is curable and is not cured within [***] after the receipt of written notice to WUXI BIOLOGICS specifying such default, AMICUS shall have the right to terminate this Agreement upon written notice to WUXI BIOLOGICS.

10.3.1. AMICUS shall also have the right to terminate this Agreement upon written notice to WUXI BIOLOGICS for an Adverse Regulatory Development, Quality Failure or Supply Failure.

10.4 Financial Matters. Either Party may terminate this Agreement immediately by giving written notice if

10.4.1. the other Party commences a judicial or administrative proceeding under a law relating to insolvency for the purpose of reorganizing liquidating or restructuring its debt;

10.4.2. anyone commences any such proceeding against the other Party and either (i) the proceeding is not dismissed by midnight at the end of the [***] after commencement or (ii) any court before which the proceeding is pending issues an order approving the case;

10.4.3. a receiver, trustee, administrator, or liquidator (however each is referred to) is appointed or authorized, by law or under a contract, to take charge of property of the other Party for the purpose of enforcing a lien against that property, or for the purpose of general administration of that property for the benefit of the other Party's creditors;

10.4.4. the other Party makes a general assignment for the benefit of creditors; or

10.4.5. the other Party generally fails to pay its debts as they become due (unless those debts are subject to a good-faith dispute as to liability or amount) or acknowledges in writing that it is unable to do so.

10.5 Other Remedies. Any termination of this Agreement as provided herein shall not be an exclusive remedy but shall be in addition to any remedies that may otherwise be available to either Party.

10.6 Effect of Termination. Upon any termination of this Agreement, WUXI BIOLOGICS will promptly return to AMICUS all relevant records, materials or AMICUS' Confidential Information relating to the Product in its (or any of its Affiliates' or contractors') possession or control. Notwithstanding the preceding sentence, WUXI BIOLOGICS may retain a single copy, and any archived electronic copy that cannot be readily removed, of AMICUS' Confidential Information as is reasonably necessary for regulatory or insurance purposes or to comply with the requirement of any surviving provision, subject to WUXI BIOLOGICS' obligations of confidentiality under this Agreement.

10.6.1. Technical Transfer. Subject to Section 6.3.1, AMICUS shall also have the right to elect WUXI BIOLOGICS to perform a technical transfer [***] to enable a third party to manufacture API and Product according to Specifications.

10.6.2. Accrued Rights. Upon termination of this Agreement, the Parties will have no further obligations to each other, except that termination or expiration of this Agreement for any reason shall be without prejudice to any rights which shall have accrued to the benefit of either Party prior to such termination or expiration including without limitation and as applicable payment to WUXI BIOLOGICS of all accrued undisputed invoices return to AMICUS of API and Product and payment of credits issued under Section 4.2.7.

10.6.3. Surviving Obligations. Further, such termination or expiration shall not relieve either Party from obligations which by their nature and context are intended to survive the termination or expiration of this Agreement or those that are expressly indicated to survive termination or expiration of this Agreement including the Parties' rights and obligations under Sections 6 (but not Section 6.3.3), 9, and 10 which shall survive termination or expiration of this Agreement.

11. Miscellaneous

11.1 Dispute Resolution. Any dispute arising from or relating to the subject matter of this Agreement that cannot be resolved within a period of [***] after notice of a dispute has been given by one Party hereunder to the other, will be escalated to the JSC or President of each Party for a period of discussion of up to fifteen (15) days following the initial 30 days (the last day of such fifteen (15) day period being herein referred to as the "Arbitration Date"). If the heads of the Parties still cannot resolve the dispute after this fifteen (15) day period, such dispute shall be finally settled by arbitration in New York, New York, using the English language in accordance with the Arbitration Rules and Procedures of JAMS then in effect, by one or more commercial arbitrator(s) with substantial experience in resolving complex commercial contract disputes, who may or may not be selected from the appropriate list of JAMS arbitrators. If the Parties cannot agree upon the number and identity of the arbitrators within fifteen (15)

days following the Arbitration Date, then a single arbitrator shall be selected on an expedited basis in accordance with the Arbitration Rules and Procedures of JAMS. Any arbitrator so selected shall have substantial experience with pharmaceutical or biopharmaceutical industry supply issues. The arbitrator(s) shall have the authority to grant specific performance and to allocate between the Parties the costs of arbitration (including service fees, arbitrator fees and all other fees related to the arbitration) in such equitable manner as the arbitrator(s) may determine. Judgment upon the award so rendered may be entered in a court having jurisdiction or application may be made to such court for judicial acceptance of any award and an order of enforcement, as the case may be. Notwithstanding the foregoing, each Party shall have the right to institute an action in a court of proper jurisdiction for preliminary injunctive relief pending a final decision by the arbitrator(s), provided that a permanent injunction and damages shall only be awarded by the arbitrator(s). For all purposes of this Section, the parties' consent to exclusive jurisdiction and venue in the United States federal courts located in the Southern District of New York (*i.e.*, New York City).

11.2 Choice of Law. This Agreement shall be governed by and interpreted under the laws of the State of New York without reference to conflicts of laws principles. The United Nations Convention on Contracts for the International Sale of Goods (Vienna, 1980) (CISG)shall not apply to this Agreement.

11.3 Notices. Any notice required or permitted under this Agreement shall be in writing and shall be deemed to have been delivered upon proof of receipt by postal service, reputable overnight courier or facsimile to the following:

| AMICUS | WUXI BIOLOGICS |
|---|---|
| Amicus Therapeutics, Inc.<br>Attention: [***]<br>With a copy to: [***] | WuXi Biologics Shanghai Co Ltd.<br>Attention: [***]<br>E-mail: [***]<br>With a copy to: [***] |

11.4

11.5 Non-Waiver. The failure or delay of either Party to enforce or to exercise, at any time or for any period of time, any term of or any right arising pursuant to this Agreement does not constitute, and shall not be construed as, a waiver of such term or right, and shall in no way affect that Party's right later to enforce or exercise such term or right.

11.6 Severability. If under applicable law or regulation, any provision of this Agreement is invalid or unenforceable, or otherwise directly or indirectly affects the validity or enforceability of any material provision of this Agreement (such invalid or unenforceable provision, a "Severed Clause"), this Agreement shall endure except for the Severed Clause. The Parties shall consult one another and use reasonable efforts to agree upon a valid and enforceable provision that is a reasonable substitute for the Severed Clause in view of the intent of this Agreement.

11.7 Force Majeure. Neither Party shall be liable to the other Party for any failure to perform any of its material obligations as required by this Agreement if the failure to perform is due to circumstances reasonably beyond such Party's control including, without limitation, acts of God, civil disorders or commotions, acts of aggression, fire, terrorism (or the threat thereof), explosions, floods, drought, war, sabotage, embargo, sanctions, restraints of governments or public authorities, disruption of suppliers,

utility failures, material shortages, labor disturbances, a national health emergency, or appropriations of property ("Force Majeure Event"). Neither Party shall be deemed to be in breach of this Agreement, or shall be otherwise liable to the other Party, by reason only of any delay in performance, or the non-performance of any of its obligations hereunder, to the extent that the delay or non-performance is due to any Force Majeure Event of which it has duly notified the other Party, and the time for performance of that material obligation shall be extended accordingly. Without limiting AMICUS' right to terminate this Agreement pursuant to Section 10.3, if the performance by either Party of any of its obligations under this Agreement is prevented or delayed by a Force Majeure Event for a continuous period in excess of [***], the Parties shall enter into bona fide discussions with a view to alleviating its effects, or to agreeing upon such alternative arrangements as may be fair and reasonable in the circumstances.

11.8 Interpretation; Headings. In this Agreement, the words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation", and the word "will" shall be construed to have the same meaning and effect as the word "shall". In the event of an ambiguity or if a question of intent or interpretation arises, this Agreement shall be construed as if drafted jointly by the Parties, and no presumption or burden of proof shall arise favoring or disfavoring any Party by virtue of the authorship of any provisions of this Agreement. The definitions of the terms used in this Agreement shall apply equally to the singular and plural forms of the terms defined.

11.9 Integration. This Agreement and any of its attachments constitutes the entire agreement between the Parties with respect to the subject matter of this Agreement and supersedes all previous agreements, whether written or oral. This Agreement may be amended only in writing signed by properly authorized representatives of each of the Parties.

11.9.1 Manufacturing and Supply Agreement. As of the Effective Date of this Agreement, the Parties hereby terminate the Manufacturing and Supply Agreement entered into on December 5, 2018. WUXI BIOLOGICS agrees that no cancellation fees or other costs are due by AMICUS as a result of this termination. The Parties agree that applicable new orders, services and supplies shall be placed under this Agreement as set forth in Appendix B. API Rolling Forecasts and Appendix C. Product Rolling Forecasts.

11.9.2 Master Services Agreement. The Parties agree that the MSA is not terminated by virtue of entering into this Agreement and that it shall govern the services outside of the scope of those in this Agreement and in particular those set forth in Section 2.17.

11.10 Independent Contractors; No Agency or Partnership. For all purposes, and notwithstanding any other provision of this Agreement to the contrary, the legal relationship between the Parties shall be that of independent contractors. Neither of WUXI BIOLOGICS and AMICUS shall hold itself out as a partner or agent of the other.

11.11 Assignability. WUXI BIOLOGICS may not assign any of its rights or delegate or subcontract any of its duties and obligations under this Agreement to any Third Party

except its own Affiliates without the prior written consent of AMICUS, at its discretion (not to be unreasonably withheld), except assignment is permitted if a Third Party acquires all or substantially all of WUXI BIOLOGICS's assets related to the manufacture of Product (including, without limitation, the sale, spin-off or such other corporate transaction by WUXI BIOLOGICS). Any such attempted assignment of rights or delegation or subcontracting of duties without such prior written consent of AMICUS shall be void and ineffective. If WUXI BIOLOGICS assigns any of its rights and delegates or subcontracts any of its duties and obligations under this Agreement to any of its Affiliates (such assignment, delegation or subcontracting to an Affiliate), such assignment shall not relieve WUXI BIOLOGICS of its responsibilities and liabilities hereunder and it shall remain liable to AMICUS for the conduct and performance of WUXI BIOLOGICS' Affiliate.

11.11.1. AMICUS may assign any of its rights or delegate or subcontract any of its duties and obligations under this Agreement to an Affiliate or Third Party upon advance written notice to WUXI BIOLOGICS (including but not limited to an AMICUS Affiliate submitting a Binding Forecast or Firm Order which will constitute sufficient notice); provided, however, that such assignment, delegation or subcontracting to a Third Party shall not relieve AMICUS of its responsibilities and liabilities hereunder except if a Third Party acquires all or substantially all of AMICUS' assets related to API or Product.

11.12 Binding upon Successors. This Agreement shall inure to the benefit of and be binding upon each Party and its permitted successors and assigns.

11.13 Third Party Beneficiaries. This Agreement is not intended to give any benefits, rights, privileges, actions or remedies to any person or entity, partnership, firm or corporation as a Third Party beneficiary or otherwise under any theory of law.

11.14 Counterparts. This Agreement may be executed in counterparts, each of which shall constitute an original and all of which taken together shall constitute one and the same instrument in effect as of the Effective Date.

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IN WITNESS WHEREOF, the Parties hereto, by their respective duly authorized representatives have executed and delivered this Agreement as of the Effective Date.

| | |
|---|---|
| For and behalf of Amicus Therapeutics, Inc.<br><br>/s/ Bradley L. Campbell<br>Signature<br>Name Bradley L. Campbell<br>Position President & Chief Executive Officer<br>Date April 18, 2023 | For and behalf of WuXi Biologics (Hong Kong) Limited<br><br>/s/ Zhisheng Chen<br>Signature<br>Name Zhisheng Chen<br>Position Director<br>Date April 14, 2023<br><br>For and behalf of WuXi Biologics Ireland Limited<br><br>/s/ Zhisheng Chen<br>Signature<br>Name Zhisheng Chen<br>Position Director<br>Date April 14, 2023<br><br>For and behalf of WuXi Biologics Germany GmbH<br><br>/s/ Zhisheng Chen<br>Signature<br>Name Zhisheng Chen<br>Position Director<br>Date April 14, 2023 |

**Exhibit 31.1**

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

I, Bradley L. Campbell, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 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, Daphne Quimi, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 8, 2023

/s/ Daphne Quimi
Daphne Quimi
**Chief Financial Officer**

**Exhibit 32.1**

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

Each of the undersigned hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, in his or her capacity as an officer of Amicus Therapeutics, Inc. (the "Company"), that, to his or her knowledge, the Quarterly Report of the Company on Form 10-Q for the period ended June 30, 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: August 8, 2023 By: /s/ Bradley L. Campbell
Bradley L. Campbell
**President and Chief Executive Officer**

Date: August 8, 2023 By: /s/ Daphne Quimi
Daphne Quimi
**Chief Financial Officer**