REFINITIV

# DELTA REPORT

## 10-Q

MORF - MORPHIC HOLDING, INC.

10-Q - JUNE 30, 2024 COMPARED TO 10-Q - MARCH 31, 2024

The following comparison report has been automatically generated

| TOTAL DELTAS | 587 |
|---|---|
| CHANGES | 146 |
| DELETIONS | 239 |
| ADDITIONS | 202 |





REFINITIV

**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 March 31, 2024 June 30, 2024**

**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: 001-38940**

**MORPHIC HOLDING, INC.**
(Exact name of registrant as specified in its charter)

| **Delaware** | **47-3878772** |
|---|---|
| (State or other jurisdiction of Incorporation or Organization) | (I.R.S. Employer Identification No.) |
| **35 Gatehouse Drive, A2**<br>**Waltham, MA** | **02451** |
| (Address of Principal Executive Offices) | (Zip Code) |

Registrant's telephone number, including area code: **(781) 996-0955**
Not Applicable
Former Name, Former Address and Former Fiscal Year, if Changed Since Last Report
**Securities registered pursuant to Section 12(b) of the Exchange Act:**

| Title of each class | Trading symbol(s) | Name of each exchange on which registered |
|---|---|---|
| Common Stock, par value $0.0001 per share | MORF | The Nasdaq Stock Market LLC |

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 (Section 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 Exchange Act Rule 12b-2). Yes ☐ No ☒

The number of shares outstanding of the registrant's Common Stock as of April 23, 2024 July 23, 2024 was 50,093,588. 50,224,699.

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## PART I—FINANCIAL INFORMATION

**Item 1.** ***Condensed Consolidated Financial Statements (unaudited)***

**CONDENSED CONSOLIDATED BALANCE SHEETS (Unaudited)**
**(In thousands, except share and per share data)**

| | March 31, 2024 | December 31, 2023 | June 30, 2024 | December 31, 2023 |
|---|---|---|---|---|
| **Assets** | | | | |
| Current assets: | | | | |
| Current assets: | | | | |
| Current assets: | | | | |
| Cash and cash equivalents | | | | |
| Cash and cash equivalents | | | | |
| Cash and cash equivalents | | | | |
| Marketable securities | | | | |
| Prepaid expenses and other current assets | | | | |
| Prepaid expenses and other current assets | | | | |
| Prepaid expenses and other current assets | | | | |
| Total current assets | | | | |
| Operating lease right-of-use assets | | | | |
| Property and equipment, net | | | | |

| |
|---|
| Restricted cash |
| Other assets |
| Total assets |
| **Liabilities** |
| **Liabilities** |
| **Liabilities** |
| Current liabilities: |
| Current liabilities: |
| Current liabilities: |
| Accounts payable |
| Accounts payable |
| Accounts payable |
| Accrued expenses |
| Total current liabilities |
| Total current liabilities |
| Total current liabilities |
| Long-term liabilities: |
| Long-term liabilities: |
| Long-term liabilities: |
| Operating lease liability, net of current portion |
| Operating lease liability, net of current portion |
| Operating lease liability, net of current portion |
| Total liabilities |
| Total liabilities |
| Total liabilities |
| Commitments and contingencies (Note 9) |
| Commitments and contingencies (Note 9) |
| Commitments and contingencies (Note 9) |
| **Stockholders' Equity** |
| **Stockholders' Equity** |
| **Stockholders' Equity** |
| Preferred shares, $0.0001 par value, 10,000,000 shares authorized, no shares issued and outstanding as of March 31, 2024 and December 31, 2023 |
| Preferred shares, $0.0001 par value, 10,000,000 shares authorized, no shares issued and outstanding as of March 31, 2024 and December 31, 2023 |
| Preferred shares, $0.0001 par value, 10,000,000 shares authorized, no shares issued and outstanding as of March 31, 2024 and December 31, 2023 |
| Common shares, $0.0001 par value, 400,000,000 shares authorized, 50,093,588 shares issued and outstanding as of March 31, 2024 and 49,747,286 shares issued and outstanding as of December 31, 2023 |
| Preferred shares, $0.0001 par value, 10,000,000 shares authorized, no shares issued and outstanding as of June 30, 2024 and December 31, 2023 |
| Preferred shares, $0.0001 par value, 10,000,000 shares authorized, no shares issued and outstanding as of June 30, 2024 and December 31, 2023 |
| Preferred shares, $0.0001 par value, 10,000,000 shares authorized, no shares issued and outstanding as of June 30, 2024 and December 31, 2023 |
| Common shares, $0.0001 par value, 400,000,000 shares authorized, 50,100,692 shares issued and outstanding as of June 30, 2024 and 49,747,286 shares issued and outstanding as of December 31, 2023 |
| Additional paid-in capital |
| Accumulated deficit |
| Accumulated other comprehensive (loss) income |
| Total stockholders' equity |
| Total liabilities and stockholders' equity |

The accompanying notes are an integral part of these condensed consolidated financial statements.

**MORPHIC HOLDING, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (Unaudited)**
**(In thousands, except share and per share data)**

| | Three Months Ended March 31, | Three Months Ended March 31, | Three Months Ended March 31, | Three Months Ended June 30, | Three Months Ended June 30, | Three Months Ended June 30, |
|---|---|---|---|---|---|---|
| | 2024 | 2024 | 2024 | | | |
| Collaboration revenue | | | | | | |
| Collaboration revenue | | | | | | |
| Collaboration revenue | | | | | | |
| Operating expenses: | | | | | | |
| Operating expenses: | | | | | | |
| Operating expenses: | | | | | | |
| Research and development | | | | | | |
| Research and development | | | | | | |
| Research and development | | | | | | |
| General and administrative | | | | | | |
| General and administrative | | | | | | |
| General and administrative | | | | | | |
| Total operating expenses | | | | | | |
| Total operating expenses | | | | | | |
| Total operating expenses | | | | | | |
| Loss from operations | | | | | | |
| Loss from operations | | | | | | |
| Loss from operations | | | | | | |
| Other income: | | | | | | |
| Other income: | | | | | | |
| Other income: | | | | | | |
| Interest income, net | | | | | | |
| Interest income, net | | | | | | |
| Interest income, net | | | | | | |
| Other income, net | | | | | | |
| Other income, net | | | | | | |
| Other income, net | | | | | | |
| Other (expense) income, net | | | | | | |
| Other (expense) income, net | | | | | | |
| Other (expense) income, net | | | | | | |
| Total other income, net | | | | | | |
| Total other income, net | | | | | | |
| Total other income, net | | | | | | |
| Loss before provision for income taxes | | | | | | |
| Loss before provision for income taxes | | | | | | |

| |
|---|
| Loss before provision for income taxes |
| Provision for income taxes |
| Provision for income taxes |
| Provision for income taxes |
| Net loss |
| Net loss |
| Net loss |
| Net loss per share, basic and diluted |
| Net loss per share, basic and diluted |
| Net loss per share, basic and diluted |
| Weighted average common shares outstanding, basic and dilutive |
| Weighted average common shares outstanding, basic and diluted |
| Weighted average common shares outstanding, basic and dilutive |
| Weighted average common shares outstanding, basic and diluted |
| Weighted average common shares outstanding, basic and dilutive |
| Weighted average common shares outstanding, basic and diluted |
| Comprehensive loss: |
| Comprehensive loss: |
| Comprehensive loss: |
| Net loss |
| Net loss |
| Net loss |
| Other comprehensive (loss) income : |
| Other comprehensive (loss) income : |
| Other comprehensive (loss) income : |
| Other comprehensive (loss) income: |
| Other comprehensive (loss) income: |
| Other comprehensive (loss) income: |
| Unrealized holding (losses) gains on marketable securities, net of tax |
| Unrealized holding (losses) gains on marketable securities, net of tax |
| Unrealized holding (losses) gains on marketable securities, net of tax |
| Total other comprehensive (loss) income |
| Total other comprehensive (loss) income |
| Total other comprehensive (loss) income |
| Comprehensive loss |
| Comprehensive loss |
| Comprehensive loss |

The accompanying notes are an integral part of these condensed consolidated financial statements.

**MORPHIC HOLDING, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (Unaudited)**
**(In thousands, except share data)**

| | Common Shares | | Common Shares | Additional Paid-in Capital | Accumulated Deficit | Accumulated Other Comprehensive Income (Loss) | Total Stockholders' Equity | | Common Shares | Additional Paid-in Capital | Accumulated Deficit | Accumulated Other Comprehensive Income (Loss) | Total Stockholders' Equity |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Shares | Shares | Amount | | | | | Total Stockholders' Equity | Amount | | | | |
| **Balance at December 31, 2023** | | | | | | | | | | | | | |

| | | | | | | |
|---|---|---|---|---|---|---|
| Equity-based compensation expense | | | | | | |
| Vesting of restricted shares | | | | | | |
| Issuance of common shares upon stock option exercises | | | | | | |
| Issuance of common shares under the Employee Stock Purchase Plan | | | | | | |
| Unrealized holding losses on marketable securities | | | | | | |
| Net loss | | | | | | |
| **Balance at March 31, 2024** | | | | | | |
| Equity-based compensation expense | | | | | | |
| Vesting of restricted shares | | | | | | |
| Issuance of common shares upon stock option exercises | | | | | | |
| Unrealized holding losses on marketable securities | | | | | | |
| Net loss | | | | | | |
| **Balance at June 30, 2024** | | | | | | |

| | Common Shares | | Additional Paid-in Capital | Accumulated Deficit | Accumulated Other Comprehensive Income (Loss) | Total Stockholders' Equity |
|---|---|---|---|---|---|---|
| | Shares | Amount | | | | |
| **Balance at December 31, 2022** | **38,584,678** | **$ 4** | **$ 649,549** | **$ (297,095)** | **$ (3,339)** | **$ 349,119** |
| Equity-based compensation expense | — | — | 9,576 | — | — | 9,576 |
| Vesting of restricted shares | 60,060 | — | — | — | — | — |
| Issuance of common shares upon stock option exercises | 124,620 | — | 1,927 | — | — | 1,927 |
| Issuance of common shares under the Employee Stock Purchase Plan | 23,449 | — | 578 | — | — | 578 |
| Issuance of pre-funded warrant shares through private placement, net of issuance costs of $0.1 million | — | — | 69,859 | — | — | 69,859 |
| Issuance of common shares through private placement, net of issuance costs of $0.1 million | 848,655 | — | 29,940 | — | — | 29,940 |
| Unrealized holding gains on marketable securities | — | — | — | — | 1,651 | 1,651 |
| Net loss | — | — | — | (36,135) | — | (36,135) |
| **Balance at March 31, 2023** | **39,641,462** | **$ 4** | **$ 761,429** | **$ (333,230)** | **$ (1,688)** | **$ 426,515** |

| | Common Shares | | Additional Paid-in Capital | Accumulated Deficit | Accumulated Other Comprehensive Income (Loss) | Total Stockholders' Equity |
|---|---|---|---|---|---|---|
| | Shares | Amount | | | | |
| **Balance at December 31, 2022** | **38,584,678** | **$ 4** | **$ 649,549** | **$ (297,095)** | **$ (3,339)** | **$ 349,119** |
| Equity-based compensation expense | — | — | 9,576 | — | — | 9,576 |
| Vesting of restricted shares | 60,060 | — | — | — | — | — |
| Issuance of common shares upon stock option exercises | 124,620 | — | 1,927 | — | — | 1,927 |
| Issuance of common shares under the Employee Stock Purchase Plan | 23,449 | — | 578 | — | — | 578 |
| Issuance of pre-funded warrant shares through private placement, net of issuance costs of $0.1 million | — | — | 69,859 | — | — | 69,859 |

| | | | | | | |
|---|---|---|---|---|---|---|
| Issuance of common shares through private placement, net of issuance costs of $0.1 million | 848,655 | — | 29,940 | — | — | 29,940 |
| Unrealized holding gains on marketable securities | — | — | — | — | 1,651 | 1,651 |
| Net loss | — | — | — | (36,135) | — | (36,135) |
| **Balance at March 31, 2023** | **39,641,462** | **$ 4** | **$ 761,429** | **$ (333,230)** | **$ (1,688)** | **$ 426,515** |
| Equity-based compensation expense | — | — | 10,315 | — | — | 10,315 |
| Vesting of restricted shares | 1,500 | — | — | — | — | — |
| Issuance of common shares upon stock option exercises | 390,490 | — | 5,511 | — | — | 5,511 |
| Issuance of common stock upon exercise of pre-funded warrants | 499,998 | — | — | — | — | — |
| Issuance of common shares through at-the-market offering, net of issuance costs of $1.4 million | 1,216,418 | — | 67,201 | — | — | 67,201 |
| Issuance of common shares in secondary offering, net of offering costs of $16.9 million | 6,133,334 | 1 | 259,060 | — | — | 259,061 |
| Unrealized holding losses on marketable securities | — | — | — | — | (229) | (229) |
| Net loss | — | — | — | (39,013) | — | (39,013) |
| **Balance at June 30, 2023** | **47,883,202** | **$ 5** | **$ 1,103,516** | **$ (372,243)** | **$ (1,917)** | **$ 729,361** |

The accompanying notes are an integral part of these condensed consolidated financial statements.

**MORPHIC HOLDING, INC.**
**CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)**
**(In thousands)**

| | Three Months Ended March 31, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | 2024 | 2023 | 2024 | 2023 |
| **Cash flows from operating activities:** | | | | |
| Net loss | | | | |
| Net loss | | | | |
| Net loss | | | | |
| Adjustments to reconcile net loss to net cash used in operating activities: | | | | |
| Depreciation and amortization | | | | |
| Depreciation and amortization | | | | |
| Depreciation and amortization | | | | |
| Discount accretion and premium amortization on marketable securities | | | | |
| Equity-based compensation | | | | |
| Change in operating assets and liabilities: | | | | |
| Change in operating assets and liabilities: | | | | |
| Change in operating assets and liabilities: | | | | |
| Accounts receivable | | | | |
| Accounts receivable | | | | |
| Accounts receivable | | | | |
| Prepaid expenses and other current assets | | | | |
| Other assets | | | | |
| Operating lease right-of-use assets | | | | |
| Accounts payable | | | | |
| Accrued expenses | | | | |
| Deferred revenue | | | | |

| | |
|---|---|
| Operating lease liability | |
| Net cash used in operating activities | |
| **Cash flows from investing activities:** | |
| Purchases of marketable securities | |
| Purchases of marketable securities | |
| Purchases of marketable securities | |
| Proceeds from maturities of marketable securities | |
| Purchases of property and equipment | |
| Purchases of property and equipment | |
| Purchases of property and equipment | |
| Net cash provided by (used in) investing activities | |
| **Cash flows from financing activities:** | |
| Proceeds from issuance of common shares and pre-funded warrants through the private placement | |
| Proceeds from issuance of common shares and pre-funded warrants through the private placement | |
| Proceeds from issuance of common shares and pre-funded warrants through the private placement | |
| Proceeds from issuance of common shares under Employee Stock Purchase Plan | |
| Proceeds from issuance of common shares upon stock option exercises | |
| Proceeds from issuance of common shares upon stock option exercises | |
| Proceeds from at-the-market offering, net of issuance costs | |
| Proceeds from secondary offering, net of issuance costs | |
| Proceeds from issuance of common shares upon stock option exercises | |
| Net cash provided by financing activities | |
| Net decrease in cash, cash equivalents and restricted cash | |
| Net (decrease) increase in cash, cash equivalents and restricted cash | |
| **Cash and cash equivalents and restricted cash, beginning of period** | |
| **Cash and cash equivalents and restricted cash, end of period** | |
| **Non-cash activities:** | |
| **Non-cash activities:** | |
| **Non-cash activities:** | |
| Right-of-use assets obtained in exchange for operating lease liabilities | |
| Right-of-use assets obtained in exchange for operating lease liabilities | |
| Right-of-use assets obtained in exchange for operating lease liabilities | |
| Purchases of property and equipment included in accounts payable and accrued expenses | |
| Amounts from exercise of stock options included in prepaid expenses and other current assets | |
| Unpaid issuance costs for the private placement included in accounts payable and accrued expenses | |
| Unpaid issuance costs for the at-the-market and secondary offerings included in accounts payable and accrued expenses | |

The accompanying notes are an integral part of these condensed consolidated financial statements.

**NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)**

**1. Nature of the Business and Basis of Presentation**

***Organization and Liquidity Description of Business***

Morphic Holding, Inc. (the “Company”) was formed under the laws of the State of Delaware in August 2014. The Company is a biopharmaceutical company applying proprietary insights into integrin medicine to discover and develop potentially first-in-class oral small molecule integrin therapeutics. Integrins are a target class with multiple approved injectable blockbuster drugs for the treatment of serious chronic diseases, including autoimmune, cardiovascular and metabolic diseases, fibrosis and cancer. To date, no oral small molecule integrin therapies have been approved by the U.S. Food and Drug Administration (“FDA”). The Company believes its unique platform can unlock the potential to reliably generate high-quality oral molecules against specific integrin targets. The Morphic integrin technology platform (“MInT Platform”) was created by leveraging the Company's unique understanding of integrin structure and function to develop novel product candidates designed to achieve the potency, high selectivity, and pharmaceutical properties required for oral administration.

***Pending Transaction with Eli Lilly and Company***

On July 7, 2024, the Company entered into an Agreement and Plan of Merger (the "Merger Agreement") with Eli Lilly and Company, an Indiana corporation ("Lilly" or "Parent"), and Rainier Acquisition Corporation, a Delaware corporation and a wholly owned subsidiary of Lilly ("Merger Sub"). On the terms and subject to the conditions of the Merger Agreement, on July 19, 2024, Merger Sub commenced a cash tender offer (the "Offer") to purchase all of the outstanding shares of the Company's common stock at a price of $57.00 per share, net to the stockholder in cash, without interest thereon and subject to applicable tax withholding. Following consummation of the Offer, Merger Sub will merge with and into the Company, with the Company surviving as a wholly owned subsidiary of Parent (the "Merger"). If the Merger Agreement is terminated under specified circumstances, the Company will be required to pay Parent a termination fee of $118.0 million. The Offer and the Merger are subject to customary closing conditions. The Merger is anticipated to close in the third quarter of 2024, assuming satisfaction or waiver of all of the conditions of the Offer and the Merger. If the Merger is consummated, the Company will cease to be a publicly traded company.

Concurrently with the execution of the Merger Agreement, Parent entered into tender and support agreements (collectively, the "Support Agreements") with certain stockholders of the Company (collectively, the "Supporting Stockholders"), who in the aggregate beneficially owned approximately 20.5% of the Company's common stock as of July 3, 2024, pursuant to which each Supporting Stockholder has agreed, among other things, to (i) tender all of the shares of the Company's common stock held by such Supporting Stockholder in the Offer, subject to certain exceptions (including the valid termination of the Merger Agreement), (ii) vote against other proposals to acquire the Company and (iii) certain other restrictions on its ability to take actions with respect to the Company and the shares of the Company's common stock held by such Supporting Stockholder.

***Liquidity and Capital Resources***

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities. Even if the Company's drug development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales. The Company expects to continue to incur losses from operations for the foreseeable future. The Company expects that its cash, cash equivalents and marketable securities will be sufficient to fund its operating expenses and capital expenditure requirements through at least the next 12 months from the date these financial statements were issued.

In July 2020, the Company entered into an Open Market Sale Agreement, (the "Original Agreement") which was amended by Amendment No. 1 thereto in August 2021, with Jefferies LLC ("Jefferies") with respect to an at-the-market offering program (the "Previous "Jefferies ATM"), under which the Company could offer and sell, from time to time at its sole discretion, shares of its common stock, having an aggregate offering amount of up to $75.0 $150.0 million, referred to as Jefferies Placement Shares, through Jefferies as sales agent. The Company paid Jefferies a commission on the gross sales proceeds of any Jefferies Placement Shares sold through Jefferies under the Original Agreement, Jefferies ATM, and also provided Jefferies with customary indemnification and contribution rights. On August 11, 2021, In connection with the Company entered Company's entry into an Amendment No. 1 to the Original Agreement with Jefferies, establishing a new at-the-market offering ("New ATM") with an aggregate offering amount of up to $150.0 million, also program, on April 25, 2024, the Company terminated the Jefferies ATM. The Company was not subject to a commission on the gross proceeds from sales of Placement Shares. The Company refers any termination penalties related to the Previous ATM and termination of the New ATM, collectively, as Jefferies ATM. During the six months ended June 30, 2024, no shares were issued under the Jefferies ATM. The Company may not sell any additional Jefferies Placement Shares under the Previous Jefferies ATM. Under

On April 26, 2024, the New ATM, Company entered into a Sales Agreement with TD Securities (USA) LLC ("TD Cowen"), under which the Company may offer and sell, from time to time at its sole discretion, shares of its common stock having an aggregate offering amount of up to $350.0 million, referred to as Cowen Placement Shares, through TD Cowen as sales agent pursuant to an at-the-market offering program (the "TD Cowen ATM"). The Company agreed to pay TD Cowen a commission on the gross sales proceeds of any Cowen Placement Shares sold through TD Cowen and also provided TD Cowen with customary indemnification and contribution rights. In conjunction with its entry into the TD Cowen ATM, the Company terminated the Jefferies as its sales agent. ATM. During the three six months ended March 31, 2024 June 30, 2024, no shares were issued under the New TD Cowen ATM. As of March 31, 2024 At June 30, 2024, the Company had approximately $10.9 million $350.0 million of common stock remaining remained available for sale under the New TD Cowen ATM.

In February 2023, the Company entered into a securities purchase agreement with existing investors, consisting of a board member and holder of more than 5% of the Company's common stock and a then holder of more than 5% of the Company's common stock, pursuant to which the Company sold to the investors, in a private placement, 848,655 shares of common stock at a price of $35.35 per share (the "PIPE Shares") and pre-funded warrants to purchase up to 1,980,198 shares of common stock at a purchase price of $35.3499 per pre-funded warrant where each pre-funded warrant has an exercise price of $0.0001 per share (the "Pre-Funded Warrants"). The Company received aggregate net proceeds of approximately $100.0 million, before deducting costs and offering expenses payable by the Company.

In May 2023, the Company completed an underwritten public offering of 6,133,334 shares of its common stock, which includes 800,000 shares sold upon the exercise in full of the underwriters' option to purchase additional shares of common stock, at a price to the public of $45.00 per share. Gross proceeds from the secondary offering were approximately $276.0 million, before deducting underwriting discounts, commissions and other offering expenses payable by the Company of approximately $16.9 million, resulting in net proceeds of approximately $259.1 million.

**2. Basis of Presentation and Significant Accounting Policies**

***Basis of Presentation***

The unaudited interim condensed consolidated financial statements include the accounts of Morphic Holding, Inc. and its wholly owned subsidiaries, Morphic Therapeutic, Inc., Morphic Therapeutic UK Ltd and Morphic Security Corporation. All intercompany balances have been eliminated in consolidation.

The accompanying condensed consolidated financial statements are unaudited and have been prepared by the Company in accordance with accounting principles generally accepted in the United States ("GAAP") as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB"). Certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted. These unaudited

interim condensed consolidated financial statements, in the opinion of management, reflect all normal recurring adjustments necessary for a fair presentation of the Company's financial position and results of operations for the interim periods ended March 31, 2024 June 30, 2024 and 2023.

The results of operations for the interim periods are not necessarily indicative of the results of operations to be expected for the full year. These unaudited interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements as of and for the year ended December 31, 2023, and the notes thereto, which are included in the Company's Annual Report on Form 10-K, for the fiscal year ended December 31, 2023, filed with the Securities and Exchange Commission (the "SEC") on February 22, 2024.

***Use of Estimates and Summary of Significant Accounting Policies***

The preparation of financial statements in accordance with GAAP requires management to make estimates and judgments that may affect the reported amounts of assets and liabilities and related disclosures of contingent assets and liabilities at the date of the financial statements and the related reporting of revenues and expenses during the reporting period. Significant estimates of accounting reflected in these consolidated financial statements include, but are not limited to, estimates related to accrued research and development expenses. Actual results could differ from those estimates.

***Significant accounting policies***

The significant accounting policies used in preparation of these condensed consolidated financial statements as of and for the three and six months ended March 31, 2024 June 30, 2024 are consistent with those discussed in Note 2 to the consolidated financial statements in the Company's 2023 Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on February 22, 2024.

**3. Fair Value of Financial Assets and Liabilities**

The Company has certain financial assets and liabilities that are recorded at fair value which have been classified as Level 1, 2 or 3 within the fair value hierarchy as described in the accounting standards for fair value measurements:

- Level 1 — Quoted market prices in active markets for identical assets or liabilities.
- Level 2 — Inputs other than Level 1 inputs that are either directly or indirectly observable, such as quoted market prices, interest rates and yield curves.
- Level 3 — Unobservable inputs developed using estimates of assumptions developed by the Company, which reflect those that a market participant would use.

At March 31, 2024 June 30, 2024, investments include U.S. Treasury securities and U.S. government-sponsored enterprise securities, which are valued either based on recent trades of securities in inactive markets or based on quoted market prices of similar instruments and other significant inputs derived from or corroborated by observable market data.

To the extent the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair values requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized as Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

The Company believes that the carrying amounts of the Company's consolidated financial instruments, including prepaid expenses and other current assets, accounts receivable, accounts payable, and accrued expenses approximate fair value due to the short-term nature of those instruments.

The tables below present information about the Company's financial assets that are measured at fair value on a recurring basis as of March 31, 2024 June 30, 2024 and December 31, 2023 (in thousands) and indicate the level within the fair value hierarchy where each measurement is classified.

| | Fair Value Measurements at March 31, 2024 | Fair Value Measurements at March 31, 2024 | Fair Value Measurements at March 31, 2024 | | Fair Value Measurements at June 30, 2024 | Fair Value Measurements at June 30, 2024 | Fair Value Measurements at June 30, 2024 | |
|---|---|---|---|---|---|---|---|---|
| | Total | Total | Level 1 | Level 2 | Level 3 | Total | Level 1 | Level 2 | Level 3 |
| Assets: | | | | | | | | | |
| Cash equivalents | | | | | | | | | |
| Cash equivalents | | | | | | | | | |
| Cash equivalents | | | | | | | | | |
| Marketable securities: | | | | | | | | | |
| U.S. Treasury securities | | | | | | | | | |
| U.S. Treasury securities | | | | | | | | | |
| U.S. Treasury securities | | | | | | | | | |
| U.S. government-sponsored enterprise securities | | | | | | | | | |
| Total assets | | | | | | | | | |
| Total assets | | | | | | | | | |
| Total assets | | | | | | | | | |

| | Fair Value Measurements at December 31, 2023 | | | |
|---|---|---|---|---|
| | Total | Level 1 | Level 2 | Level 3 |

| | | | | |
|---|---|---|---|---|
| Assets: | | | | |
| Cash equivalents | $ 57,988 | $ 57,988 | $ — | $ — |
| Marketable securities: | | | | |
| U.S. Treasury securities | 573,394 | — | 573,394 | — |
| U.S. government-sponsored enterprise securities | 54,906 | — | 54,906 | — |
| Corporate bonds | 17,472 | — | 17,472 | — |
| Total assets | $ 703,760 | $ 57,988 | $ 645,772 | $ — |

Cash equivalents consist of money market funds and U.S. Treasury securities as of March 31, 2024 June 30, 2024 and money market funds as of December 31, 2023. The money market funds included in the tables above invest in U.S. government securities that are valued using quoted market prices. Accordingly, money market funds are categorized as Level 1 as of March 31, 2024 June 30, 2024 and December 31, 2023. The U.S. Treasury securities included in cash equivalents as of March 31, 2024 June 30, 2024 are considered highly liquid investments and mature within three months from the date of purchase. Marketable securities included in the tables above consist of U.S. Treasury securities and U.S. government-sponsored enterprise securities as of March 31, 2024 June 30, 2024 and U.S. Treasury securities, U.S. government-sponsored enterprise securities and corporate bonds as of December 31, 2023, and these securities are categorized as Level 2 as of March 31, 2024 June 30, 2024 and December 31, 2023. The Company had no liabilities measured at fair value on a recurring basis at March 31, 2024 June 30, 2024 and December 31, 2023.

**4. Marketable securities**

The following tables summarize the Company's investments in marketable securities classified as available-for-sale (in thousands):

| | As of March 31, 2024 | | | | | | As of June 30, 2024 | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Maturity | Maturity | Amortized cost | Gross unrealized holding gains | Gross unrealized holding losses | Aggregate estimated fair value | Maturity | Amortized cost | Gross unrealized holding gains | Gross unrealized holding losses | Aggregate estimated fair value |
| Marketable securities: | | | | | | | | | | | |
| U.S. Treasury securities | | | | | | | | | | | |
| U.S. Treasury securities | | | | | | | | | | | |
| U.S. Treasury securities | | | | | | | | | | | |
| U.S. government-sponsored enterprise securities | | | | | | | | | | | |
| Total marketable securities | | | | | | | | | | | |
| Total marketable securities | | | | | | | | | | | |
| Total marketable securities | | | | | | | | | | | |

| | As of December 31, 2023 | | | | |
|---|---|---|---|---|---|
| | Maturity | Amortized cost | Gross unrealized holding gains | Gross unrealized holding losses | Aggregate estimated fair value |
| Marketable securities: | | | | | |
| U.S. Treasury securities | within 3 years | $ 570,964 | $ 2,499 | $ (69) | $ 573,394 |
| U.S. government-sponsored enterprise securities | less than 1 year | 54,997 | — | (91) | 54,906 |
| Corporate bonds | less than 1 year | 17,498 | — | (26) | 17,472 |
| Total marketable securities | | $ 643,459 | $ 2,499 | $ (186) | $ 645,772 |

All of the Company's investments are classified as available-for-sale and are carried at fair value with unrealized gains and losses recorded as a component of accumulated other comprehensive loss. The Company considers all available-for-sale securities, including those with maturity dates beyond 12 months, as available to support current operational liquidity needs and therefore classifies all available-for-sale securities as current assets.

The Company determined that there was no material change in the credit risk of the above securities during the three six months ended March 31, 2024 June 30, 2024. As such, an allowance for credit losses was not recognized. As of March 31, 2024 June 30, 2024, the Company does not intend to sell such securities and it is not more likely than not that the Company will be required to sell the securities before recovery of its amortized cost basis.

Accrued interest receivable on the Company's available-for-sale debt securities totaled $4.2 million as of March 31, 2024 June 30, 2024 and $4.4 million as of December 31, 2023.

**5. Cash, Cash Equivalents and Restricted Cash**

Cash and cash equivalents are primarily maintained with three financial institutions located in the U.S. Deposits balances with financial institutions may exceed the Federal Deposit Insurance Corporation insurance limit of $250,000 on such deposits. The Company has not experienced losses on these accounts and does not believe it is exposed to any significant credit risk with respect to these accounts. Restricted cash consists of cash collateralizing letters of credit in the amount of $616,030, which includes a letter of credit issued to the landlord of the Company's facility lease and a letter of credit issued to the Company's sublease landlord for the sublease that commenced subsequent to March 31, 2024, see Note 9 for additional disclosure on the sublease. April 1, 2024. The terms of the letters of credit extend beyond one year. The following table reconciles cash, cash equivalents and restricted cash per the balance sheet to the statements of cash flows (in thousands):

| | March 31, |
|---|---|

| | March 31, | March 31, |
|---|---|---|
| | June 30, | June 30, |
| | June 30, | 2024 |
| | 2024 | 2024 |
| | 2024 | |
| Cash and cash equivalents | | |
| Cash and cash equivalents | | |
| Cash and cash equivalents | | |
| Restricted cash | | |
| Restricted cash | | |
| Restricted cash | | |
| Total cash, cash equivalents, and restricted cash | | |
| Total cash, cash equivalents, and restricted cash | | |
| Total cash, cash equivalents, and restricted cash | | |

**6. Accrued Expenses**

At March 31, 2024 June 30, 2024 and December 31, 2023 accrued expenses consisted of the following (in thousands):

| | March 31, | | December 31, | | |
|---|---|---|---|---|---|
| | June 30, | | December 31, | | |
| | 2024 | 2024 | 2023 | 2024 | 2023 |
| Payroll and related expenses | | | | | |
| Research and development activities | | | | | |
| Current portion of operating lease liability | | | | | |
| Other expenses | | | | | |
| Total | | | | | |

**7. Equity-Based Compensation**

In connection with the Company's initial public offering in July 2019, the Company adopted the 2019 Equity Incentive Plan (the "Original 2019 Plan") in June 2019, which replaced the 2018 Stock Incentive Plan.

The board of directors adopted the Amended and Restated 2019 Equity Incentive Plan (the "A&R 2019 Plan" and, together with the Original 2019 Plan, the "2019 Plan") on April 27, 2022, which was subsequently approved by the Company's stockholders on June 8, 2022, to revise the total annual compensation that may be awarded to the Company's non-employee directors thereunder. The A&R 2019 Plan provides for the grant of stock options, restricted stock awards, stock bonus awards, cash awards, stock appreciation right, restricted stock units, and performance awards to directors, officers and employees of the Company, as well as consultants and advisors of the Company. As a result of the automatic increase provision of the A&R 2019 Plan, the number of shares of common stock available for issuance thereunder increased by 2.0 million shares in January 2024. As of March 31, 2024 June 30, 2024, there were a total of 0.6 million 0.5 million shares available for future award grants under the A&R 2019 Plan.

On February 17, 2024, the Company's board of directors adopted the 2024 Equity Inducement Plan (the "Inducement Plan"). The Inducement Plan provides for the grant of stock options and restricted stock awards to persons who were not previously an employee or director of the Company, as an inducement material to such person's entry into employment with the Company and in accordance with the requirements of the Nasdaq Stock Market Rule 5635(c)(4). As of March 31, 2024 June 30, 2024, there were a total of 0.3 million shares available for future award grants under the Inducement Plan.

The Company recognized equity-based compensation expense in the condensed consolidated statements of operations and comprehensive loss, by award type, as follows (in thousands):

| | Three Months Ended March 31, | Three Months Ended March 31, |
|---|---|---|
| | Three Months Ended June 30, | Three Months Ended June 30, |
| | Three Months Ended June 30, | 2024 |
| | 2024 | |

| | 2024 |
|---|---|
| | 2024 |
| Stock options | |
| Stock options | |
| Stock options | |
| Restricted stock units | |
| Restricted stock units | |
| Restricted stock units | |
| Employee Stock Purchase Plan | |
| Employee Stock Purchase Plan | |
| Employee Stock Purchase Plan | |
| Total | |
| Total | |
| Total | |

The following table summarizes the allocation of equity-based compensation expense in the condensed consolidated statements of operations and comprehensive loss, by expense category (in thousands):

| | Three Months Ended March 31, | Three Months Ended June 30, |
|---|---|---|
| | 2024 | 2024 |
| | 2024 | 2024 |
| Research and development expense | | |
| Research and development expense | | |
| Research and development expense | | |
| General and administrative expense | | |
| General and administrative expense | | |
| General and administrative expense | | |
| Total | | |
| Total | | |
| Total | | |

*Restricted Stock Units*

The following table summarizes the Company's restricted stock unit activity during the three six months ended March 31, 2024 June 30, 2024:

| | Number of Shares | Number of Shares | Weighted Average Fair Value per Share at Issuance | Number of Shares | Weighted Average Fair Value per Share at Issuance |
|---|---|---|---|---|---|
| Unvested restricted stock units as of December 31, 2023 | | | | | |
| Granted | | | | | |
| Vested | | | | | |
| Forfeited | | | | | |
| Unvested restricted stock units as of March 31, 2024 | | | | | |
| Unvested restricted stock units as of June 30, 2024 | | | | | |

*Stock Options*

The following table summarizes the Company's stock option activity during the three six months ended March 31, 2024 June 30, 2024:

| | Number of Shares | Number of Shares | Number of Shares |
|---|---|---|---|

| | | | |
|---|---|---|---|
| Outstanding as of December 31, 2023 | | | |
| Outstanding as of December 31, 2023 | | | |
| Outstanding as of December 31, 2023 | | | |
| Granted | | | |
| Granted | | | |
| Granted | | | |
| Exercised | | | |
| Exercised | | | |
| Exercised | | | |
| Forfeited or expired | | | |
| Forfeited or expired | | | |
| Forfeited or expired | | | |
| Outstanding as of March 31, 2024 | | | |
| Outstanding as of March 31, 2024 | | | |
| Outstanding as of March 31, 2024 | | | |
| Options exercisable as of March 31, 2024 | | | |
| Options exercisable as of March 31, 2024 | | | |
| Options exercisable as of March 31, 2024 | | | |
| Outstanding as of June 30, 2024 | | | |
| Outstanding as of June 30, 2024 | | | |
| Outstanding as of June 30, 2024 | | | |
| Options exercisable as of June 30, 2024 | | | |
| Options exercisable as of June 30, 2024 | | | |
| Options exercisable as of June 30, 2024 | | | |

**8. Income Taxes**

Deferred tax assets and deferred tax liabilities are recognized based on temporary differences between the financial reporting and tax basis of assets and liabilities using statutory rates. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of the deferred tax assets will not be realized.

Beginning in 2022, the Tax Cuts and Jobs Act (“TCJA”) amended Section 174 and now requires U.S.-based and non-U.S.-based research and experimental expenditures to be capitalized and amortized over a period of five and 15 years, respectively, for amounts paid in tax years starting after December 31, 2021. The Company’s ability to use its operating loss carryforwards and tax credits to offset future taxable income is subject to restrictions under Sections 382 and 383 of the United States Internal Revenue Code (“Internal Revenue Code”). Net operating loss and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant stockholders over a three-year period in excess of 50 percent, as defined under Sections 382 and 383 of the Internal Revenue Code. Such changes would limit the Company’s use of its operating loss carryforwards and tax credits. In such a situation, the Company may be required to pay income taxes, even though significant operating loss carryforwards and tax credits exist.

The Company records a provision or benefit for income taxes on ordinary pre-tax income or loss based on its estimated effective tax rate for the year. As of March 31, 2024 June 30, 2024, the Company forecasts an ordinary pre-tax loss for the year ended December 31, 2024 and, since it maintains a full valuation allowance on its deferred tax assets, the Company did not record an income tax benefit in 2024.

**9. Commitments and Contingencies**

***Guarantees and Indemnifications***

The Company entered, and intends to continue to enter, into separate indemnification agreements with directors, officers, and certain other key employees, in addition to the indemnification provided for in the restated certificate of incorporation and restated bylaws, as amended. These agreements, among other things, require the Company to indemnify directors, officers, and certain other key employees for certain expenses, including attorneys’ fees, judgments, penalties, fines, and settlement amounts actually incurred by these individuals in any action or proceeding arising out of their service to the Company or any of its subsidiaries or any other company or enterprise to which these individuals provide services at the Company’s request. Subject to certain limitations, the indemnification agreements also require the Company to advance expenses incurred by directors, officers, and key employees for the defense of any action for which indemnification is required or permitted.

The Company has standard indemnification arrangements in its leases for laboratory and office space that require it to indemnify the landlord against any liability for injury, loss, accident, or damage from any claims, actions, proceedings, or costs resulting from certain acts, breaches, violations, or non-performance under the Company’s lease.

Through March 31, 2024 June 30, 2024, the Company had not experienced any losses related to these indemnification obligations, and no material claims were outstanding. The Company does not expect significant claims related to these indemnification obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related reserves were established.

On March 29, 2024, the Company entered into a lease extension with its current landlord for its existing leased office and laboratory space to extend the lease through December 31, 2025. The future rent payments for the leased space increased by $1.0 million as a result of the lease extension. As part of the lease modification, which was not accounted for as a separate contract, the Company reassessed and concluded that the classification of the lease continues to be an operating lease, remeasured, using the discount rate at the effective date of the modification, the remaining rent payments to increase the lease liability and right of use asset.

On March 26, 2024, the Company entered into a sublease agreement for additional office space in the same building as the Company's corporate headquarters. The sublease agreement is for the Company to occupy 7,257 square feet of office space from April 1, 2024, the date the Company gained access to the space, through December 30, 2025. The future rent payments total $0.6 million, which does not include operating expenses, taxes or other non-lease component payments that are not fixed.

There were no additional material changes to the Company's contractual obligations and commitments previously disclosed in Note 11 to the consolidated financial statements appearing in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on February 22, 2024.

***Legal Proceedings***

The Company is not currently a party to any material legal proceedings.

**10. Option and License Agreements**

A detailed description of contractual terms and the Company's accounting for the agreement described below was included in the Company's audited financial statements and notes in the Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on February 22, 2024.

***Janssen Agreement***

In February 2019, the Company entered into a research collaboration and option agreement with Janssen Pharmaceuticals, Inc. (the "Janssen Agreement"), a subsidiary of Johnson & Johnson ("Janssen"), to discover and develop novel integrin therapeutics for patients with conditions not adequately addressed by current therapies. In January 2023, Janssen informed the Company that it had decided to exercise its right to terminate the Janssen Agreement for convenience. Certain remaining research and development performance obligations under the Janssen Agreement were completed, including the termination of the third integrin research program thereunder, through the effective date of the termination in March 2023. In March 2023, the Company recognized the remaining deferred revenue allocated to the material right upon expiration of the Janssen license option.

The following table summarizes research and development costs incurred and revenue recognized in connection with Company's performance under the Janssen Agreement during the three six months ended March 31, 2023 June 30, 2023 (in thousands):

| | Three Six Months Ended March 31, June 30, 2023 |
|---|---|
| Reimbursement revenue | $ 51 |
| Upfront payment revenue | 470 |
| Total revenue recognized | $ 521 |
| Costs incurred | $ 51 |

As of March 31, 2023 June 30, 2024, the Company had no remaining deferred revenue related to the Janssen Agreement, as all of the performance obligations thereunder were satisfied as of March 31, 2023.

**11. Net Loss per Share**

Basic net loss per share is calculated by dividing net loss allocable to common stockholders by the weighted-average common shares outstanding during the period, without consideration of common stock equivalents.

For periods with net income, diluted net income per share is calculated by adjusting the weighted-average shares outstanding for the dilutive effect of common stock equivalents, including stock options and restricted common stock and stock units outstanding for the period as determined using the treasury stock method.

For purposes of the diluted net loss per share calculation, common stock equivalents are excluded from the calculation if their effect would be anti-dilutive. As such, basic and diluted net loss per share applicable to common stockholders are the same for periods with a net loss.

The following tables illustrate the determination of basic and diluted loss per share for each period presented (in thousands, except share and per share data):

| | Three Months Ended March 31, Three Months Ended March 31, Three Months Ended March 31, Three Months Ended June 30, Three Months Ended June 30, Three Months Ended June 30, 2024 2024 2024 |
|---|---|
| Net loss | |

| | |
|---|---|
| Net loss | |
| Net loss | |
| Weighted average common shares outstanding, basic and diluted | |
| Weighted average common shares outstanding, basic and diluted | |
| Weighted average common shares outstanding, basic and diluted | |
| Net loss per share, basic and diluted | |
| Net loss per share, basic and diluted | |
| Net loss per share, basic and diluted | |

In February 2023, the Company sold and issued the Pre-Funded Warrants (see Note 1). The shares of common stock into which the Pre-Funded Warrants were exercisable were considered outstanding for the purposes of computing basic earnings per share because the shares could be issued for little or no consideration, and because the Pre-Funded Warrants were fully vested and immediately exercisable upon issuance. The Pre-Funded Warrants were net exercised in their entirety during the year-ended December 31, 2023.

The following table sets forth the outstanding common stock equivalents, presented based on amounts outstanding at each period end, that have been excluded from the calculation of diluted net loss per share for the periods indicated because their inclusion would have been anti-dilutive (in common stock equivalent shares, as applicable):

| | Three Months Ended March 31, | Three and Six Months Ended June 30, |
|---|---|---|
| | 2024 | 2024 |
| Restricted stock units | | |
| Restricted stock units | | |
| Restricted stock units | | |
| Stock options | | |
| Stock options | | |
| Stock options | | |
| Total | | |
| Total | | |
| Total | | |

In addition to the securities listed in the table above, as of March 31, 2024 June 30, 2024 the Company had reserved 1,971,633 shares of common stock for sale under the Company's Employee Stock Purchase Plan, which, if issued, would be anti-dilutive if included in calculation of diluted net loss per share for the three and six months ended March 31, 2024 June 30, 2024.

**Item 2. *Management's Discussion and Analysis of Financial Condition and Results of Operations***

*You should read the following discussion of our financial condition and results of operations in conjunction with our unaudited condensed consolidated financial statements and the related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q and our audited consolidated financial statements and the related notes included as part of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on February 22, 2024.*

*In addition to historical financial information, this discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties, such as statements of our plans, objectives, expectations, intentions and belief. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in the section titled "Risk Factors" under Part II, Item 1A. These forward-looking statements may include, but are not limited to, statements regarding our expectations related to the Merger Agreement (as defined below), including our ability to consummate the Offer (as defined below), the Merger (as defined below) and the other transactions contemplated by the Merger Agreement (the "Transactions"), the parties' ability to satisfy the conditions to the consummation of the Offer and the other conditions set forth in the Merger Agreement, the expected timetable for consummating the Transactions, and the potential benefits of the Transactions for us and our stockholders; our future results of operations and financial position, position; our business strategy, market size and, potential growth opportunities, opportunities; our preclinical and clinical development activities, activities; the efficacy and safety profile of our product candidates, candidates; the, use of net proceeds from our offerings, any offerings; our ability to maintain and recognize the benefits of certain designations received by product candidates, candidates; the timing and results of preclinical studies and clinical trials, trials; commercial collaborations with third parties, parties; the receipt and timing of potential regulatory designations, approvals and commercialization of product candidates, candidates;*

*and the impact of risks and uncertainties in connection with the current macroeconomic and geopolitical environments, increases in inflation, interest rate fluctuations, uncertainty with respect to the federal debt ceiling and budget and the related potential for government shutdowns, the ongoing labor shortage, disruptions to global supply chains, and regional conflicts around the world. The words "believe," "may," "will," "potentially," "estimate," "continue," "anticipate," "predict," "target," "intend," "could," "would," "should," "project," "plan," "expect," and similar expressions that convey uncertainty of future events or outcomes are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.*

*These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements.*

**Pending Transaction with Eli Lilly and Company**

On July 7, 2024, we entered into an Agreement and Plan of Merger (the "Merger Agreement") with Eli Lilly and Company, an Indiana corporation ("Parent" or "Lilly"), and Rainier Acquisition Corporation, a Delaware corporation and a wholly owned subsidiary of Lilly ("Merger Sub"). On the terms and subject to the conditions of the Merger Agreement, on July 19, 2024 Merger Sub commenced a cash tender offer (the "Offer") to purchase all of the outstanding shares of our common stock at a price of $57.00 per share, net to the stockholder in cash, without interest thereon and subject to applicable tax withholding. Following consummation of the Offer, Merger Sub will merge with and into us, with us surviving as a wholly owned subsidiary of Parent (the "Merger"). If the Merger Agreement is terminated under specified circumstances, we will be required to pay Parent a termination fee of $118.0 million. The Offer and the Merger are subject to customary closing conditions. The Merger is anticipated to close in the third quarter of 2024, assuming satisfaction or waiver of all of the conditions of the Offer and the Merger. The Merger Agreement contemplates that the Merger will be effected pursuant to Section 251(h) of the General Corporation Law of Delaware (the "DGCL"), which permits completion of the Merger without a vote of the holders of our common stock upon the acquisition by Merger Sub of a majority of the aggregate number of our issued and outstanding common stock. If the Merger is consummated, we will cease to be a publicly traded company. This is not a recommendation and is neither an offer to purchase nor a solicitation of an offer to sell any securities, nor is it a substitute for the tender offer materials that Lilly and Merger Sub have filed with the SEC in connection with the Offer.

**Overview**

We are a biopharmaceutical company applying our proprietary insights into integrins to discover and develop a pipeline of potentially first-in-class oral small molecule integrin therapeutics. Integrins are a target class with multiple approved injectable blockbuster drugs for the treatment of serious chronic diseases, including autoimmune, cardiovascular and metabolic diseases, fibrosis and cancer. To date, no oral small molecule integrin therapies have been approved by the U.S. Food and Drug Administration ("FDA"). We believe our unique platform can unlock the potential to reliably generate high-quality oral molecules against specific integrin targets. The Morphic integrin technology platform ("MInT Platform") was created by leveraging our unique understanding of integrin structure and function to develop novel product candidates designed to achieve the potency, high selectivity, and pharmaceutical properties required for oral administration.

We are advancing our pipeline, including our lead product candidate, MORF-057, an orally administered α4β7-specific integrin inhibitor affecting inflammation, into clinical development for the treatment of inflammatory bowel disease ("IBD") an indication for which there is significant unmet need. Only about one in five patients achieve clinical remission with approved advanced therapies, and approximately half of those patients lose response over time. As such, even newer biologic and oral agents may not adequately control tissue inflammation or symptoms for many of the sicker patients, and some will therefore develop complications that require surgical removal of the colon and rectum. In addition, many patients with moderate-severe IBD do not receive adequate treatment for their disease due to the inconvenience and fear of injectable biologics, or the safety profile of systemically immunosuppressive therapies. We believe that MORF-057 has the potential to address these unmet needs in the IBD treatment landscape as an orally administered agent with gastrointestinal ("GI") targeted immunosuppression that may be able to avoid some of the concerns associated with other approved drug classes. Furthermore, as the IBD treatment landscape evolves from monotherapy to combination therapy in order to increase therapeutic response rates in certain patient populations, we believe that MORF-057's profile is promising as a foundational backbone for next generation therapeutic regimens. We submitted an investigational new drug application ("IND") for MORF-057 in July 2020, and the FDA permitted the study submitted under the IND to proceed in August 2020. In September 2020, we initiated a Phase 1 clinical trial of MORF-057 in healthy volunteers to establish our clinical program and select doses for our Phase 2 program in IBD with an initial focus on ulcerative colitis ("UC").

The MORF-057 Phase 1 study included single ascending dose ("SAD"), multiple ascending dose ("MAD"), and food effect ("FE") cohorts evaluating MORF-057 safety, pharmacokinetics ("PK") and pharmacodynamics ("PD"). Healthy subjects were randomized 3:1 to receive a single dose of MORF-057 at 25, 50, 100, 150 and 400 mg or matching placebo in the SAD cohorts; or twice daily, or BID, doses of 25, 50 and 100 mg MORF-057 or matching placebo for a total of 14 days in the MAD cohorts. A total of 67 eligible healthy subjects were enrolled into the studies, with 36 in the SAD, nine in the FE and 22 in the MAD cohorts. 66 subjects completed study treatment and one from the 50 mg BID MAD cohort withdrew consent for personal reasons.

MORF-057 was well tolerated in all cohorts and no safety signals were identified. MORF-057 demonstrated a favorable PK profile, where target engagement was confirmed, and a clear PK and PD relationship was established. MORF-057 was rapidly absorbed and systemic exposure was confirmed to increase approximately dose proportionally. A slight reduction in exposure without effect on trough concentrations was observed upon administration with a high fat meal in the FE study. The results suggest food intake has no significant effect on trough MORF-057 levels and that MORF-057 can be administered without regard to food in planned studies in patients.

The α4β7 receptor occupancy ("RO") increased with dose and study day, achieving saturation (>99% RO) in individual patients from all cohorts above 25 mg by day 14. In the 100 mg BID cohort, MORF-057 saturated the α4β7 receptor (mean RO >99%). Dose-and time-dependent changes in biomarkers including specific α4β7 high expressing immune cell populations were observed, adding to evidence of proof of biology for MORF-057. These changes were consistent with those reported with other integrin inhibitors including the antibody drug vedolizumab which is approved for the treatment of IBD.

In an additional MORF-057 Phase 1 study, subjects were dosed up to 200 mg BID and those receiving MORF-057 at 100 BID or 200 mg BID demonstrated α4β7 receptor saturation and statistically significant increases in circulating central memory, effector memory T lymphocyte and switched memory B lymphocyte populations compared with placebo. At the 25 mg and 50 mg BID exploratory doses, directionally increasing trends were also observed in key PD measures. All doses were well tolerated, no safety signals were identified, and a favorable PK profile was observed. In both single doses of 200 mg MORF-057 and 200 mg BID over the 14 days, MORF-057 demonstrated α4β7 receptor saturation at Ctrough. Statistically significant changes in lymphocyte subset populations and CCR9 mRNA were observed, consistent with previous studies.

Based on the results from the Phase 1 studies, we initiated a Phase 2 clinical program of MORF-057 in March 2022. EMERALD-1, which is an open-label, single-arm multi-center Phase 2a trial designed to evaluate the efficacy, safety and tolerability of MORF-057 in adults with moderate to severe UC, completed targeted enrollment in October 2022, with 30 patients enrolled in the study. Additionally, patients that were undergoing screening at the time the study completed targeted enrollment were enrolled in the study for a total of 35 patients enrolled in the main cohort. We elected to stop enrollment of an exploratory cohort at four patients who have previously failed treatment with vedolizumab. Patients enrolled

in the EMERALD-1 study are being treated with 100 mg BID at sites in the United States and Poland. The primary endpoint of the trial was the change in Robarts Histopathology Index (“RHI”), a validated instrument that measures histological disease activity in UC at 12 weeks compared to baseline. Patients will then continue for an additional 40 weeks of maintenance therapy followed by a 52-week assessment. Additional outcome measures in the EMERALD-1 study include change in the modified Mayo clinic score (“mMCS”), safety, PK parameters and key PD measures. In April 2023, we announced topline results from the main cohort of the EMERALD-1 Phase 2a clinical trial of MORF-057, which met the primary endpoint and demonstrated a statistically significant reduction of 6.4 points (p=0.002) from baseline at week 12 in the RHI score. In the study, 25.7% of patients achieved clinical remission by mMCS. MORF-057 was generally well tolerated at the dose of 100 mg BID with no serious adverse events (“SAEs”) and no safety signal observed. Additionally, MORF-057 achieved saturation of α4β7 receptor and demonstrated changes in α4β7 lymphocyte subsets that are consistent with Phase 1 MORF-057 data. In August 2023, we announced the acceptance of a moderated poster presentation describing the EMERALD-1 study at UEG Week 2023 in October in Copenhagen. We presented the moderated poster presentation for the EMERALD-1 trial at UEG Week 2023, including 12 weeks of safety, PK parameters and key PD measures compared to baseline. On October 12, 2023, we presented additional data from the EMERALD-1 trial including 44 weeks of safety, PK parameters and key PD measures compared to baseline. Data from the 52-week readout of the EMERALD-1 trial, including the 40-week maintenance phase of the main cohort and the 12-week induction phase of the exploratory cohort of four patients of secondary non-responders to vedolizumab, have been collected and analyzed. No safety signals have been identified in either cohort. We believe the data from the 52-week readout, including safety, clinical efficacy and PK/PD measures, are substantially consistent with data trends from the 12-week induction phase and the 44-week readout that we reported in October 2023 for EMERALD-1. We are preparing a manuscript for submission and intend to publish the EMERALD-1 data set in an appropriate medical journal or forum.

EMERALD-2, which is a global Phase 2b randomized controlled trial of MORF-057 began dosing patients in November 2022. Patients enrolled in the EMERALD-2 study are randomized to receive one of three active doses or a placebo: 100 mg BID, 200 mg BID, QD (once daily), or a placebo that will crosses over to MORF-057 after the 12-week induction phase. The primary endpoint of the trial is the clinical remission rate as measured by the mMCS at 12 weeks. The secondary endpoints include the change in RHI, PK and PD measures, as well as safety parameters. Following the 12-week induction phase, patients will move to a 40-week maintenance phase. We believe that we will achieve complete analysis of the data for the primary endpoint from the EMERALD-2 Phase 2b trial of MORF-057 in patients with moderate to severe UC in the first half of 2025.

Launch activities are underway for GARNET, which is a global Phase 2b randomized controlled trial of MORF-057 in Crohn’s disease, is actively enrolling and we expect the has randomized its first patients to be dosed in the second quarter of 2024. patient. Patients enrolled in the GARNET study will be randomized to receive one of two active doses or a placebo: 200 mg BID, 100 mg BID or a placebo that will cross over to MORF-057 after the 14-week induction phase. The primary endpoint of the trial is the proportion of participants in endoscopic response (>=50% reduction) at week 14 as determined using Simple Endoscopic Score for Crohn’s Disease (“SES-CD”). The secondary endpoints will include the change in Crohn’s Disease Activity Index (“CDAI”) measures, as well as safety parameters. Following the 14-week induction phase, patients will move to a 38-week maintenance phase. We continue to expand our α4β7 portfolio and have positioned next-generation α4β7 small molecule development candidates for clinical studies in the future.

Beyond our lead molecule, MORF-057, we are using our MInT Platform to advance a broad pipeline of preclinical programs across a variety of therapeutic areas, all of which aim to harness the potential of inhibition or activation of an integrin receptor. Additional wholly-owned programs have advanced to the lead optimization phase of discovery. We presented positive preclinical data from our αvβ8 program at the American Association for Cancer Research Annual Meeting in April 2021. Based on the data we have generated to date and the potential role of TGF-β in treating myelofibrosis, we have nominated MORF-088, a selective small molecule inhibitor of αvβ8, as a development candidate for myelofibrosis. Further pre-clinical research is ongoing with MORF-088 in the treatment of myelofibrosis to create a robust translational plan to efficiently measure if this mechanism will be effective in patients. We also have an additional research stage program ongoing against α5β1 in pulmonary hypertensive diseases, including pulmonary arterial hypertension (“PAH”). We have determined that α5β1 promotes cell proliferation, survival, hypertrophic growth and fibrosis, which are key elements in the progression of PAH.

Since June, 2015 we have had an exclusive integrin focused collaboration agreement in place with Schrödinger, a leader in chemical simulation, machine learning models and in silico drug discovery. We have successfully used their technology platform to perform virtual screens on members of the target class of human integrins, and we and Schrödinger collaborate to facilitate prioritization of integrin targets, perform target validation and analysis, identify leads, and perform lead optimization to establish a portfolio of integrin programs. We believe that our collaboration with Schrödinger enables us to undertake accelerated drug discovery through design, iteration and optimization of leads using a variety of next-generation physics-based computational and machine learning technologies.

With our internal proven capabilities in structural biology, medicinal chemistry and screening, the Schrödinger platform accelerates our ability to design molecules with atomic precision utilizing our significant expertise in advanced structure-guided drug design technology, and machine learning protocols. In December 2022, we expanded our access as a special Schrödinger software customer enabling utilization of their full software suite beyond the scope of integrins. As a result, in 2023, we began advancing additional clinically validated targets with a focus in the inflammation and immunology therapeutic areas, which are highly complementary to our current assets within the integrin space. Specifically, we have initiated projects targeting the IL23 and TL1A pathways, among others. Injectable inhibitors of these targets have been shown to provide significant clinical benefits to IBD patients. Utilizing our expertise in small molecule drug design and optimization, we are pursuing inhibitors against these targets. If we are successful, we believe these agents could be important monotherapy agents as well as optimal to combine with MORF-057 to achieve enhanced clinical efficacy in IBD patients.

In March 2021, we announced an upsized underwritten public offering of 3,500,000 shares of our common stock at a price to the public of $70.00 per share, resulting in net proceeds of approximately $230.0 million, after deducting underwriting discounts, commissions and other offering expenses paid by us.

In July 2020, we entered into an Open Market Sale Agreement, (“Original Agreement”) which was amended by Amendment No. 1 thereto in August 2021, with Jefferies LLC (“Jefferies”), with respect to an at-the-market offering program (the “Previous “Jefferies ATM”), under which we could offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering amount of up to $75.0 million $150.0 million, referred to as Jefferies Placement Shares, through Jefferies as sales agent. We paid Jefferies a commission on the gross sales proceeds of any Jefferies Placement Shares sold through Jefferies under the Jefferies ATM, and also provided Jefferies with customary indemnification and contribution rights. In August 2021, connection with our entry into a new at-the-market offering program, on April 25, 2024 we terminated the Jefferies ATM. We were not subject to any termination penalties related to the termination of the Jefferies ATM. During the six months ended June 30, 2024, no shares were issued under the Jefferies ATM. We may not sell any additional Jefferies Placement Shares under the Jefferies ATM.

On April 26, 2024, we entered into Amendment No. 1 to the Original a Sales Agreement with Jefferies (the “New ATM” TD Securities (USA) LLC (“TD Cowen”) to increase the total value of Placement Shares subject to , under which we may offer and sale sell, from time to up to time at our sole discretion, shares of our common stock having an aggregate offering amount of up to $150.0 million $350.0 million, referred to as Cowen Placement Shares, through TD Cowen as sales agent pursuant to an at-the-market offering program (the “TD Cowen ATM”). We may not sell agreed to pay TD Cowen a commission on the gross sales proceeds of any Cowen Placement Shares under sold through TD Cowen and also provided TD Cowen with customary indemnification and contribution rights. In conjunction our entry into the Previous ATM. We refer to TD Cowen ATM, we terminated the Previous ATM and the New ATM, collectively, as the Jefferies ATM. During the three six months ended March 31, 2024 June 30, 2024, no shares were issued under the New TD Cowen ATM. As of March 31, 2024 At June 30, 2024, we had approximately $10.9 million $350.0 million of common stock remaining available for sale under the New TD Cowen ATM.

In February 2023, we entered into a securities purchase agreement with existing investors pursuant to which we agreed to sell and issue, in a private placement, the PIPE Shares and the Pre-Funded Warrants. We received aggregate net proceeds of approximately $100.0 million before deducting costs and offering expenses payable by us. The Pre-Funded Warrants are exercisable at any time after their original issuance and will not expire. Per their terms, the Pre-Funded Warrants generally may not be exercised if the holder's aggregate beneficial ownership would be more than 9.99% of the total issued and outstanding shares of our common stock following such exercise. The exercise price per share and number of shares of common stock issuable upon the exercise of the Pre-Funded Warrants were subject to adjustment in the event of any stock dividends and splits, recapitalization, reorganization or similar transaction, as described in the Pre-Funded Warrants. During the year ended December 31, 2023, 1,980,188 shares of common stock were issued upon the net exercise of 1,980,198 Pre-Funded Warrants. As of March 31, 2024 June 30, 2024, there were no Pre-Funded Warrants outstanding.

In May 2023, we completed an underwritten public offering of shares of our common stock, which included the exercise in full of the underwriters' option to purchase additional shares of common stock. We received gross proceeds from the secondary offering of approximately $276.0 million, before deducting underwriting discounts, commissions and other offering expenses payable by us of approximately $16.9 million, resulting in net proceeds of approximately $259.1 million.

Since inception, our operations have focused on organizing and staffing our company, business planning, raising capital, establishing our intellectual property portfolio, and performing research to discover and develop oral small-molecule integrin therapeutics. Revenue generation activities to date have been limited to payments received from our collaboration agreements with AbbVie Biotechnology Ltd. ("AbbVie") and Janssen Pharmaceuticals, Inc. ("Janssen") discussed further in Note 10 of the accompanying condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q. We do not have any products approved for sale and have not generated any revenue from product sales to date. From inception through March 31, 2024 June 30, 2024, we raised an aggregate of approximately $1.2 billion of gross proceeds primarily through the issuance of equity, including our convertible preferred equity securities, through our initial public offering, our underwritten public offering in March 2021, our private issuance of common stock and pre-funded warrants in February 2023, our underwritten public offering in May 2023 and sales of shares of our common stock pursuant to the ATM, our at-the-market offering programs, along with payments received under our collaboration agreements.

Since inception, we have incurred significant operating losses. As of March 31, 2024 June 30, 2024, we had an accumulated deficit of $494.5 million $552.1 million. We expect to continue to incur significant and increasing expenses and operating losses for the foreseeable future, as we advance our current and future product candidates through preclinical and clinical development, seek regulatory approval for them, maintain and expand our intellectual property portfolio, hire additional research and development and business personnel, and operate as a public company.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for our product candidates. In addition, if we obtain regulatory approval for our product candidates and do not enter into a third-party commercialization partnership, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing, manufacturing, and distribution activities.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings and debt financings or other sources, such as additional collaboration agreements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on acceptable terms, or at all. Our failure to raise capital or enter into such agreements as, and when, needed, could have a material adverse effect on our business, results of operations, and financial condition.

As of March 31, 2024 June 30, 2024, we had cash, cash equivalents, and marketable securities of $658.8 million $628.4 million. Based If we are unable to timely complete the Offer and the Merger, based on our current operating plan, we believe that our existing available cash and cash equivalents and marketable securities, will be sufficient to fund our operating expenses and capital expenditure requirements into planned level of operations for at least the second half of 2027.

next 12 months.

***Risks and Uncertainties***

We are subject to continuing risks and uncertainties in connection with the current macroeconomic and geopolitical environments, including risks related to supply chain disruptions, increases in consumer prices, inflation, market volatility, interest rate fluctuations, instability in the banking sector, uncertainty with respect to the federal debt ceiling and budget and the related potential for government shutdowns, labor shortages, cybersecurity events and ongoing regional conflicts around the world. We are closely monitoring the impact of these factors on all aspects of our operational and financial performance. To date, we have not experienced much of an impact on our business, excluding minor changes to our development timelines. Our future results of operations and liquidity could be adversely impacted by a variety of factors, including those discussed in the section titled "Risk Factors" included elsewhere in this Quarterly Report on Form 10-Q. As of the date of issuance of these consolidated financial statements, the extent to which the current macroeconomic and geopolitical environments may materially impact our financial condition, liquidity, or results of operations remains uncertain.

**Financial Operations Overview**

***Collaboration Revenue***

We do not have any products approved for sale, and as a result, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the foreseeable future.

To date, all of our collaboration revenue has been derived from collaboration agreements with AbbVie and Janssen. Our collaborations with AbbVie and Janssen are now concluded, and prospectively we remain open to opportunistically evaluating and entering into strategic partnerships around certain therapeutic candidates, geographic markets or disease areas. We expect that our revenue, until we have a marketed product, will be derived primarily from payments under collaboration and license agreements that we may enter into in the future, if any.

**Expenses**

***Research and Development***

Research and development expenses consist primarily of costs incurred for our research and development activities, including our product candidate discovery efforts and preclinical studies under our research programs, which include:

- employee-related expenses, including salaries, benefits, and equity-based compensation expense for our research and development personnel;
- costs of funding research performed by third parties that conduct research and development and preclinical activities on our behalf;
- costs of manufacturing clinical supply related to any of our current or future product candidates;
- expenses incurred under agreements with contract research organizations (“CROs”) and investigative sites that conduct our clinical trials;
- costs of conducting preclinical studies of any of our current or future product candidates;
- consulting and professional fees related to research and development activities, including equity-based compensation to non-employees;
- costs of purchasing laboratory supplies and non-capital equipment used in our preclinical studies;
- costs related to compliance with clinical regulatory requirements;
- facility costs and other allocated expenses, which include expenses for rent and maintenance of facilities, insurance, depreciation and other supplies; and
- fees for maintaining licenses and other amounts due under our third-party licensing agreements.

Research and development costs are expensed as incurred. Costs for certain activities are recognized based on an evaluation of the progress to completion of specific tasks using data such as information provided to us by our vendors and analyzing the progress of our preclinical studies or other services performed. Judgments and estimates are made in determining the accrued expense balances at the end of any reporting period. Non-refundable advance payments for research and development goods or services to be received in the future from third parties are capitalized and expensed as the related goods are delivered or the services are performed.

The successful development of our product candidates is highly uncertain. As such, at this time, we cannot reasonably estimate or know the nature, timing, and costs of the efforts that will be necessary to complete the clinical development process for our product candidates. We are also unable to predict when, if ever, material net cash inflows will commence from the sale of our product candidates, if approved. This is due to the numerous risks and uncertainties associated with developing product candidates, including the uncertainty of:

- the scope, rate of progress, and expenses of our ongoing research activities as well as any additional preclinical studies and clinical trials and other research and development activities;
- establishing an appropriate safety profile;
- successful enrollment in and completion of clinical trials;
- whether our product candidates show safety and efficacy in our clinical trials;
- receipt of marketing approvals from applicable regulatory authorities, if any;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- commercializing the product candidates, if and when approved, whether alone or in collaboration with others; and
- continued acceptable safety profile of the products following any regulatory approval.

A change in the outcome of any of these variables with respect to the development of our current and future product candidates would significantly change the costs and timing associated with the development of those product candidates.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect research and development costs to increase significantly for the foreseeable future as we continue the development of our product candidates. However, we do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will impact our clinical development programs and plans.

***General and Administrative***

General and administrative expenses consist primarily of employee-related expenses, including salaries, benefits, and equity-based compensation expenses for personnel in executive, finance, accounting, business development, legal, information technology and human resources functions. Other significant general and administrative expenses include facility costs not otherwise included in research and development expenses, legal fees relating to patent and corporate matters, and fees for accounting and consulting services.

We anticipate that our general and administrative expenses will increase in the future as our business expands to support expected growth in research and development activities, including our future clinical programs. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, among other expenses. We also incur expenses associated with being a public company, including costs for audit, legal, regulatory, and tax-related services related to compliance with the rules and regulations of the SEC, listing standards applicable to companies listed on Nasdaq, director and officer compensation and insurance premiums, and investor relations costs. In addition, if we obtain regulatory approval for any of our product candidates and do not enter into a third-party commercialization collaboration, we expect to incur significant general and administrative expenses related to supporting product sales, marketing and distribution activities.

***Interest Income, Net***

Interest income, net consists primarily of interest income earned on our cash, cash equivalents and marketable securities.

***Provision for Income Tax Expense***

We record a provision or benefit for income taxes on pre-tax income or loss based on our effective tax rate for the year. For additional details about the current year tax provision, refer to the Notes to the Condensed Consolidated Financial Statements appearing elsewhere in this Quarterly Report on Form 10-Q.

**Results of Operations**

***Comparison of the Three Months Ended March 31, 2024 June 30, 2024 and 2023***

The following table summarizes our results of operations for the three months ended March 31, 2024 June 30, 2024 and 2023:

| | Three Months Ended March 31, | | Change | | Three Months Ended June 30, | | Change | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 2024 | | 2024 | | 2023 | | $ | | % | | | | 2024 | | | | | | | | | | | |
| | (in thousands, except percentages) | | (in thousands, except percentages) | | (in thousands, except percentages) | | | | | | | | | | | | | | | | | | | |
| Collaboration revenue | $ | — | $ | 521 | $ | (521) | | (100) | % | | | | | | | | | | | | | | | |
| Operating expenses: | | | | | | | | | | | | | | | | | | | | | | | | |
| Research and development | | | | | | | | | | | | | | | | | | | | | | | | |
| Research and development | | | | | | | | | | | | | | | | | | | | | | | | |
| Research and development | 42,441 | | 30,449 | | 30,449 | | 11,992 | | 11,992 | | 39 | | 39 | % | $ | 49,271 | | $ | | $ | 35,719 | | $ | |
| General and administrative | General and administrative | 11,163 | | 9,277 | | 9,277 | | 1,886 | | 1,886 | | 20 | | 20 | % | General and administrative | 15,962 | | 9,583 | | | 9,583 | | |
| Total operating expenses | Total operating expenses | 53,604 | | 39,726 | | 39,726 | | 13,878 | | 13,878 | | 35 | | 35 | % | Total operating expenses | 65,233 | | 45,302 | | | 45,302 | | |
| Loss from operations | Loss from operations | (53,604) | | (39,205) | | (39,205) | | (14,399) | | (14,399) | | 37 | | 37 | % | Loss from operations | (65,233) | | (45,302) | | | (45,302 | | |
| Other income: | | | | | | | | | | | | | | | | | | | | | | | | |
| Interest income, net | | | | | | | | | | | | | | | | | | | | | | | | |
| Interest income, net | | | | | | | | | | | | | | | | | | | | | | | | |
| Interest income, net | 8,390 | | 3,100 | | 3,100 | | 5,290 | | 5,290 | | 171 | | 171 | % | | 7,903 | | 6,427 | | | 6,427 | | |
| Other income, net | — | | | | 2 | | (2) | | | | (100) | % | | | | | | | | | | | | |
| Other expense, net | (15) | | | | — | | (15) | | | | * | | | | | | | | | | | | | |
| Total other income, net | Total other income, net | 8,390 | | 3,102 | | 3,102 | | 5,288 | | 5,288 | | 170 | | 170 | % | Total other income, net | 7,888 | | 6,427 | | | 6,427 | | |
| Loss before provision for income taxes | Loss before provision for income taxes | (45,214) | | (36,103) | | (36,103) | | (9,111) | | (9,111) | | 25 | | 25 | % | Loss before provision for income taxes | (57,345) | | (38,875) | | | (38,875 | | |
| Provision for income taxes | Provision for income taxes | (80) | | (32) | | (32) | | (48) | | (48) | | 150 | | 150 | % | Provision for income taxes | (240) | | (138) | | | (138 | | |
| Net loss | Net loss | $(45,294) | $ | $(36,135) | $ | $(9,159) | | 25 | | 25 | % | Net loss | $ | (57,585) | | $ | | $(39,013) | | $ | | | | |

Collaboration Revenue

The decrease in collaboration revenue of $0.5 million is attributable the conclusion of the Janssen Agreement in March 2023. There were no outstanding revenue generating collaboration agreements during three months ended March 31, 2024. * Percentage not meaningful

**Research and Development Expenses**

Research and development expense increased by $12.0 million $13.6 million, or 39% 38%, from $30.4 million $35.7 million for the three months ended March 31, 2023 June 30, 2023 to $42.4 million $49.3 million for the three months ended March 31, 2024 June 30, 2024. A significant portion of our research and development costs have been external clinical and preclinical CRO costs, which we track on a program-by-program basis related to a clinical product candidate, once the candidate has been identified. Our internal

research and development costs are primarily personnel-related costs, depreciation, and other indirect costs. The following table summarizes our research and development expense for three months ended March 31, 2024 June 30, 2024 and 2023:

| | Three Months Ended March 31, | | | Change | | | | Three Months Ended June 30, | | | Change | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 2024 | | 2024 | | 2023 | | $ | | % | | 2024 | | |
| | (in thousands, except percentages) | | | | | | | | | | | | |
| External costs by program: | | | | | | | | | | | | | |
| MORF-057 | | | | | | | | | | | | | |
| MORF-057 | | | | | | | | | | | | | |
| MORF-057 | $17,322 | $ | $11,515 | $ | $ | 5,807 | 50 | | 50 % | $ | 20,536 | $ | $ 15,433 | $ |
| MORF-088 | MORF-088 1,227 | 1,905 | 1,905 | (678) | | (678) | (36) | | (36) | % | MORF-088 827 | 1,719 | | 1,719 |
| Janssen Agreement programs | — | | 51 | (51) | | | (100) | % | | | | | | |
| Other early development candidates and unallocated costs | | | | | | | | | | | | | | |
| Other early development candidates and unallocated costs | | | | | | | | | | | | | | |
| Other early development candidates and unallocated costs | 5,048 | 3,453 | 3,453 | 1,595 | | 1,595 | 46 | | 46 | % | Other early development candidates and unallocated costs 8,598 | 4,452 | | 4,452 |
| Total external costs | Total external costs 23,597 | 16,924 | 16,924 | 6,673 | | 6,673 | 39 | | 39 | % | Total external costs 29,961 | 21,604 | | 21,604 |
| Internal costs: | | | | | | | | | | | | | | |
| Employee compensation and benefits | | | | | | | | | | | | | | |
| Employee compensation and benefits | | | | | | | | | | | | | | |
| Employee compensation and benefits | 17,269 | 12,400 | 12,400 | 4,869 | | 4,869 | 39 | | 39 | % | 17,645 | 13,100 | | 13,100 | 4, |
| Facility and other | Facility and other 1,575 | 1,125 | 1,125 | 450 | | 450 | 40 | | 40 | % | Facility and other 1,665 | 1,015 | | 1,015 |
| Total internal costs | Total internal costs 18,844 | 13,525 | 13,525 | 5,319 | | 5,319 | 39 | | 39 | % | Total internal costs 19,310 | 14,115 | | 14,115 |
| Total research and development expense | Total research and development expense $42,441 | $ | $30,449 | $ | $ | 11,992 | 39 | | 39 % | | Total research and development expense $ 49,271 | $ | $ 35,719 | $ |

The changes in research and development expense were primarily attributable to the following:

- The $6.7 million $8.4 million increase in external costs from the three months ended March 31, 2023 June 30, 2023 to the three months ended March 31, 2024 June 30, 2024 was primarily related to costs associated with the ongoing Phase 2 clinical studies and other development activities for MORF-057, as well as other external research costs to support our early development candidates. These increases were partially offset by decreases in activity under the Janssen Agreement and for MORF-088. The decrease in activity under MORF-088, which is primarily a result of the timing of incurring manufacturing costs and other development activities.
- The $5.3 million $5.2 million increase in internal costs from the three months ended March 31, 2023 June 30, 2023 to the three months ended March 31, 2024 June 30, 2024 was primarily driven by an increase in non-cash equity-based compensation expense and headcount to support the ongoing clinical activity for MORF-057 as well as our early-stage pipeline candidates.

**General and Administrative Expenses**

General and administrative expense increased by $1.9 million $6.4 million, or 20% 67%, from $9.3 million $9.6 million for the three months ended March 31, 2023 June 30, 2023 to $11.2 million $16.0 million for the three months ended March 31, 2024 June 30, 2024. The increase in general and administrative expense was primarily attributable to a $1.6 million $1.0 million increase in non-cash equity-based compensation expense. expense and $4.2 million related to acquisition related expenses.

**Interest Income, Net**

Interest income increased by $5.3 million $1.5 million due to an increase in effective interest rates on cash equivalents and marketable securities and an increase in invested marketable securities during the three months ended March 31, 2024 June 30, 2024 compared to the three months ended March 31, 2023 June 30, 2023.

***Comparison of the Six Months Ended June 30, 2024 and 2023***

The following table summarizes our results of operations for the six months ended June 30, 2024 and 2023:

| | Six Months Ended June 30, | | Change | |
|---|---|---|---|---|
| | 2024 | 2023 | $ | % |
| | (in thousands, except percentages) | | | |
| Collaboration revenue | $ — | $ 521 | $ (521) | (100)% |
| Operating expenses: | | | | |
| Research and development | 91,712 | 66,168 | 25,544 | 39 % |
| General and administrative | 27,125 | 18,860 | 8,265 | 44 % |
| Total operating expenses | 118,837 | 85,028 | 33,809 | 40 % |
| Loss from operations | (118,837) | (84,507) | (34,330) | 41 % |
| Other income: | | | | |
| Interest income, net | 16,293 | 9,527 | 6,766 | 71 % |
| Other income (expense), net | (15) | 2 | (17) | * |
| Total other income, net | 16,278 | 9,529 | 6,749 | 71 % |
| Loss before provision for income taxes | (102,559) | (74,978) | (27,581) | 37 % |
| Provision for income taxes | (320) | (170) | (150) | 88 % |
| Net loss | $ (102,879) | $ (75,148) | $ (27,731) | 37 % |

* Percentage not meaningful

**Collaboration Revenue**

The decrease in collaboration revenue of $0.5 million is attributable to the conclusion of the Janssen Agreement in March 2023. There were no outstanding revenue generating collaboration agreements during the six months ended June 30, 2024.

**Research and Development Expenses**

Research and development expense increased by $25.5 million, or 39%, from $66.2 million for the six months ended June 30, 2023 to $91.7 million for the six months ended June 30, 2024. A significant portion of our research and development costs have been external preclinical CRO costs, which we track on a program-by-program basis related to a clinical product candidate, once the candidate has been identified. Our internal research and development costs are primarily personnel-related costs, depreciation, and other indirect costs.

The following table summarizes our research and development expense for six months ended June 30, 2024 and 2023:

| | Six Months Ended June 30, | | Change | |
|---|---|---|---|---|
| | 2024 | 2023 | $ | % |
| | (in thousands, except percentages) | | | |

| | | | | |
|---|---|---|---|---|
| External costs by program: | | | | |
| MORF-057 | $ 37,858 | $ 26,948 | $ 10,910 | 40 % |
| MORF-088 | 2,054 | 3,624 | (1,570) | (43)% |
| Janssen Agreement programs | — | 51 | (51) | (100)% |
| Other early development candidates and unallocated costs | 13,646 | 7,905 | 5,741 | 73 % |
| Total external costs | 53,558 | 38,528 | 15,030 | 39 % |
| Internal costs: | | | | |
| Employee compensation and benefits | 34,914 | 25,500 | 9,414 | 37 % |
| Facility and other | 3,240 | 2,140 | 1,100 | 51 % |
| Total internal costs | 38,154 | 27,640 | 10,514 | 38 % |
| Total research and development expense | $ 91,712 | $ 66,168 | $ 25,544 | 39 % |

The increase in research and development expense was primarily attributable to the following:

- The $15.0 million increase in external costs from the six months ended June 30, 2023 to the six months ended June 30, 2024 was primarily related to costs associated with the Phase 2 clinical study which commenced in the fourth quarter of 2022 and other development activities for MORF-057, as well as other external research costs to support our early development candidates. These increases were partially offset by decreases in activity under MORF-088, which is primarily a result of the timing of incurring manufacturing costs and other development activities.
- The $10.5 million increase in internal costs from the six months ended June 30, 2023 to the six months ended June 30, 2024 was primarily driven by an increase in non-cash equity-based compensation expense and headcount to support the ongoing clinical activity for MORF-057 as well as our early-stage pipeline candidates.

**General and Administrative Expenses**

General and administrative expense increased by $8.3 million, or 44%, from $18.9 million for the six months ended June 30, 2023 to $27.1 million for the six months ended June 30, 2024. The increase in general and administrative expense was primarily attributable to a $2.6 million increase in non-cash equity-based compensation expense and a $5.4 million increase in other costs of which included an increase in acquisition related costs of $4.2 million.

**Interest Income, Net**

Interest income increased by $6.8 million due to an increase in effective interest rates on cash equivalents and marketable securities and an increase in invested marketable securities during the six months ended June 30, 2024 compared to the six months ended June 30, 2023.

**Liquidity and Capital Resources**

***Sources of Liquidity***

From inception through March 31, 2024 June 30, 2024, we raised an aggregate of approximately $1.2 billion of gross proceeds primarily through the issuance of equity, including our convertible preferred equity securities, our initial public offering and secondary equity offerings, our private placement of common stock and pre-funded warrants, and sales of shares of our common stock under the ATM, our at-the-market offering programs, along with payments received under our collaboration agreements.

The following table provides information regarding our total cash, cash equivalents, and marketable securities, each of which are stated at their respective fair values as of March 31, 2024 June 30, 2024 and December 31, 2023:

| | | March 31, 2024 | | | December 31, 2023 | |
|---|---|---|---|---|---|---|
| | | June 30, 2024 | | | December 31, 2023 | |
| | | (in thousands) | | | | |
| | | (in thousands) | | | | |
| | | (in thousands) | | | | |
| Cash | | | | | | |
| Cash equivalents | Cash equivalents | 43,819 | 57,988 | Cash equivalents | 50,208 | 57,988 |
| Marketable securities | Marketable securities | 614,356 | 645,772 | Marketable securities | 577,595 | 645,772 |
| Total cash, cash equivalents and marketable securities | | | | | | |

***Cash Flows***

The following table provides information regarding our cash flows for the three six months ended March 31, 2024 June 30, 2024 and 2023:

| | Three Months Ended March 31, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| 2024 | 2024 | 2023 | 2024 | 2023 |
| | (in thousands) | | | |
| | (in thousands) | | | |
| | (in thousands) | | | |

| |
|---|
| Net cash used in operating activities |
| Net cash provided by (used in) investing activities |
| Net cash provided by financing activities |
| Net decrease in cash, cash equivalents and restricted cash |
| Net (decrease) increase in cash, cash equivalents and restricted cash |

**Net Cash Used in Operating Activities**

The use of cash in all periods presented resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital. Net cash used in operating activities was $46.4 million $78.5 million for the three six months ended March 31, 2024 June 30, 2024 compared to $31.5 million $54.5 million in cash used in operating activities for the three six months ended March 31, 2023 June 30, 2023. The increase in cash used in operating activities was primarily driven by a $13.9 million $33.8 million increase in operating expenses and increase decrease in cash outflows from changes in operating assets and liabilities in the first quarter half of 2024, offset by increases in interest income and non-cash items recorded as operating expenses.

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

Net cash provided by investing activities was $31.4 million $69.7 million for the three six months ended March 31, 2024 June 30, 2024 compared to $88.4 million $221.6 million used in investing activities for the three six months ended March 31, 2023 June 30, 2023. The change in cash provided by or used in investing activities is primarily based on the timing of purchases or maturities in marketable securities in the period. During the three six months ended March 31, 2024 June 30, 2024, the cash provided by investing activities was primarily based on the timing of maturities and purchases in marketable securities during the three six months ended March 31, 2024 June 30, 2024. During the three six months ended March 31, 2023 June 30, 2023, the cash used in investing activities was primarily from the deployment of the proceeds from the private issuance of common stock and pre-funded warrants that was completed in February 2023. 2023, the proceeds from the secondary equity offering completed in May 2023 and the proceeds from the sale of common stock under the Jefferies ATM offering program.

**Net Cash Provided by Financing Activities**

Net cash provided by financing activities of $0.9 million $1.0 million for the three six months ended March 31, 2024 June 30, 2024 resulted from $0.9 million $1.0 million in proceeds received from the issuance of common shares under the ESPP and stock option exercises. Net cash provided by financing activities during the three six months ended March 31, 2023 June 30, 2023 of $102.5 million $434.1 million resulted from $100.0 million $99.8 million in net proceeds received from our private issuance of common stock and pre-funded warrants completed in February 2023, the $259.2 million in net proceeds from the underwritten public offering of common stock completed in May 2023, $67.2 million in net proceeds from the sale of common stock under the Jefferies ATM offering program and from the $2.5 million $8.0 million in proceeds received from the issuance of common shares under the ESPP and stock option exercises.

***Funding Requirements***

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue research and development, conduct clinical trials, and seek marketing approval for our current and any of our future product candidates. In addition, if we obtain marketing approval for any of our current or our future product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution, which costs we might offset through entry into collaboration agreements with third parties. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed on acceptable terms, or at all, including, but not limited to, as a result of macroeconomic factors related to ongoing regional conflicts around the world, inflation and market volatility, interest rate fluctuations, instability in the global banking sector, uncertainty with respect to the federal debt ceiling and budget and the related potential for government shutdowns, we would be forced to delay, reduce, or eliminate our research and development programs or future commercialization efforts. Based on our current plans and strategies, we anticipate our operating expenses will decrease as we do not plan to invest in commercializing our product candidates and plan to complete the Offer and the Merger. We do not intend to pursue further funding and, instead, are seeking to complete the Offer and the Merger with Lilly and Merger Sub. If we are unable to timely complete the Offer and the Merger, based on our current operating plan, we believe that our existing available cash and cash equivalents and marketable securities, will enable us be sufficient to fund our operating expenses and capital expenditure requirements into planned level of operations for at least the second half of 2027. next 12 months.

We have based this estimate on assumptions that may prove to be wrong, and we may use our available capital resources sooner than we currently expect. Our future capital requirements will depend on many factors, including:

- our ability to complete the Offer and the Merger;
- the costs of conducting additional clinical and preclinical studies and future clinical trials;
- the costs of future manufacturing;
- the scope, progress, results and costs of discovery, preclinical development, laboratory testing, and clinical trials for other potential product candidates we may develop, if any;
- the costs, timing, and outcome of regulatory review of our product candidates;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements we might have at such time;
- the costs and timing of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;

- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- the costs of preparing, filing and prosecuting patent applications, obtaining, maintaining and enforcing our intellectual property rights, and defending intellectual property-related claims;
- our ability to file and prosecute patent applications, obtain, maintain, and enforce our intellectual property rights, and defend intellectual property-related claims in certain countries that are subject to economic sanctions and/or hostile to U.S. and international companies;
- our headcount growth and associated costs as we expand our business operations and research and development activities;
- potential delays in our preclinical studies, our development programs and our current and planned clinical trials due to geo-political actions, including war and regional conflicts around the world (such as the current armed conflicts in Ukraine and Israel), the ongoing labor shortage, global supply chain disruptions, or cybersecurity events;
- general economic conditions and trends, including inflation and market volatility, interest rate fluctuations, the ongoing labor shortage, instability in the global banking sector, uncertainty with respect to the federal debt ceiling and budget and the related potential for government shutdowns or the weakening of the global and U.S. economies; and
- the cost of operating as a public company.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements.

***Contractual Obligations***

On March 29, 2024, we modified the lease for our 32,405 square feet of office and laboratory space of corporate headquarters to extend the expiration date of the lease from May 2025 through December 31, 2025, which increased the future rental payments through the end of the term of the lease by $1.0 million.

On March 26, 2024, we entered into a sublease agreement for additional office space in the same building as our corporate headquarters. The sublease agreement is for 7,257 square feet of office space commencing April 1, 2024, the date we gained access to the space, through December 30, 2025 with future rental payments totaling $0.6 million.

For additional information about our lease commitments, see Note 9 of the accompanying condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

As of March 31, 2024 June 30, 2024, the Company's our lease and sublease was for 32,405 39,662 square feet of office and laboratory space through and separate vivarium, both all through December 31, 2025, has the end of December 2025, have an aggregate of $3.5 million $4.1 million in future rent payments.

***Critical Accounting Policies and Significant Estimates***

Our critical accounting policies are those policies which require the most significant judgments and estimates in the preparation of our condensed consolidated financial statements.

During the quarter ended March 31, 2024 June 30, 2024, there were no material changes to our critical accounting policies as detailed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on February 22, 2024.

For detailed information regarding recently issued accounting pronouncements and the actual and expected impact on our condensed consolidated financial statements, see Note 2 in the accompanying condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

**Item 3. *Quantitative and Qualitative Disclosures about Market Risk***

There were no material changes in our exposure to market risk from December 31, 2023 to March 31, 2024 June 30, 2024.

**Item 4. *Controls and Procedures***

**Management's Evaluation of our Disclosure Controls and Procedures**

Under the supervision and with the participation of our management, including our Chief Executive Officer and our Chief Financial Officer (our principal executive officer and principal financial officer, respectively), we evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under Exchange Act as of March 31, 2024 June 30, 2024. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on our management's evaluation (with the participation of our Chief Executive Officer and our Chief Financial Officer), as of the end of the period covered by this report, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level.

**Changes in Internal Control over Financial Reporting**

There has been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act) during the quarter ended March 31, 2024 June 30, 2024 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***

From time to time, we may be involved in legal proceedings arising in the ordinary course of our business. We are not presently a party to any legal proceedings that, in the opinion of management, would have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us due to defense and settlement costs, diversion of management resources, negative publicity and reputational harm, and other factors.

**Item 1A. *Risk Factors***

*Investing in our common stock involves a high degree of risk. Before making your decision to invest in shares of our common stock, you should carefully consider the risks described below, together with the other information contained in this Quarterly Report on Form 10-Q, including our condensed, consolidated financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations". The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties that we are unaware of, or that we currently believe are not material, may also become important factors that affect us. We cannot assure you that any of the events discussed below will not occur. These events could have a material and adverse impact on our business, financial condition, results of operations and prospects. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment. Except as otherwise indicated, the following risk factors do not take into account the proposed Merger and assume that we will remain a stand-alone company.*

**Summary of Risk Factors**

The below summary risks provide an overview of many of the risks we are exposed to in the normal course of our business activities. As a result, the below summary risks do not contain all of the information that may be important to you, and you should read the summary risks together with the more detailed discussion of risks set forth following this section under the heading "Risk Factors," as well as elsewhere in this Quarterly Report on Form 10-Q under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations." Additional risks, beyond those summarized below or discussed in "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," may apply to our activities or operations as currently conducted or as we may conduct them in the future or in the markets in which we operate or may in the future operate. Consistent with the foregoing, we are exposed to a variety of risks, including risks associated with:

- The completion of the Offer and the Merger is subject to conditions, some or all of which may not be satisfied or completed on a timely basis, if at all. Failure to complete the Offer and the Merger within the timeframe we anticipate or at all could have material adverse effects on our company.
- We are a clinical stage biopharmaceutical company with a limited operating history and no products approved for commercial sale. We have a history of significant losses and expect to continue to incur significant losses for the foreseeable future.
- We will need substantial additional funds to advance development of our product candidates, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development programs, commercialization efforts or other operations.
- Our product candidates are in various stages of development and may fail in development or suffer delays that materially adversely affect their commercial viability. If we or our collaborators are unable to complete development of, or commercialize, our product candidates or experience significant delays in doing so, our business will be materially harmed.
- Our current and future clinical trials or those of any collaborators may reveal significant adverse events not seen in our preclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.
- We have historically entered into collaborations and may, in the future, seek to enter into collaborations with third parties for the discovery and development of our therapeutic candidates. If our future collaborators cease development efforts under collaboration agreements, or if those agreements are terminated, the collaborations may fail to lead to commercial products, and we may never receive milestone payments or future royalties under the agreements.
- We and/or our collaborators may be unable to obtain, or may be delayed in obtaining, U.S. or foreign regulatory approval and, as a result, unable to commercialize our product candidates.
- Any inability to attract and retain qualified key management and technical personnel would impair our ability to implement our business plan.
- Our principal stockholders and management own a significant percentage of our stock and will be able to control matters subject to stockholder approval.
- Even if we are able to commercialize any product candidate, such product candidate may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.
- We face competition from entities that have developed or may develop product candidates for autoimmune, cardiovascular and metabolic diseases, fibrosis and cancer, including companies developing novel treatments and technology platforms. If these companies develop technologies or product candidates more rapidly than we do or their technologies are more effective, our ability to develop and successfully commercialize product candidates may be adversely affected.

- Anti-takeover provisions in our charter documents and under Delaware law could prevent or delay an acquisition of us, which may be beneficial to our stockholders, and may prevent attempts by our stockholders.
- The exclusive forum provision in our restated certificate of incorporation may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims.

**Risks Related to the Pending Transaction with Eli Lilly and Company**

***The completion of the Offer and the Merger is subject to conditions, some or all of which may not be satisfied or completed on a timely basis, if at all. Failure to complete the Offer and the Merger within the timeframe we anticipate or at all could have material adverse effects on the Company.***

As described above, on July 7, 2024, we entered into the Merger Agreement with Lilly and Merger Sub, pursuant to which Merger Sub commenced the Offer on July 19, 2024. The Offer is initially scheduled to expire at one minute after 11:59 p.m., Eastern time, on August 15, 2024 (the "Expiration Time").

Consummation of the Offer is subject to the satisfaction or waiver of various conditions set forth in the Merger Agreement, including (1) a majority of shares of our common stock then outstanding being validly tendered and not validly withdrawn in the Offer prior to the Expiration Time (as defined in the Merger Agreement); (2) the expiration or termination of the waiting period under the HSR Act; (3) the accuracy of our representations and warranties contained in the Merger Agreement (except, generally, for any inaccuracies that have not had, individually or in the aggregate, a Company Material Adverse Effect (as defined in the Merger Agreement)); (4) our performance in all material respects of our obligations under the Merger Agreement; and (5) the other conditions set forth in Exhibit A to the Merger Agreement. There is no financing condition to the Offer or the Merger. There can be no assurance that the conditions to the completion of the Offer and the Merger will be satisfied or waived, that the Offer and the Merger will be completed or that the Offer and the Merger will be consummated as contemplated by the Merger Agreement.

If one or more of these conditions are not satisfied, and as a result, we do not complete the Offer and the Merger, we would remain liable for significant transaction costs, and the focus of our management would have been diverted from seeking other potential strategic opportunities, in each case without realizing any benefits of the Offer and the Merger. We could be required to pay Lilly a termination fee of approximately $118.0 million if the Merger Agreement is terminated under specific circumstances described in the Merger Agreement. Certain costs associated with the Offer and the Merger have already been incurred or may be payable even if the Offer and the Merger are not consummated. Finally, any disruptions to our business resulting from the announcement and pendency of the Offer and the Merger, including any adverse changes in our relationships with our partners, suppliers and employees, could continue or accelerate in the event that we fail to consummate the Offer and the Merger. We may also be required to devote significant time and resources to litigation related to any failure to complete the Merger or related to any enforcement proceeding commenced against us to perform our obligations under the Merger Agreement.

The price of our common stock may also fluctuate significantly based on announcements by Parent, other third parties, or us regarding the Offer and the Merger or based on market perceptions and other conditions to the consummation of the Offer and the Merger. Such announcements may lead to perceptions in the market that the Offer and the Merger may not be completed, which could cause our share price to fluctuate or decline.

If we do not consummate the Offer and the Merger, the price of our common stock may decline significantly from the current market price, which may reflect a market assumption that the Offer and the Merger will be consummated. Any of these events could have a material adverse effect on our business, operating results and financial condition and could cause a decline in the price of our common stock.

***The Offer and the Merger will involve substantial costs and will require substantial management resources.***

In connection with the consummation of the Offer and the Merger, management and financial resources have been diverted and will continue to be diverted towards the completion of the Offer and the Merger. We expect to incur substantial costs and expenses relating to, as well as the direction of management resources towards, the Offer and the Merger. Such costs, fees and expenses include fees and expenses payable to financial advisors, other professional fees and expenses, fees and costs relating to regulatory filings and filings with the SEC and notices and other transaction-related costs, fees and expenses. Further, if the Merger Agreement is terminated by us under specified circumstances, we will be required to pay Parent a termination fee of $118.0 million. If the Offer and the Merger are not completed, we will have incurred substantial expenses and expended substantial management resources for which we will have received little or no benefit if the closing of the Offer and the Merger does not occur.

***If the Merger occurs, our stockholders will not be able to participate in any financial upside to our business after the Merger.***

Pursuant to the Merger Agreement, on July 19, 2024, Merger Sub commenced the Offer to purchase, subject to the satisfaction or waiver of certain conditions set forth in the Merger Agreement, any and all of the issued and outstanding shares of our common stock, at the Offer Price, net to the stockholder in cash, without interest thereon and subject to any applicable tax withholding, upon the terms and subject to the conditions set forth in the Merger Agreement. In the Merger, each share of our common stock issued and outstanding immediately prior to the effective time of the Merger that is not tendered and accepted pursuant to the Offer (other than the shares of our common stock owned by us or any of our wholly-owned subsidiaries, the shares of our common stock held by Lilly, Merger Sub or any other subsidiary of Lilly, and shares of our common stock as to which appraisal rights have been perfected in accordance with applicable law, if any) will be canceled and the holder of such share of our common stock will be entitled to receive the Offer Price in cash without interest, less any applicable tax withholding. Our stockholders will not receive any shares of Lilly or Merger Sub common stock in connection with the Offer or the Merger. As a result, if our business following the consummation of the Merger performs well, our current stockholders will not receive any benefit from the performance of our business following the consummation of the Merger.

***In certain instances, the Merger Agreement requires us to pay a termination fee to Lilly, which could require us to use available cash that would have otherwise been available for general corporate purposes.***

Under the terms of the Merger Agreement, we will be required to pay Lilly a termination fee of approximately $118.0 million if the Merger Agreement is terminated under specific circumstances, as described in the Merger Agreement. If the Merger Agreement is terminated under such circumstances, the termination fee we may be required to pay under the Merger Agreement may require us to use available cash that would have otherwise been available for general corporate purposes and other uses.

***The consideration payable to holders of our common stock that validly tender and do not validly withdraw their shares of common stock in the Offer will not be adjusted for changes in our business, assets liabilities, prospects, outlook, financial condition or results of operations, or in the event of any change in the price of our common stock.***

The consideration payable to holders of our common stock that validly tender and do not validly withdraw their shares of common stock in the Offer will not be adjusted for changes in our business, assets, liabilities, prospects, outlook, financial condition or results of operations, or changes in the market price of, analyst estimates of, or projections relating to, our common stock. For example, if we experienced an improvement in our business, assets, liabilities, prospects, outlook, financial condition or results of operations prior to the consummation of the Offer and Merger, there would be no adjustment to the amount of consideration payable to holders of our common stock that validly tender and do not validly withdraw their shares of common stock in the Offer.

***The Merger Agreement contains provisions that could discourage a potential competing acquirer.***

The Merger Agreement provides that, upon the terms and subject to the conditions thereof, we and our representatives cannot solicit or initiate discussions with third parties regarding other proposals to acquire us and we are subject to restrictions on our ability to respond to any such proposal, except as permitted under the terms of the Merger Agreement. In the event that we receive an acquisition proposal from a third party, we must notify Parent of such proposal and negotiate in good faith with Parent prior to terminating the Merger Agreement or effecting a change in the recommendation of our board of directors to our stockholders with respect to the Offer and the Merger. The Merger Agreement also contains certain termination rights for Parent and us and further provides that, upon termination of the Merger Agreement under specified circumstances, including certain terminations in connection with an alternative business combination transaction as permitted by the terms of the Merger Agreement, we will be required to pay Parent a termination fee of $118.0 million. These provisions could discourage a potential third-party acquirer that might have an interest in acquiring all or a significant portion of us from considering or proposing such acquisition, even if it were prepared to pay consideration with a higher per share cash or market value than the market value proposed to be received or realized in the Offer and the Merger. These provisions also might result in a potential third-party acquirer proposing to pay a lower price to our stockholders than it might otherwise have proposed to pay due to the added expense of the $118.0 million termination fee that may become payable in certain circumstances. If the Merger Agreement is terminated and we determine to seek another business combination, we may not be able to negotiate a transaction with another party on terms comparable to, or better than, the terms of the Offer and the Merger.

***Review under the HSR Act could prevent or delay the consummation of the Offer and Merger.***

Under the HSR Act, and the related rules and regulations that have been issued by the FTC, certain transactions having a value above specified thresholds may not be consummated until specified information and documentary material, or Premerger Notification and Report Forms, have been furnished to the FTC and the Antitrust Division of the Department of Justice, or the Antitrust Division, and certain waiting period requirements have been satisfied.

It is a condition to Merger Sub's obligation to accept for payment and pay for shares of our common stock tendered pursuant to the Offer that the waiting period (and any extension of the waiting period) applicable to the Offer under the HSR Act shall have expired or been terminated. Under the HSR Act, the purchase of shares of our common stock in the Offer may not be undertaken until the expiration of a 15 calendar day waiting period following the filing by Parent of a Premerger Notification and Report Form concerning the Offer with the FTC and the Antitrust Division, unless the waiting period is earlier terminated by the FTC and the Antitrust Division. If within the 15 calendar day waiting period either the FTC or the Antitrust Division were to issue a request for additional information and documentary material, or a Second Request, the waiting period with respect to the Transactions would be extended until 10 calendar days following the date of substantial compliance by Parent with that request, unless the FTC and the Antitrust Division terminated the additional waiting period before its expiration. The 10 calendar day waiting period can be extended with the consent of Parent and us. If either the 15 calendar day or 10 calendar day waiting period expires on a Saturday, Sunday or federal holiday, then such waiting period will be extended until 11:59 p.m. Eastern Time of the next day that is not a Saturday, Sunday or federal holiday. After that time, the waiting period may be extended only by court order or with Parent's and our consent. The FTC and the Antitrust Division may terminate the additional 10-day waiting period before its expiration. In practice, complying with a Second Request can take a significant period of time.

The FTC and the Antitrust Division may scrutinize the legality under U.S. federal antitrust laws of transactions such as Merger Sub's proposed acquisition of us. At any time before or after Merger Sub's acceptance for payment of shares of our common stock pursuant to the Offer, notwithstanding the termination or expiration of the applicable waiting period under the HSR Act, if the Antitrust Division or the FTC believes that the Offer would violate the U.S. federal antitrust laws by substantially lessening competition in any line of commerce affecting U.S. consumers, the FTC and the Antitrust Division could take such action as they deem necessary under the applicable statutes, including seeking to enjoin the completion of the Transactions, seeking divestiture of substantial assets of the parties, or requiring the parties to license, or hold separate, assets, to terminate existing relationships and contractual rights, or to take other actions or agree to other restrictions limiting the freedom of action of the parties. At any time before or after consummation of the Transactions, notwithstanding the termination or expiration of the applicable waiting period under the HSR Act, U.S. state attorneys general and private persons may also bring legal action under the antitrust laws seeking similar relief or seeking conditions to the completion of the Offer. There can be no assurance that a challenge to the Offer on antitrust grounds will not be made or, if a challenge is made, what the result will be. If any such action is threatened or commenced by the FTC, the Antitrust Division or any state or any other person, Merger Sub may not be obligated to consummate the Offer or the Merger.

We and Parent filed our respective Premerger Notification and Report Forms with the FTC and Antitrust Division on July 16, 2024.

***Stockholder litigation could prevent or delay the consummation of the Offer and the Merger or otherwise negatively impact our business, operating results and financial condition.***

We may incur additional costs in connection with the defense or settlement of existing and any future stockholder litigation in connection with the Offer and the Merger. These demands, lawsuits or other future litigation may adversely affect our ability to complete the Offer and the Merger. We could incur significant costs in connection with any such litigation, including costs associated with the indemnification of our directors and officers.

Furthermore, one of the conditions to the consummation of the Offer and the Merger is the absence of any governmental order or law preventing the consummation of the Offer and the Merger or making the consummation of the Offer and the Merger illegal. Consequently, if a plaintiff were to secure injunctive or other relief prohibiting, delaying or otherwise adversely affecting our ability to complete the consummation of the Offer and the Merger, then such injunctive or other relief may prevent the Offer and the Merger from becoming effective within the expected time frame or at all.

***Our executive officers and directors may have interests in the Offer and the Merger that are different from, or in addition to, those of our stockholders generally.***

Our executive officers and directors may have interests in the Offer and the Merger that are different from, or are in addition to, those of our stockholders generally. These interests include direct or indirect ownership of our common stock and equity awards, the acceleration of equity awards upon consummation of the Merger and other interests. Such interests of our directors and executive officers are set forth in further detail in the Schedule 14D-9 that we filed with the SEC on July 19, 2024.

***While the Offer and the Merger are pending, we are subject to business uncertainties and contractual restrictions that could disrupt our business, and the Offer and the Merger may impair our ability to attract and retain qualified employees or retain and maintain relationships with our suppliers and other business partners.***

Whether or not the Offer and the Merger are consummated, the Offer and the Merger may disrupt our current plans and operations, which could have an adverse effect on our business and financial results. The pendency of the Offer and the Merger may also divert management's attention and our resources from ongoing business and operations and our employees and other key personnel may have uncertainties about the effect of the Offer and the Merger, and the uncertainties may impact our ability to retain, recruit and

hire key personnel while the Offer and the Merger are pending or if the Offer and the Merger fail to close. Furthermore, if key personnel depart because of such uncertainties, or because they do not wish to remain with the combined company after the consummation of the Offer and the Merger, our business and results of operations may be adversely affected. In addition, we cannot predict how our suppliers and other business partners will view or react to the Offer and the Merger upon consummation. If we are unable to reassure our suppliers and other business partners to continue their business with us, our financial condition and results of operations may be adversely affected.

In addition, the Merger Agreement generally requires us to operate in the ordinary course of business consistent with past practice, pending consummation of the Offer and the Merger, and restricts us from taking certain actions with respect to our business and financial affairs without Parent's consent. Such restrictions will be in place until either the Offer and the Merger are consummated or the Merger Agreement is terminated. These restrictions could restrict our ability to, or prevent us from, pursuing attractive business opportunities (if any) that arise prior to the consummation of the Offer and the Merger. For these and other reasons, the pendency of the Offer and the Merger could adversely affect our business, operating results and financial condition.

***We have incurred, and will continue to incur, direct and indirect costs as a result of the pending transactions with Lilly.***

We have incurred, and will continue to incur, significant costs and expenses, including fees for professional services and other transaction costs, in connection with the transactions contemplated by the Merger Agreement. We are obligated to pay these costs and expenses whether or not the transactions are completed. There are a number of factors beyond our control that could affect the total amount or the timing of these costs and expenses, any of which could materially and adversely affect our business, financial condition, results of operations and prospects.

***If the Offer and the Merger are not consummated, we may need to raise additional capital to continue our operations and execute our operating plans.***

If the Offer and the Merger are not consummated, we may need to raise additional capital or we may need to delay, scale back or eliminate some planned operations or reduce expenses to remain a going concern, any of which would have a significant negative impact on our prospects and financial condition, as well as the trading price of our common stock. There can be no assurance that we can raise capital when needed or on terms favorable to us and our stockholders. Macroeconomic conditions and heightened global uncertainties may adversely affect general commercial activity and the U.S. and global economies and financial markets, which increases uncertainty around our ability to access the capital markets when needed and on acceptable terms.

**Risks Related to Our Financial Position and Need for Capital**

***We are a clinical stage biopharmaceutical company with a limited operating history and no products approved for commercial sale. We have a history of significant losses and expect to continue to incur significant losses for the foreseeable future.***

We are a clinical stage biopharmaceutical company with a limited operating history. Biopharmaceutical product development is a highly speculative undertaking because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval or become commercially viable.

Our lead product candidate, MORF-057, has completed a Phase 1 clinical trial in healthy volunteers. We continue our Phase 2 program for MORF-057, initially in UC, and in April 2023 presented positive data from the main cohort (n=35) of the EMERALD-1 open-label, single-arm Phase 2a trial of MORF-057 at a dose of 100 mg BID in patients with moderate to severe UC. We began dosing patients with moderate to severe UC under our EMERALD-2 global Phase 2b randomized controlled trial of MORF-057 in November 2022, and expect to dose the randomized our first patients patient in our Phase 2b study for MORF-057 in Crohn's disease in the second quarter of 2024. disease. We have no products approved for commercial sale and have not generated any revenue from commercial product sales to date, and we will continue to incur significant research and development and other expenses related to our clinical development and ongoing operations. For the three six months ended March 31, 2024 June 30, 2024, we reported a net loss of $45.3 million $102.9 million. As of March 31, 2024 June 30, 2024, we had an accumulated deficit of approximately $494.5 million $552.1 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of our product candidates.

We anticipate that our expenses will increase substantially if, and as, we:

- conduct clinical trials for our current and any future product candidates;
- discover and develop new product candidates, and conduct research and development activities, preclinical studies and clinical trials on those candidates;
- manufacture, or have manufactured, preclinical, clinical and commercial supplies of our product candidates;
- seek regulatory approvals for our product candidates or any future product candidates;
- commercialize our current product candidates or any future product candidates, if approved;
- attempt to transition from a company with a research focus to a company capable of supporting commercial activities, including establishing sales, marketing and distribution infrastructure;
- hire additional clinical, scientific and management personnel;
- add operational, financial and management information systems and personnel, including international operations;
- identify additional compounds or product candidates and acquire rights from third parties to those compounds or product candidates through licenses; and
- experience any delays in our preclinical or clinical studies and efforts to obtain regulatory approval for our product candidates, whether as a result of regional conflicts around the world, instability in the banking sector, inflation and market volatility, interest rate fluctuations, uncertainty with respect to the federal debt ceiling and budget and the related potential for government shutdowns, cybersecurity events, the ongoing labor shortage, global supply chain disruptions, the weakening of the global and U.S. economies, or otherwise). otherwise.

Even if we succeed in commercializing one or more product candidates, we may continue to incur substantial research and development and other expenditures to develop and market additional product candidates. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our

business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital.

***We have never generated revenue from product sales and may never be profitable.***

Our ability to become and remain profitable depends on our ability to generate revenue. We do not expect to generate significant revenue unless and until we, either alone or with a collaborator, are able to obtain regulatory approval for, and successfully commercialize, our lead product candidate for our α4β7 program, or any other product candidates we may develop. Successful commercialization will require achievement of many key milestones, including demonstrating safety and efficacy in clinical trials, obtaining regulatory, including marketing, approval for these product candidates, manufacturing, marketing and selling those products for which we, or any of our current or future collaborators, may obtain regulatory approval, satisfying any post-marketing requirements and obtaining reimbursement for our products from private insurance or government payors. Because of the uncertainties and risks associated with these activities, we are unable to accurately and precisely predict the timing and amount of any future revenue, the extent of any further losses or if or when we might achieve profitability. We and any current or future collaborators may never succeed in these activities and, even if we do, or any collaborators do, we may never generate revenues that are large enough for us to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis.

Our failure to become and remain profitable may depress the market price of our common stock and could impair our ability to raise capital, expand our business or continue our operations. If we continue to suffer losses as we have in the past, investors may not receive any return on their investment and may lose their entire investment.

***We will need substantial additional funds to advance development of our product candidates, which may not be available on acceptable terms, or at all. Failure to obtain this necessary capital when needed may force us to delay, limit or terminate our product development programs, commercialization efforts or other operations.***

The development of biopharmaceutical product candidates is capital-intensive. As our product candidates enter and advance through preclinical studies and clinical trials, we will need substantial additional funds to expand or create our development, regulatory, manufacturing, marketing and sales capabilities. We have used substantial funds to develop our technology and product candidates to date, and will require significant funds to conduct further research and development and preclinical testing and clinical trials of our product candidates, to seek regulatory approvals for our product candidates and to manufacture and market products, if any, which are approved for commercial sale.

Since our inception, we have invested a significant portion of our efforts and financial resources in research and development activities and preclinical testing and clinical trials of our product candidates. As of March 31, 2024 June 30, 2024, we had $658.8 million $628.4 million in cash, cash equivalents and marketable securities. Based on our current operating plan, we believe that our existing cash, cash equivalents and marketable securities as of June 30, 2024 will be sufficient to fund our operating expenses and capital expenditure requirements into for at least twelve months from the second half issuance date of 2027. these unaudited condensed consolidated financial statements. However, our future capital requirements and the period for which we expect our existing resources to support our operations and future capital requirements may vary significantly from what we expect and we may need to seek additional funds sooner than planned. Because the length of time and activities associated with successful research and development of our product candidates is highly uncertain, we are unable to estimate the actual funds we will require for development and any marketing and commercialization activities for approved products. Our future funding requirements, both near- and long-term, will depend on many factors, including, but not limited to:

- the timing, cost and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the progress of the development efforts of parties with whom we have entered or may in the future enter into collaborations and/or research and development agreements;
- the timing and amount of milestone and other payments we may receive or make under any collaboration agreements;
- our ability to maintain our current licenses and research and development programs and to establish new collaboration arrangements;
- the costs involved in prosecuting and enforcing patent and other intellectual property claims;
- the costs of manufacturing our product candidates by third parties;
- the cost of regulatory submissions and timing of regulatory approvals;
- the cost of commercialization activities if our product candidates or any future product candidates are approved for sale, including marketing, sales and distribution costs;
- our efforts to enhance operational systems and hire additional personnel, including personnel to support development of our product candidates; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems to satisfy our obligations as a public company.

Our ability to raise additional funds may be adversely impacted by worsening global economic conditions, including as a result of disruptions to and volatility in the credit and financial markets in the United States and worldwide, increases in inflation, interest rate fluctuations, uncertainty with respect to the federal debt ceiling and budget and the related potential for government shutdowns, the ongoing labor shortage, disruptions to global supply chains, and regional conflicts around the world. Moreover, there has been recent turmoil in the global banking system. For example, on March 10, 2023, Silicon Valley Bank ("SVB"), was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver for SVB. Similarly, on March 12, 2023, Silvergate Capital Corp. and Signature Bank

were each swept into receivership. While the FDIC took steps to make depositors of SVB whole, First-Citizens Bank & Trust Company assumed our deposits from SVB, and we regained access to those funds, there is no guarantee that the federal government would similarly guarantee all depositors in the event of future bank closures. Any further instability in the global banking system may adversely impact our business and financial condition. Moreover, events such as the closure of SVB, in addition to global macroeconomic conditions discussed above, may cause further turbulence and uncertainty in the capital markets. Further deterioration of the macroeconomic environment and any regulatory action taken in response thereto may adversely affect our business, operating results, and financial condition. If we are unable to obtain funding on a timely basis or on acceptable terms, we may have to delay, reduce or terminate our research and development programs and preclinical studies or clinical trials, limit strategic opportunities or undergo reductions in our workforce or other corporate restructuring activities. To date, we have primarily financed our operations through payments received under our collaboration agreements, the sale of equity securities and debt financing.

We will be required to seek additional funding in the future and currently intend to do so through public or private equity offerings or debt financings, additional collaborations and/or licensing agreements, credit or loan facilities, or a combination of one or more of these funding sources. If we raise additional funds by issuing equity securities, including pursuant to our currently effective registration statement on Form S-3ASR and any shelf registration statement on Form S-3ASR that we may file in the future, our stockholders may suffer dilution and the terms of any financing may adversely affect the rights of our stockholders.

In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Our future debt financings, if any, are likely to involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities received any distribution of our corporate assets. If we raise additional funds through licensing or collaboration arrangements with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. We also could be required to seek collaborators for product candidates at an earlier stage than otherwise would be desirable or relinquish our rights to product candidates or technologies that we otherwise would seek to develop or commercialize ourselves. Failure to obtain capital when needed on acceptable terms or at all may force us to delay, limit or terminate our product development and commercialization of our current or future product candidates, which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

**Risks Related to Discovery, Development and Commercialization**

***Our business is heavily dependent on the success of our current and future product candidates, including our lead product candidate for our α4β7 program. Existing and future preclinical studies and clinical trials of these product candidates may not be successful, and if we are unable to commercialize these product candidates or experience significant delays in doing so, our business will be materially harmed.***

We have invested a significant portion of our efforts and financial resources in the development of our α4β7- specific integrin inhibitors program. Our ability to generate commercial product revenues, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of our lead product candidate for our α4β7 program. We have not previously submitted a new drug application (“NDA”) to the FDA, or similar regulatory approval filings to comparable foreign authorities, for any product candidate, and we cannot be certain that our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in clinical trials. In addition, regulatory authorities may not complete their review processes in a timely manner, or additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials and the review process. Regulatory authorities also may approve a product candidate for more limited indications than requested or with labeling that includes warnings, contraindications or precautions with respect to conditions of use. Regulatory authorities may also require Risk Evaluation and Mitigation Strategies (“REMS”) or the performance of costly post-marketing clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to market our product candidates, our revenues will be dependent, in part, upon the size of the markets in the territories for which we gain regulatory approval and have commercial rights. If the markets for patient subsets that we are targeting are not as significant as we estimate, we may not generate significant revenues from sales of such products, if approved.

We plan to seek regulatory approval to commercialize our product candidates both in the United States and in selected foreign countries. In order to obtain separate regulatory approvals in other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy. Other countries also have their own regulations governing, among other things, clinical trials and commercial sales, as well as pricing and distribution of our product candidates, and we may be required to expend significant resources to obtain regulatory approval, which may not be successful, and to comply with ongoing regulations in these jurisdictions.

The success of our current and future product candidates will depend on many factors, including the following actions to be taken by us or our collaborators, as applicable:

- successful completion of necessary preclinical studies to enable the initiation of clinical trials;
- successful enrollment of patients in, and the completion of, our clinical trials with favorable results;
- receiving required regulatory authorizations for the development and approvals for the commercialization of our product candidates;
- establishing and maintaining arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and non-patent exclusivity for our product candidates and their components;
- enforcing and defending our intellectual property rights and claims;
- achieving desirable therapeutic properties for our product candidates’ intended indications;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with third parties;
- acceptance of our product candidates, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies; and
- maintaining an acceptable safety profile of our product candidates through clinical trials and following regulatory approval.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business, financial condition, results of operations and prospects.

***Our product candidates are in various stages of development and may fail in development or suffer delays that materially adversely affect their commercial viability. If we or our collaborators are unable to complete development of, or commercialize, our product candidates or experience significant delays in doing so, our business will be materially harmed.***

We have no products on the market and our product candidates are in various stages of development. Additionally, we have a portfolio of targets and programs that are in earlier stages of discovery and preclinical development and may never advance to clinical-stage development. Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for and successfully commercializing our product candidates, either alone or with third parties, and we cannot guarantee you that we will ever obtain regulatory approval for any of our product candidates. We have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. Before obtaining regulatory approval for the commercial distribution of our product candidates, we or any existing or future collaborator must conduct extensive preclinical tests and clinical trials to demonstrate the safety and efficacy in humans of our product candidates.

We may not have the financial resources to continue development of, or to modify existing or enter into new collaborations for, a product candidate if we experience any issues that delay or prevent regulatory approval of, or our ability to commercialize, product candidates, including:

- preclinical study results may show the product candidate to be less effective than desired or to have harmful or problematic side effects;
- preclinical studies conducted outside of the United States may be affected by tariffs or import/export restrictions imposed by the United States or other governments;
- negative or inconclusive results from our clinical trials or the clinical trials of others for product candidates similar to ours, leading to a decision or requirement to conduct additional preclinical testing or clinical trials or abandon a program;
- product-related side effects experienced by patients in our clinical trials or by individuals using drugs or therapeutic biologics similar to our product candidates;
- our third-party manufacturers' inability to successfully manufacture our products;
- inability of any third-party contract manufacturer to scale up manufacturing of our product candidates and those of our collaborators to supply the needs of clinical trials or commercial sales;
- delays in submitting INDs or comparable foreign applications or delays or failures in obtaining the necessary approvals from regulators to commence a clinical trial, or a suspension or termination of a clinical trial once commenced;
- conditions imposed by the FDA or comparable foreign authorities regarding the scope or design of our clinical trials;
- delays in enrolling patients in our clinical trials;
- high drop-out rates of our clinical trial patients;
- inadequate supply or quality of product candidate components or materials or other supplies necessary for the conduct of our clinical trials;
- inability to obtain alternative sources of supply for which we have a single source for product candidate components or materials;
- harmful side effects or inability of our product candidates to meet efficacy endpoints during clinical trials;
- failure to demonstrate a benefit-risk profile acceptable to the FDA or other regulatory agencies;
- unfavorable FDA or other regulatory agency inspection and review of one or more clinical trial sites or manufacturing facilities used in the testing and manufacture of any of our product candidates;
- failure of our third-party contractors or investigators to comply with regulatory requirements or otherwise meet their contractual obligations in a timely manner, or at all;
- delays and changes in regulatory requirements, policy and guidelines, including the imposition of additional regulatory oversight around clinical testing generally or with respect to our trials in particular; or
- varying interpretations of our data by the FDA and similar foreign regulatory agencies.

Our or any of our collaborators' inability to complete development of or commercialize our product candidates, or significant delays in doing so due to one or more of these factors, could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our products may be delayed and, as a result, our stock price may decline.***

From time to time, we estimate the timing of the anticipated accomplishment of various scientific, clinical, regulatory and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of scientific studies and clinical trials and the submission of regulatory filings. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are and will be based on numerous assumptions and estimates that may prove to be incorrect. The actual timing of these milestones can vary dramatically compared to our estimates, in some cases for reasons beyond our control. If we do not meet these milestones as publicly announced, or at all, the commercialization of our products may be delayed or never achieved and, as a result, our stock price may decline.

***Our approach to the discovery and development of our therapeutic treatments is based on novel technologies that are unproven and may not result in marketable products.***

We are developing a pipeline of product candidates using our MInT Platform. Historically, dozens of integrin-targeted oral small molecule candidates of other companies that entered late-stage clinical trials have failed to result in FDA or EMA approved medicines. Development efforts and clinical results of other companies exploring oral approaches to integrins may be unsuccessful, resulting in a negative perception of oral integrins and negatively impacting the regulatory approval process of our product candidates, which would have a material and adverse effect on our business. We believe that product candidates identified with our MInT Platform may offer an optimized therapeutic approach by taking advantage of conformational targeting next-generation physics-based technologies augmented with machine learning and artificial intelligence, which allow us to design, iterate and optimize leads in our discovery process. However, the scientific research that forms the basis of our efforts to develop product candidates using our MInT Platform is ongoing and may not result in viable product candidates.

We may ultimately discover that our MInT Platform and any product candidates resulting therefrom do not possess certain properties required for therapeutic effectiveness, including the ability to lock specific integrin conformations. Our product candidates may also be unable to remain stable in the human body for the period of time required for the drug to reach the target tissue or they may trigger immune responses that inhibit the ability of the product candidate to reach the target tissue or that cause adverse side effects in humans. In addition, product candidates based on our

MInT Platform may demonstrate different chemical and pharmacological properties in patients than they do in laboratory studies. Our MInT Platform and any product candidates resulting therefrom may not demonstrate the same chemical and pharmacological properties in humans and may interact with human biological systems in unforeseen, ineffective or harmful ways. For example, AbbVie Biotechnology Ltd. (“AbbVie”) informed us that it did not intend to advance any of its selective oral αvβ6-specific integrin inhibitors under our collaboration agreement, or the AbbVie Agreement, due to a suspected on-target / αvβ6-mediated safety signal that was observed in pre-clinical testing, and subsequently exercised its right to terminate the AbbVie Agreement for convenience, which termination became effective in December 2022.

The regulatory approval process for novel product candidates such as ours can be more expensive and take longer than for other, better known or extensively studied product candidates. To our knowledge, no regulatory authority in the United States or Europe has granted approval for an oral small-molecule integrin inhibitor. We believe the FDA has limited experience with integrin-based therapeutics, which may increase the complexity, uncertainty and length of the regulatory approval process for our product candidates. We and our existing or future collaborators may never receive approval to market and commercialize any product candidate. Even if we or an existing or future collaborator obtains regulatory approval, the approval may be for targets, disease indications or patient populations that are not as broad as we or they intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We or an existing or future collaborator may be required to perform additional or unanticipated clinical trials to obtain approval or be subject to post-marketing testing requirements to maintain regulatory approval. If the products resulting from our MInT Platform and research programs prove to be ineffective, unsafe or commercially unviable, our MInT Platform and pipeline would have little, if any, value, which would have a material and adverse effect on our business, financial condition, results of operations and prospects.

***Preclinical and clinical development involve a lengthy and expensive process, with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current product candidates or any future product candidates.***

All of our product candidates are in preclinical or clinical development, and the risk of failure is high for all programs. It is impossible to predict accurately when or if any of our product candidates will receive regulatory approval. To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and lengthy, complex and expensive clinical trials that our product candidates are safe and effective in humans. Clinical testing can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. We may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, and a clinical trial can fail at any stage of testing. Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Additionally, comparing the results from different trials may be unreliable due to different protocol designs, trial designs, patient selection and populations, number of patients, trial endpoints, trial objectives and other parameters that may not be the same between trials. Therefore, cross-study comparisons provide very limited information about the efficacy or safety of a drug. Moreover, clinical data are often susceptible to varying interpretations and analyses,

and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or to unfavorable safety profiles, notwithstanding promising results in earlier trials. There is typically a high rate of failure of product candidates proceeding through clinical trials. Most product candidates that commence clinical trials are never approved as products and there can be no assurance that any of our future clinical trials will ultimately be successful or support clinical development of our current or any of our future product candidates.

Commencement of clinical trials is subject to finalizing the trial design and submitting an IND or similar submission to the FDA or similar foreign regulatory authority. Even after we submit our IND or comparable submissions in other jurisdictions, the FDA or other regulatory authorities could disagree that we have satisfied their requirements to commence our clinical trials or disagree with our study design, which may require us to complete additional preclinical studies or amend our protocols or impose stricter conditions on the commencement of clinical trials.

We or our collaborators may experience delays in initiating or completing clinical trials. We or our collaborators also may experience numerous unforeseen events during, or as a result of, current or future clinical trials that we could conduct that could delay or prevent our ability to receive marketing approval or commercialize our integrin inhibitor programs or any future product candidates, including:

- regulators or institutional review boards (“IRBs”), the FDA or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trial sites may deviate from a trial’s protocol or drop out of a trial;
- clinical trials of any product candidates may fail to show safety or efficacy, produce negative or inconclusive results and we may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials or we may decide to abandon product development programs;
- the number of subjects required for clinical trials of any product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or subjects may drop out of these clinical trials or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may deviate from the clinical trial protocol or drop out of the trial, which may require that we add new clinical trial sites or investigators;
- we may elect to, or regulators, IRBs, or ethics committees may require that we or our investigators, suspend or terminate clinical research or trials for various reasons, including noncompliance or perceived noncompliance with regulatory requirements or a finding that the participants in our trials are being exposed to unacceptable health risks;
- the cost of clinical trials of any of our product candidates may be greater than we anticipate;
- the quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be inadequate to initiate or complete a given clinical trial;
- we or our third-party contract manufacturers may be unable to manufacture sufficient quantities of our product candidates for use in clinical trials;
- reports from clinical testing of other therapies may raise safety or efficacy concerns about our product candidates;
- we may fail to establish an appropriate safety profile for a product candidate based on clinical or preclinical data for such product candidate as well as data emerging from other molecules in the same class as our product candidate; and
- the FDA, EMA or other regulatory authorities may require us to submit additional data such as long-term toxicology studies or impose other requirements before permitting us to initiate a clinical trial.

Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors including the size and nature of the patient population, the number and location of clinical sites we enroll, the proximity of patients to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, the inability to obtain and maintain patient consents, the risk that enrolled participants will drop out before completion, competing clinical trials and clinicians’ and patients’ perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs or therapeutic biologics that may be approved for the indications being investigated by us. Furthermore, we expect to rely on our collaborators, CROs and clinical trial sites to ensure the proper and timely conduct of our current or future clinical trials, including the patient enrollment process, and we have limited influence over their performance. Additionally, we could encounter delays if treating physicians encounter unresolved ethical issues associated with enrolling patients in current or future clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles.

We could also encounter delays if a clinical trial is suspended or terminated by us, the IRBs of the institutions in which such trials are being conducted, or the FDA, EMA or other regulatory authorities, or if a clinical trial is recommended for suspension or termination by the Data Safety Monitoring Board (the “DSMB”) for such trial. A suspension or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, EMA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a product or treatment, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Clinical studies may also be delayed or terminated as a result of ambiguous or negative interim results. Many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. Further, the FDA, EMA or other regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

Our product development costs will increase if we experience delays in clinical testing or marketing approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates and harming our business and results of operations. Any delays in our clinical development programs may harm our business, financial condition and results of operations significantly.

***Results of preclinical studies and early clinical trials may not be predictive of results of later clinical trials.***

The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and interim results of clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in earlier development, and we could face similar setbacks. As is common for early trials, we may examine a number of efficacy measures without accounting for multiplicity, and positive results in early clinical trials, including nominally statistically significant results, may not be replicated in future trials with a different design or in other future trials. The design of a clinical trial can determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have

nonetheless failed to obtain marketing approval for the product candidates. Even if we, or future collaborators, believe that the results of clinical trials for our product candidates warrant marketing approval, the FDA or comparable foreign regulatory authorities may disagree and may not grant marketing approval of our product candidates.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including differences in trial procedures set forth in protocols, including endpoints, differences in the size and characteristics of the patient populations, differences in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial patients. If we fail to receive positive results in clinical trials of our product candidates, the development timeline and regulatory approval and commercialization prospects for our product candidates, and, correspondingly, our business and financial prospects would be negatively impacted.

***Interim and preliminary or topline data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.***

From time to time, we may publish interim and preliminary or topline data from our anticipated clinical trials. Data from prespecified interim analyses from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary or topline data we previously published. As a result, interim and preliminary or topline data should be viewed with caution until the final data are available. Adverse differences between interim, preliminary or topline data and final data could significantly harm our reputation and business prospects.

***Our current and future clinical trials or those of our current and future collaborators may reveal significant adverse events not seen in our preclinical studies and may result in a safety profile that could inhibit regulatory approval or market acceptance of any of our product candidates.***

If significant adverse events or other side effects are observed in any of our clinical trials or the clinical trials of our collaborators, we may have difficulty recruiting patients to our clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. For example, progressive multifocal leukoencephalopathy (“PML”), has been observed by others as an adverse effect during late-stage clinical development of infusible antibody inhibitor of $\alpha_4\beta_1$ integrin, natalizumab. This adverse effect was not observed in the preclinical studies or during early clinical development of natalizumab. We, the FDA, EMA or other applicable regulatory authorities, or an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects or patients in such trials are being exposed to unacceptable

health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance of the approved product due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects.

***We may not be successful in our efforts to use our MInT Platform to expand our pipeline of product candidates and develop marketable products.***

The success of our business depends in part upon our ability to discover, develop and commercialize products based on our MInT Platform. Our lead program for α4β7 and our research programs, or those of our any collaborators, may fail to identify other potential product candidates for clinical development for a number of reasons. Our research methodology may be unsuccessful in identifying potential product candidates or our potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unmarketable or unlikely to receive marketing approval. If any of these events occur, we may be forced to abandon our development efforts for a program or for multiple programs, which would materially harm our business and could potentially cause us to cease operations. Research programs to identify new product candidates require substantial technical, financial and human resources.

***We may expend our limited resources to pursue a particular product candidate and fail to capitalize on product candidates that may be more profitable or for which there is a greater likelihood of success.***

Because we have limited financial and managerial resources, we focus our research and development efforts on certain selected product candidates. For example, we are initially focused on our lead product candidate, MORF-057, in our α4β7-specific integrin inhibitor program. As a result, we may forgo or delay pursuit of opportunities with other product candidates that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

***We face competition from entities that have developed or may develop product candidates for autoimmune, cardiovascular and metabolic diseases, fibrosis and cancer, including companies developing novel treatments and technology platforms. If these companies develop technologies or product candidates more rapidly than we do or their technologies or product candidates are more effective, our ability to develop and successfully commercialize product candidates may be adversely affected.***

The development and commercialization of drugs is highly competitive. Our product candidates, if approved, will face significant competition and our failure to effectively compete may prevent us from achieving significant market penetration. Most of our competitors have significantly greater resources than we do, and we may not be able to successfully compete. We compete with a variety of multinational biopharmaceutical companies, specialized biotechnology companies and emerging biotechnology companies, as well as with technologies and product candidates being developed at universities and other research institutions. Our competitors have developed, are developing or will develop product candidates and processes competitive with our product candidates and processes. Competitive therapeutic treatments include those that have already been approved and accepted by the medical community and any new treatments, including those based on novel technology platforms that enter the market. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we are trying, or may try, to develop product candidates. There is intense and rapidly evolving competition in the biotechnology, biopharmaceutical and integrin and immunoregulatory therapeutics fields. Competition from many sources exists or may arise in the future. Our competitors include larger and better funded biopharmaceutical, biotechnological and therapeutics companies, including companies focused on therapeutics for autoimmune, cardiovascular and metabolic diseases, fibrosis and cancer, as well as numerous small companies. Moreover, we also compete with current and future therapeutics developed at universities and other research institutions. Some of these companies and institutions

are well-capitalized and, in contrast to us, have significant clinical experience, and may include our existing or future collaborators. In addition, these companies and institutions compete with us in recruiting scientific and managerial talent.

Our success will depend partially on our ability to develop and commercialize therapeutics that are safer and more effective than competing products. Our commercial opportunity and success will be reduced or eliminated if competing products are safer, more effective, or less expensive than the therapeutics we develop.

Despite significant biopharmaceutical industry investment, no oral integrin therapies have been approved in the United States or Europe. We are developing MORF-057, an oral small molecule α4β7-specific integrin inhibitor, for the treatment of IBD. Currently approved IBD therapies include Entyvio (vedolizumab), an injectable α4β7 monoclonal antibody marketed by Takeda Pharmaceutical Company Limited, as well as therapies with different mechanisms of action marketed by AbbVie, Johnson & Johnson, UCB, Biogen Inc., Pfizer Inc., and Bristol-Myers Squibb, in addition to other pharmaceutical companies, against which our product candidate may compete, if approved. Further, we are aware of oral α4β7 therapies in clinical development for IBD by Gilead Sciences, Inc, and EA Pharma Co. LTD and Ensho Therapeutics, as well as therapies with different mechanisms of action in clinical development by AbbVie, Johnson & Johnson, Pfizer, Inc., Eli Lilly and Company, and Bristol-Myers Squibb, in addition to other pharmaceutical companies.

Our αvβ8-specific small molecule integrin inhibitor program is under development for the treatment of myelofibrosis and solid tumors. Currently approved myelofibrosis therapies include the oral JAK inhibitors Jakafi (ruxolitinib), marketed by Incyte Corp and Novartis International AG, Inrebic (fedratinib), marketed by Bristol-Myers Squibb, Vonjo (pacritinib), marketed by Swedish Orphan Biovitrum AB, and Ojjaara (momelotinib), marketed by GlaxoSmithKline plc. We are aware of myelofibrosis therapies in clinical development by MorphoSys AG, Incyte Corp, Geron Corporation, AbbVie, and Bristol-Myers Squibb in addition to other pharmaceutical companies. There are currently no approved αvβ8 inhibitors for any indication. We are aware of an anti-αvβ8 monoclonal antibody in clinical development for the treatment of solid tumors by Pfizer, Inc. In addition, we are aware of preclinical stage anti-αvβ8 monoclonal antibody programs for solid tumors from Corbus Pharmaceuticals Holdings, Inc., and a small molecule program from Pliant Therapeutics. Furthermore, there are multiple antibody and small molecule therapeutics targeting the TGF-β pathway for the treatment of solid tumors in development by Novartis International AG, AbbVie, Roche Holding AG, Merck & Co., Inc., Bristol-Myers Squibb, and Scholar Rock, in addition to other pharmaceutical companies.

Many of these competitors have significantly greater financial, technical, manufacturing, marketing, sales, and supply resources or experience than we have. If we successfully obtain approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our products, the ease with which our products can be administered and the extent to which patients accept relatively new routes of administration, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

***Our current product candidates or any future product candidates may not achieve adequate market acceptance among physicians, patients, healthcare third-party payors and others in the medical community necessary for commercial success, if approved, and we may not generate any future revenue from the sale or licensing of product candidates.***

Even if regulatory approval is obtained for a product candidate, we may not generate or sustain revenue from sales of the product due to factors such as whether the product can be sold at a competitive cost and whether it will otherwise be accepted in the market. Historically, several injectable integrin inhibitors have been approved by the FDA for treatment of inflammatory bowel disease, multiple sclerosis, psoriasis, acute coronary syndrome and dry eye disease. However, our product candidates are based on a novel approach to oral integrin therapies, and while integrins are a well-understood receptor family, to date, no oral small molecule integrin therapies have been approved by the FDA. Market participants with significant influence over acceptance of new treatments, such as physicians and third-party payors, may not adopt an orally bioavailable product based on our novel technologies, and we may not be able to convince the medical community and third-party payors to accept and use, or to provide favorable reimbursement for, any product candidates developed by us or our existing or future collaborators. Market acceptance of our product candidates will depend on, among other factors:

- the timing of our receipt of any marketing and commercialization approvals;
- the terms of any approvals and the countries in which approvals are obtained;
- the safety and efficacy of our product candidates as demonstrated in clinical trials;
- the prevalence and severity of any adverse side effects associated with our product candidates;
- limitations or warnings contained in any labeling approved by the FDA or other regulatory authority;
- relative convenience and ease of administration of our product candidates;
- the willingness of patients to accept any new methods of administration;
- unfavorable publicity relating to our current product candidates or any future product candidates;
- the success of our physician education programs;

- the effectiveness of sales and marketing efforts;
- the availability of coverage and adequate reimbursement from government and third-party payors;
- the pricing of our products, particularly as compared to alternative treatments; and
- the availability of alternative effective treatments for the disease indications our product candidates are intended to treat and the relative risks, benefits and costs of those treatments.

Sales of medical products also depend on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe, therapeutically effective and cost effective. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that our product is safe, therapeutically effective and cost effective as compared with competing treatments. If any product candidate is approved but does not achieve an adequate level of acceptance by such parties, we may not generate or derive sufficient revenue from that product candidate and may not become or remain profitable.

Because our product candidates are based on new technology, we expect that they will require extensive research and development and have substantial manufacturing and processing costs. In addition, our estimates regarding potential market size for any indication may be materially different from what we discover to exist at the time we commence commercialization, if any, for a product, which could result in significant changes in our business plan and have a material adverse effect on our business, financial condition, results of operations and prospects. Moreover, if any product candidate we commercialize fails to achieve market acceptance, it could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***If in the future we are unable to establish U.S. or global sales and marketing capabilities or enter into agreements with third parties to sell and market any of our product candidates that are approved, we may not be successful in commercializing such product candidates and may not be able to generate any revenue.***

We currently do not have a marketing or sales team for the marketing, sales and distribution of any of our product candidates that are able to obtain regulatory approval. To commercialize any product candidates after approval, we will need to build, on a territory-by-territory basis, marketing, sales, distribution, managerial and other non-technical capabilities or arrange with third parties to perform these services, and we may not be successful in doing so. If our product candidates receive regulatory approval, we may decide to establish an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates, which would be expensive and time consuming and would require significant attention of our executive officers to manage. For example, some state and local jurisdictions have licensing and continuing education requirements for pharmaceutical sales representatives, which requires time and financial resources. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of any of our product candidates that we obtain approval to market.

With respect to the commercialization of our product candidates that obtain regulatory approval, if any, we may choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements when needed on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval, or any such commercialization may experience delays or limitations. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer, and we may incur significant additional losses.

***If any of our product candidates receives marketing approval and we or others later identify undesirable side effects caused by the product candidate, our ability to market and derive revenue from the product candidates could be compromised.***

Undesirable side effects caused by our product candidates could cause regulatory authorities to interrupt, delay or halt clinical trials and could result in more restrictive labeling or the delay or denial of regulatory approval by the FDA or other regulatory authorities. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our future clinical trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Such side effects could also affect patient recruitment or the ability of enrolled patients to initiate or complete the clinical trial or result in potential product liability claims. Any of these occurrences may materially and adversely affect our business, financial condition, results of operations and prospects.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate.

If any of our product candidates receive regulatory approval and we or others identify undesirable side effects caused by such product, any of the following adverse events could occur:

- regulatory authorities may withdraw their approval of the product or seize the product;
- we may be required to recall the product or change the way the product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a boxed warning or a contraindication;
- we may be required to create a Medication Guide outlining the risks of such side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- our reputation may suffer.

Any of these occurrences could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***We anticipate that some of our product candidates may be studied in combination with third-party drugs, some of which may still be in development, and we have limited or no control over the supply, regulatory status, or regulatory approval of such drugs.***

Some of our product candidates may be studied in combination with third-party drugs. The development of product candidates for use in combination with another product or product candidate may present challenges that are not faced for single agent product candidates. The FDA or other regulatory authorities may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. It is possible that the results of these trials could show that any positive previous trial results are attributable to the combination therapy and not our product candidates. Moreover, following product approval, the FDA or other regulatory authorities may require that products used in conjunction with each other be cross labeled for combined use. To the extent that we do not have rights to the other product, this may require us to work with a third party to satisfy such a requirement. Moreover, developments related to the other product may impact our clinical trials for the combination as well as our commercial prospects should we receive marketing approval. Such developments may include changes to the other product's safety or efficacy profile, changes to the availability of the approved product, and changes to the standard of care.

If we pursue such combination therapies, we cannot be certain that a steady supply of such drugs will be commercially available. Any failure to enter into such commercial relationships, or the expense of purchasing therapies in the market, may delay our development timelines, increase our costs and jeopardize our ability to develop our product candidates as commercially viable combination therapies. The occurrence of any of these could adversely affect our business, results of operations and financial condition.

In the event that any future collaborator or supplier becomes unable or unwilling to supply their products on commercially reasonable terms or at all, we would need to identify alternatives for accessing such products. Additionally, should the supply of products of any collaborator or supplier be interrupted, delayed or otherwise be unavailable to us, our clinical trials may be delayed. In the event we are unable to source a supply of any alternative therapy, or are unable to do so on commercially reasonable terms, our business, results of operations and financial condition may be adversely affected.

**Risks Related to Our Reliance on Third Parties**

***We have historically entered into collaborations and may, in the future, seek to enter into collaborations with third parties for the discovery and development of our therapeutic candidates. If our future collaborators cease development efforts under collaboration agreements, or if those agreements are terminated, the collaborations may fail to lead to commercial products, and we may never receive milestone payments or future royalties under the agreements.***

We have in the past and may in the future seek to enter into collaboration agreements with third parties for the discovery or development of certain integrin-based therapeutics, and such collaborations could represent a significant portion of our product pipeline. We have derived substantially all of our revenue to date from collaboration agreements with third parties, and we may derive a portion of our future revenue from collaboration agreements or other similar agreements into which we may enter in the future. Revenue from research and development collaborations depends upon continuation of the collaborations, payments for research and development services and resulting options to acquire any licenses of successful product candidates, and the achievement of milestones, contingent payments and royalties, if any, derived from future products developed from our research. If we are unable to successfully advance the development of our product candidates or achieve milestones, or if our collaborations are otherwise not successful, revenue and cash resources from milestone payments under any collaboration agreements that we may enter into will be substantially less than expected. For example, in June 2022 AbbVie exercised its right to terminate the AbbVie Agreement for convenience, effective December 2022, due to a suspected on-target / αvβ6-mediated safety signal that was observed in preclinical testing. In January 2023, Janssen exercised its right to terminate the Janssen Agreement for convenience, effective March 2023, following a lack of target validation in the specific disease of Janssen's interest, and we have since focused efforts on a third integrin research program with Janssen that includes the potential development of integrin antibody activators.

In addition, we may in the future seek third-party collaborators for research, development and commercialization of other therapeutic technologies or product candidates. Biopharmaceutical companies are our prior and likely future collaborators for any marketing, distribution, development, licensing or broader collaboration arrangements. If we fail to enter into future collaborations on commercially reasonable terms, or at all, or such collaborations are not successful or are terminated, we may not be able to execute our strategy to develop certain targets, product candidates or disease areas that we believe could benefit from the resources of either larger biopharmaceutical companies or those specialized in a particular area of relevance.

With respect to collaboration agreements, we have historically had and expect to have in the future limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Moreover, our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates currently pose, and will continue to pose, the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on preclinical studies or clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- collaborators with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;

- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources; and
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates.

As a result of the foregoing, our current and any future collaboration agreements may not lead to development or commercialization of any or all of our product candidates in the most efficient manner or at all. If a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated. Any failure to successfully develop or commercialize our product candidates pursuant to our current or any future collaboration agreements could have a material and adverse effect on our business, financial condition, results of operations and prospects.

Moreover, to the extent that any of our existing or future collaborators were to terminate a collaboration agreement, we may be forced to independently develop these product candidates, including funding preclinical studies or clinical trials, assuming marketing and distribution costs and defending intellectual property rights, or, in certain instances, abandon product candidates altogether, any of which could result in a change to our business plan and have a material adverse effect on our business, financial condition, results of operations and prospects.

***Our existing discovery collaboration with Schrödinger is important to our business. If we are unable to maintain this collaboration, or if this collaboration is not successful, our business could be adversely affected.***

In June 2015, we entered into a Collaboration Agreement with Schrödinger, which was subsequently amended in March 2018 and in May 2019 (the “Schrödinger Agreement”). Under the collaboration, Schrödinger uses its technology platform to perform virtual screens of members of the target class of human integrins, and we and Schrödinger collaborate to facilitate prioritization of targets, perform target validation and analysis, identify leads and perform lead optimization. Schrödinger has granted us an exclusive license for all intellectual property for our product candidates.

Because we currently rely on Schrödinger for a substantial portion of our discovery capabilities, if Schrödinger experiences delays in performance of or fails to perform its obligations under the Schrödinger Agreement, disagrees with our interpretation of the terms of the collaboration or our discovery plan or terminates the Schrödinger Agreement, our pipeline of product candidates would be adversely affected. Schrödinger may also fail to properly maintain or defend the intellectual property we have licensed from them, or even infringe upon, our intellectual property rights, leading to the potential invalidation of our intellectual property or subjecting us to litigation or arbitration, any of which would be time-consuming and expensive. Additionally, either party has the right to terminate the collaboration pursuant to the terms of the Schrödinger Agreement. If our collaboration with Schrödinger is terminated, especially during our discovery phase, the development of our product candidates would be materially delayed or harmed.

***We may have conflicts with our collaborators that could delay or prevent the development or commercialization of our product candidates.***

We may have conflicts with our collaborators, such as conflicts concerning the interpretation of preclinical or clinical data, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations or the ownership of intellectual property developed during our collaboration. If any conflicts arise with any of our collaborators, such collaborator may act in a manner that is averse to our best interests. Any such disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating revenues: unwillingness on the part of a collaborator to pay us milestone payments or royalties we believe are due to us under a collaboration, which could require us to raise additional capital; uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into additional collaborations; unwillingness by the collaborator to cooperate in the development or manufacture of the product, including providing us with product data or materials; unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities; initiating of litigation or alternative dispute resolution options by either party to resolve the dispute; or attempts by either party to terminate the agreement.

***We may engage in strategic transactions, including collaboration agreements, that could adversely affect our ability to develop and commercialize product candidates, impact our cash position, increase our expenses and present significant distractions to our management.***

From time to time, we may consider strategic transactions, such as collaboration agreements, acquisitions of companies, asset purchases and out or in licensing of product candidates or technologies that we believe will complement or augment our existing business. In particular, we will evaluate and, if strategically attractive, seek to enter into collaboration agreements with third parties, including with major biotechnology or biopharmaceutical companies. The competition for collaborators is intense, and the negotiation process is time-consuming and complex. Any new collaboration may be on terms that are not optimal for us, and we may not be able to maintain any new collaboration if, for example, development or approval of a product candidate is delayed, sales of an approved product candidate do not meet expectations or the collaborator terminates the collaboration. In addition, a significant number of recent business combinations among large pharmaceutical companies has resulted in a reduced number of potential future strategic partners. Our collaborators may consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Our ability to reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the strategic partner’s resources and expertise, the terms and conditions of the proposed collaboration and the proposed strategic partner’s evaluation of a number of factors. These factors may include the design or results of clinical trials, the likelihood of approval by the FDA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge and industry and market conditions generally. Moreover, if we acquire assets with promising markets or technologies, we may not be able to realize the benefit of acquiring such assets if we are not able to successfully integrate them with our existing technologies. We may encounter numerous difficulties in developing, testing, manufacturing and marketing any new products resulting from a strategic acquisition that delay or prevent us from realizing their expected benefits or enhancing our business.

We cannot assure you that following any such collaboration, or other strategic transaction, we will achieve the expected synergies to justify the transaction. For example, such transactions may require us to incur non-recurring or other charges, increase our near and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business. These transactions would entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management’s time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-

downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers,

manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business.

Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and would have a material and adverse effect on our business, financial condition, results of operations and prospects. Conversely, any failure to enter any additional collaboration or other strategic transaction that would be beneficial to us could delay the development and potential commercialization of our product candidates and have a negative impact on the competitiveness of any product candidate that reaches market.

***We rely and expect to continue to rely on third parties to conduct certain of our preclinical studies or clinical trials. If those third parties do not perform as contractually required, fail to satisfy legal or regulatory requirements, miss expected deadlines or terminate the relationship, our development program could be delayed with potentially material and adverse effects on our business, financial condition, results of operations and prospects.***

We rely and intend to rely in the future on third-party clinical investigators, CROs, clinical data management organizations and consultants to assist or provide the design, conduct, supervision and monitoring of preclinical studies and clinical trials of our product candidates. Because we rely on these third parties and will not have the ability to conduct all preclinical studies or clinical trials independently, we will have less control over the timing,

quality and other aspects of preclinical studies and clinical trials than we would have had we conducted them on our own. These investigators, CROs and consultants will not be our employees and we will have limited control over the amount of time and resources that they dedicate to our programs. These third parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs. The third parties with which we may contract might not be diligent, careful or timely in conducting our preclinical studies or clinical trials, resulting in the preclinical studies or clinical trials being delayed or unsuccessful.

If we cannot contract with acceptable third parties on commercially reasonable terms, or at all, or if these third parties do not carry out their contractual duties, satisfy legal and regulatory requirements for the conduct of preclinical studies or clinical trials or meet expected deadlines, our clinical development programs could be delayed and otherwise adversely affected. In all events, we will be responsible for ensuring that each of our preclinical studies and clinical trials are conducted in accordance with the general investigational plan and protocols for the trial as well as applicable legal and regulatory requirements. The FDA generally requires preclinical studies to be conducted in accordance with good laboratory practices and clinical trials to be conducted in accordance with good clinical practices, including for designing, conducting, recording and reporting the results of preclinical studies and clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. Our reliance on third parties that we do not control will not relieve us of these responsibilities and requirements. Any adverse development or delay in our preclinical studies or clinical trials as a result of our reliance on third parties could have a material and adverse effect on our business, financial condition, results of operations and prospects.

If any of our relationships with these third-party CROs or others terminate, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines.

***We rely on third-party manufacturers and suppliers to supply components of our product candidates. The loss of our third-party manufacturers or suppliers, or our or their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.***

We do not own or operate facilities for drug manufacturing, storage, distribution or quality testing. We currently rely, and may continue to rely, on third-party contract manufacturers, including in the U.K. and China, to manufacture bulk drug substances, drug products, raw materials, samples, components, or other materials and reports. Reliance on third-party manufacturers may expose us to different risks than if we were to manufacture product candidates ourselves. There can be no assurance that our preclinical and clinical development product supplies will not be limited, interrupted, terminated or of satisfactory quality or continue to be available at acceptable prices. For example, a recent escalation of trade tensions between the U.S. and China has resulted in trade restrictions and calls for sanctions that could impact our ability to rely on our third-party manufacturers in China. There is currently significant uncertainty about the future relationship between the United States and China with respect to trade policies, treaties, tariffs, taxes, and other limitations on cross-border operations. The U.S. government has made and continues to make significant additional changes in U.S. trade policy and may continue to take future actions that could negatively impact U.S. trade. For example, legislation has been introduced in Congress to limit certain U.S. biotechnology companies from using equipment or services produced or provided by select Chinese biotechnology companies, and others in Congress have advocated for the use of existing executive branch authorities to limit those Chinese service providers' ability to engage in business in the U.S. We cannot predict what actions may ultimately be taken with respect to trade relations between the U.S. and China or other countries, what products and services may be subject to such actions or what actions may be taken by the other countries in retaliation. Sustained uncertainty about, or a worsening of, current global economic conditions and further escalation of trade tensions between the U.S. and China could result in a global economic slowdown and long-term changes to global trade, including retaliatory trade restrictions. Any replacement of our manufacturers or suppliers could require significant effort and expertise because there may be a limited number of qualified replacements. If our third-party manufacturers and suppliers, or any third-party in the supply chain, are adversely impacted, including as a result of cybersecurity events or global supply chain disruptions, we may be unable to secure the supply of product candidates required for our preclinical studies.

The manufacturing process for a product candidate is subject to FDA and foreign regulatory authority review. We, and our suppliers and manufacturers, must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as current Good Manufacturing Practices ("cGMPs"). Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA and foreign regulatory authorities. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, we may not be able to rely on their manufacturing facilities for the manufacture of elements of our product candidates. Moreover, we do not control the manufacturing process at our contract manufacturers and are completely dependent on

them for compliance with current regulatory requirements. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to enter into an agreement with another third party, which we may not be able to do on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such to another third party. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to enable us, or to have another third party, manufacture our product candidates. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines; and we may be required to repeat some of the development program. The delays associated with the validation of a new manufacturer could negatively affect our ability to develop product candidates in a timely manner or within budget.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for any product candidate. To the extent that we have existing, or enter into future, manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. Any manufacturing facilities used to produce our products will be subject to periodic review and inspection by the FDA and foreign regulatory authorities, including for continued compliance with cGMP requirements, quality control, quality assurance and corresponding maintenance of records and documents. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third party's failure to execute on our manufacturing requirements, comply with cGMPs or maintain a compliance status acceptable to the FDA or foreign regulatory authorities could adversely affect our business in a number of ways, including:

- an inability to initiate or continue clinical trials of product candidates under development;
- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- loss of the cooperation of existing or future collaborators;
- subjecting third-party manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease distribution or to recall batches of our product candidates; and
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products.

Additionally, our contract manufacturers may experience manufacturing difficulties due to resource constraints or as a result of labor disputes, unstable political environments, epidemics or pandemics, cybersecurity events, or global supply chain disruptions. If our contract manufacturers were to encounter any of these difficulties, our ability to provide our product candidates to patients in preclinical and clinical trials, or to provide product for treatment of patients once approved, would be jeopardized.

For example, the U.K. formally left the European Union (the "EU"), on January 31, 2020, often referred to as Brexit, and the transition period ended on December 31, 2020. However, the EU and the U.K. have concluded a trade and cooperation agreement ("TCA"), which has been approved by the UK Parliament, European Council and European Parliament. The TCA includes specific provisions concerning pharmaceuticals, which include the mutual recognition of GMP, inspections of manufacturing facilities for medicinal products and GMP documents issued, but does not foresee wholesale mutual recognition of the U.K. and EU pharmaceutical regulations. As a result, companies now need to comply with a separate UK regulatory legal framework in order to commercialize medicinal products in Great Britain (England, Wales and Scotland). At present, Great Britain has implemented EU legislation on the marketing, promotion and sale of medicinal products through the Human Medicines Regulations 2012 (as amended) (under the Northern Ireland Protocol, the EU regulatory framework will continue to apply in Northern Ireland). While the regulatory regime in Great Britain therefore currently aligns in the most part with EU regulations, it is possible that these regimes will diverge in future now that Great Britain's regulatory system is independent from the EU and the TCA does not provide for mutual recognition of U.K. and EU pharmaceutical legislation. For example, the new Clinical Trials Regulation which became effective in the EU on January 31, 2022 and provides for a streamlined clinical trial application and assessment procedure covering multiple EU Member States has not been implemented into U.K. law, and a separate application will need to be submitted for clinical trial authorization in the U.K. Any

delay in obtaining, or an inability to obtain, any marketing approvals, as a result of the trade and cooperation agreement or otherwise, could prevent us from commercializing any product candidates in the U.K. and/or the EU and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the U.K. and/or EU for any product candidates, which could significantly and materially harm our business. The current lack of detail and resolution with regard to the Brexit implementation may result in a disruption of the manufacturing and supply of components of our product candidates in the U.K. and we are unable to confidently predict the effects of such disruption to the regulatory framework in Europe. Any adjustments we make to our business and operations as a result of Brexit could result in significant delays and additional expense. Any of the foregoing factors could have a material adverse effect on our business, results of operations, or financial condition.

***We, or our third-party contract research organizations, face risks related to health epidemics, pandemics and other outbreaks, which could significantly disrupt our operations.***

Our business could be adversely impacted by epidemics or pandemics. If there are closures or other restrictions in the places where we or our manufacturers and suppliers operate, we may experience disruptions to our operations. For example, we have in the past and may in the future experience impacts to certain of our suppliers as a result of the COVID-19 pandemic or other health epidemics or outbreaks occurring in one or more of these locations, which may materially and adversely affect our business, financial condition and results of operations. Further, our operation has in the past and may in the future experience disruptions, including in connection with temporary office closures and suspension of services by our suppliers, which may result in us having to procure the components for our product candidates from alternate suppliers, which may materially and adversely affect our development timelines, and our business, financial condition and results of operations.

***The manufacturing of our molecules is complex, and our third-party manufacturers may encounter difficulties in production. If we or any of our third-party manufacturers encounter such difficulties, our ability to provide supply of our product candidates for clinical trials, our ability to obtain marketing approval, or our ability to provide supply of our products for patients, if approved, could be delayed or stopped.***

Our product candidates are biopharmaceuticals, and the process of manufacturing biopharmaceuticals is complex, time-consuming, highly regulated and subject to multiple risks. Our contract manufacturers must comply with legal requirements, cGMPs and guidelines for the manufacturing of biopharmaceuticals used in clinical trials and, if approved, marketed products. Our contract manufacturers may have limited experience in the manufacturing of cGMP batches.

Manufacturing biopharmaceuticals is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered at our third-party manufacturers' facilities, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. Moreover, if the FDA determines that our third-party manufacturers'

facilities are not in compliance with FDA laws and regulations, including those governing cGMPs, the FDA may deny NDA approval until the deficiencies are corrected or we replace the manufacturer in our NDA with a manufacturer that is in compliance.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with cGMPs, lot consistency and timely availability of raw materials. Even if we or any collaborators obtain regulatory approval for any of our product candidates, there is no assurance that manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and prospects.

Scaling up a biopharmaceutical manufacturing process is a difficult and uncertain task, and our third-party manufacturers may not have the necessary capabilities to complete the implementation, manufacturing and development process. If we are unable to adequately validate or scale-up the manufacturing process at our current manufacturers' facilities, we will need to transfer to another manufacturer and complete the manufacturing validation process, which can be lengthy. If we are able to adequately validate and scale-up the manufacturing process for our product candidates with a contract manufacturer, we will still need to negotiate with such contract manufacturer an agreement for commercial supply and it is not certain we will be able to come to agreement on terms acceptable to us.

We cannot assure you that any stability or other issues relating to the manufacture of any of our product candidates or products will not occur in the future. If our third-party manufacturers were to encounter any of these difficulties, our ability to provide any product candidates to patients in planned clinical trials and products to patients, once approved, would be jeopardized. Any delay or interruption in the supply of clinical trial supplies could delay the completion of planned clinical trials, increase the costs associated with maintaining clinical trial programs and, depending upon the period of delay, require us to commence new clinical trials at additional expense or terminate clinical trials completely. Any adverse developments affecting clinical or commercial manufacturing of our product candidates or products may result in shipment delays, inventory shortages, lot failures, product withdrawals or recalls, or other interruptions in the supply of our product candidates or products. We may also have to take inventory write-offs and incur other charges and expenses for product candidates or products that fail to meet specifications, undertake costly remediation efforts or seek more costly manufacturing alternatives. Accordingly, failures or difficulties faced at any level of our supply chain could adversely affect our business and delay or impede the development and commercialization of any of our product candidates or products, if approved, and could have an adverse effect on our business, prospects, financial condition and results of operations.

As part of our process development efforts, we also may make changes to the manufacturing processes at various points during development, for various reasons, such as controlling costs, achieving scale, decreasing processing time, increasing manufacturing success rate or other reasons. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of our ongoing clinical trials or future clinical trials. In some circumstances, changes in the manufacturing process may require us to perform *ex vivo* comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials. For instance, changes in our process during the course of clinical development may require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial.

**Risks Relating to our Business and Operations**

***We will need to grow our organization, and we may experience difficulties in managing our growth and expanding our operations, which could adversely affect our business.***

As of March 31, 2024 June 30, 2024, we had 124 128 full time employees. As our development and commercialization plans and strategies develop, we expect to expand our employee base for managerial, operational, financial and other resources. In addition, we have limited experience in product development. As our product candidates enter and advance through preclinical studies and clinical trials, we will need to expand our development and regulatory capabilities and contract with other organizations to provide manufacturing and other capabilities for us. In the future, we expect to have to manage additional relationships with collaborators or partners, suppliers and other organizations. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Our inability to successfully manage our growth and expand our operations could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***Any inability to attract and retain qualified key management and technical personnel would impair our ability to implement our business plan.***

Our success largely depends on the continued service of Praveen P. Tipirneni, M.D., our chief executive officer, as well as other members of our management team, and other key employees and advisors. We currently do not maintain key person insurance on these individuals. On September 26, 2023, we announced that Dr. Tipirneni had experienced an unexpected medical event and was taking a temporary medical leave of absence. On January 3, 2024, we announced that Dr. Tipirneni had returned from leave and resumed his duties as Chief Executive Officer. The loss of one or more members of our management team or other key employees or advisors could delay our research and development programs and have a material and adverse effect on our business, financial condition, results of operations and prospects. The relationships that our key managers have cultivated within our industry make us particularly dependent upon their continued employment with us. We are dependent on the continued service of our technical personnel, and personnel involved with crystallization of integrins in particular, because of the highly technical nature of our product candidates and technologies

related to our MInT Platform, and the specialized nature of the regulatory approval process. Because our management team and key employees are not obligated to provide us with continued service, they could terminate their employment with us at any time without penalty.

We conduct our operations at our facility in Waltham, Massachusetts. This region is headquarters to many other biopharmaceutical companies and many academic and research institutions. Competition for skilled personnel in our market is intense and may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. We face competition for personnel from other companies, universities, public and private research institutions, government entities and other organizations. Our future success will depend in large part on our continued ability to attract and retain other highly qualified scientific, technical and management personnel, as well as personnel with expertise in clinical testing, manufacturing, governmental regulation and commercialization. If we are unable to continue to attract and retain high-quality personnel, the rate at and success with which we can discover and develop product candidates will be limited, which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.***

Our future growth may depend, in part, on our ability to develop and commercialize and/or promote our product candidates in foreign markets, for which we may rely on collaborations with third parties. We are not permitted to market or promote any of our product candidates in a foreign market before we receive regulatory approval from the applicable regulatory authority in that foreign market, and may never receive such regulatory approval for any of our product candidates. To obtain separate regulatory approval in many other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of products, and we cannot predict success in these jurisdictions. If we fail to comply with the regulatory requirements in international markets and receive applicable marketing approvals, our target market will be reduced, our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, or at all. Our failure to obtain approval of any of our product candidates by regulatory authorities in another country may significantly diminish the commercial prospects of that product candidate and our business, financial condition, results of operations and prospects could be materially and adversely affected. Moreover, even if we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to the risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and reduced protection of intellectual property rights in some foreign countries.

***Our business entails a significant risk of product liability and any inability to obtain sufficient insurance coverage could have a material and adverse effect on our business, financial condition, results of operations and prospects.***

In connection with the conduct of clinical trials of our product candidates, we may be exposed to significant product liability risks inherent in the development and testing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA investigation of the safety and effectiveness of our products, our manufacturing processes and facilities and/or our marketing programs, and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in increased difficulty enrolling participants in clinical trials, termination of clinical trial sites or entire trial programs, withdrawal of clinical trial participants, injury to our reputation and significant negative media attention, significant costs to defend the related litigation, a diversion of management's time and our resources from our business operations, substantial monetary awards to trial participants or patients, loss of revenue, the inability to commercialize and products that we may develop, and a decline in our stock price. We currently maintain general liability insurance with coverage up to $10.0 million. We may, however, need to obtain higher levels of product liability insurance for later stages of clinical development or marketing any of our product candidates. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.***

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with FDA regulations, provide true, complete and accurate information to the FDA and other comparable foreign regulatory bodies, comply with manufacturing standards we may establish, comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. If we obtain FDA approval of any of our product candidates and begin commercializing those products in the United States, our potential exposure under these laws will increase significantly, and our costs associated with compliance with these laws are likely to increase. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure or perceived failure to comply with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm.

***We depend on our information technology systems, and any failure of these systems, or those of our CROs or other contractors or consultants we may utilize, could harm our business. Security breaches, cyber-attacks, theft or exposure of confidential data, disruptions to our network and other information technology systems, and other incidents affecting the confidentiality, integrity, or availability of our data and systems could adversely affect our business, results of operations, financial condition and prospects, including by exposing us to liability and other legal risk.***

We collect and maintain information in digital form that is necessary to conduct our business, and we are dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, use and store, and transmit large amounts of confidential information, including intellectual property, proprietary business information, and personal data. It is critical that we do these things in a secure manner to maintain the confidentiality, integrity, and availability of such confidential information. We have established physical, electronic and organizational measures, and we rely on commercially available systems, software, tools, and monitoring,

to safeguard, provide security, and otherwise protect our information technology systems and our collection, use and storage, and transmission of digital information. We have outsourced elements of our information technology infrastructure and, as a result, a number of third-party vendors have access to our confidential information. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, contractors, consultants, vendors, and other third parties on which we rely, are vulnerable to cyber-attacks and other incidents which could adversely affect us. These cyber-attacks and other incidents may include unauthorized access to our network, information technology systems, and data, and those of our vendors; compromise of employee credentials and accounts; transmission of computer viruses and other malware; phishing and spamming attacks; ransomware attacks and other acts of cyber-extortion; and malicious actions by persons inside our organization and other insider threats ("cyber threats and incidents"). The increasing use of mobile devices for remote access to our systems and data also increases these vulnerabilities and risks. Our internal information technology systems and infrastructure and those of our vendors are also vulnerable to damage from natural disasters, acts of terrorism, war and other acts of foreign governments, and failures of telecommunication, electrical, and other critical systems. All of these potentially adverse incidents could compromise our ability to conduct and perform our business functions in a timely manner, could delay our financial reporting, and could materially adversely affect our operating results and financial condition.

The risk of a network intrusion or disruption, and data breach or other data loss, including by criminals and criminal enterprises, foreign governments and other state-sponsored actors, and terrorists and lone wolves, has increased as the number, intensity and sophistication of global attackers and attacks have increased. The prevalence of these threats may increase further as geopolitical tensions and warfare continue or escalate outside of the U.S., including due to regional conflicts around the world. While we have implemented security measures to protect our data security and information technology systems, our efforts may not always be successful, and the costs to us in responding to and mitigating cyber threats and incidents could be significant and problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position.

In August 2023, we suffered a network intrusion when a third party gained unauthorized access to our network and downloaded files from certain of our online depositories. The costs associated with responding to and mitigating the incident were not material and were primarily covered under an insurance policy as part of our corporate risk program. Further, in April 2023 and February 2024, we were notified separately by two of our vendors that they had suffered unrelated security breaches and that some of our data, including data related to our manufacturing processes, clinical trials and intellectual property, was among the information downloaded and/or extracted by an unknown third parties. We did not experience any significant disruption to our business, nor do we expect any significant disruption to our future prospects, as a result of the August 2023, April 2023 and February 2024 cybersecurity incidents. To date, these cybersecurity incidents have not had a material impact on our financial condition, results of operations or liquidity. However, in the future, if such an event were to lead to exposure of sensitive information or cause interruptions in our operations or those of our third-party collaborators, it could result in a material disruption of our drug development programs and potential financial losses. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Moreover, if a computer security breach affects our systems or results in the unauthorized release of personally identifiable information, our reputation could be materially damaged. In addition, such a breach may require notification to governmental agencies, the media or individuals pursuant to various federal and state privacy and security laws, if applicable, including the Health Insurance Portability and Accountability Act of 1996 as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and its implementing rules and regulations (together, "HIPAA"), as well as regulations promulgated by the Federal Trade Commission and state breach notification laws. In addition, such cyber-attacks, data breaches or destruction or loss of data could result in violation of applicable international privacy, data protection and other laws, resulting in exposure to material civil and/or criminal liability. Further, our general liability insurance and corporate risk program may not cover all potential claims to which we are exposed and may not be adequate to indemnify us for all liability that may be imposed and could materially adversely affect our business, results of operations, financial condition and prospects. In addition, we may suffer reputational harm or face litigation or adverse regulatory action as a result of cyber-attacks or other data security breaches and may incur significant additional expense to implement further data protection measures.

Further, on July 26, 2023, the SEC adopted new cybersecurity disclosure rules for public companies that require disclosure regarding cybersecurity risk management (including the board's role in overseeing cybersecurity risks, management's role and expertise in assessing and managing cybersecurity risks, and processes for assessing, identifying and managing cybersecurity risks) in annual reports on Form 10-K. The new cybersecurity disclosure rules also require the disclosure of material cybersecurity incidents by Form 8-K, within four business days of determining that an incident is material. We are have been subject to such annual report Form 10-K disclosure requirements starting with our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on February 22, 2024, and we have been subject to such Form 8-K disclosure requirements since December 18, 2023. Complying with these new cybersecurity disclosure obligations, or any additional new disclosure requirements that may apply to us in the future, could cause us to incur substantial costs and could increase negative publicity surrounding any incident that we are required to disclose.

***If we do not comply with laws regulating the protection of the environment and health and human safety, our business could be adversely affected.***

Our research and development activities include the use of hazardous chemicals and materials, including radioactive materials. We maintain quantities of various flammable and toxic chemicals in our facilities in Waltham,

Massachusetts that are required for our research and development activities. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of these hazardous chemicals and materials. Although we believe that our procedures for storing, handling and disposing such materials in our facilities comply with the standards mandated by applicable regulations and guidelines, the risk of accidental contamination or injury from these materials cannot be eliminated. If an accident occurs, we could be held liable for resulting damages, which could be substantial. We are also subject to numerous environmental, health and workplace safety laws and regulations, including those governing laboratory procedures, exposure to blood-borne pathogens and the handling of animals and biohazardous materials. Although we maintain workers' compensation insurance, this insurance may not provide adequate coverage against potential liabilities resulting from our employees' use of these materials, in connection with which we may incur significant costs and expenses. We also may incur substantial costs to comply with, and substantial fines or penalties if we violate, applicable laws and regulations related to health and human safety and the use, manufacture, storage, handling, and disposal of hazardous chemicals and materials.

***Our current operations are concentrated in one location, and we or the third parties upon whom we depend may be adversely affected by extreme weather events or other natural disasters, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.***

Our current operations are concentrated in Waltham, Massachusetts. Any unplanned event, such as a flood, fire, explosion, earthquake, extreme weather condition such as a hurricane or heavy snowstorm, medical epidemic or pandemic, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to our facilities or the manufacturing facilities of our third-party contract manufacturers may result in increased costs, delays in the development of our product candidates or interruption of our business operations. If a natural disaster, power outage or other event occurs that prevents us from using all or a significant portion of our headquarters, that damages critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupts operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which could have a material adverse effect on our business. In addition, the long-term effects of climate change on general economic conditions and the pharmaceutical industry in particular are unclear and may heighten or intensify the existing risk of natural disasters. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, we cannot assure you that such insurance coverage will be sufficient to satisfy any damages and losses we may experience. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate for any reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***We are subject to complex tax rules relating to our business, and any audits, investigations or tax proceedings could have a material adverse effect on our business, results of operations and financial condition.***

We are subject to income and non-income taxes in the United States. Income tax accounting often involves complex issues, and judgment is required in determining our provision for income taxes and other tax liabilities. We may operate in other non-United States jurisdictions in the future. We could become subject to income and non-income taxes in non-United States jurisdictions as well. In addition, many jurisdictions have detailed transfer pricing rules, which require that all transactions with non-resident related parties be priced using arm's length pricing principles within the meaning of such rules. The application of withholding tax, goods and services tax, sales taxes and other non-income taxes is not always clear and we may be subject to tax audits relating to such withholding or non-income taxes. We believe that our tax positions are reasonable. We are currently not subject to any tax audits. However, the Internal Revenue Service or other taxing authorities may disagree with our positions. If the Internal Revenue Service or any other tax authorities were successful in challenging our positions, we may be liable for additional tax and penalties and interest related thereto or other taxes, as applicable, in excess of any reserves established therefor, which may have a significant impact on our results and operations and future cash flow.

***Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.***

As of December 31, 2023, we had net operating loss ("NOL"), carryforwards for federal and state income tax purposes of $180.3 million and $191.5 million, respectively, which begin to expire in 2037. As of December 31, 2023, December 31, 2023, we also had available tax credit carryforwards for federal and state income tax purposes of $12.6 million and $5.7 million, respectively, which begin to expire in 2032. To the extent that our taxable income exceeds any current year operating losses, we plan to use our carryforwards to offset income that would otherwise be taxable. However, utilization of carryforwards generated in tax years beginning after December 31, 2017 is limited to a maximum of 80% of the taxable income for such year determined without regard to such carryforwards. In addition, under Section 382 of the Internal Revenue Code (the "Code"), changes in our ownership may limit the amount of our net operating loss carryforwards and tax credit carryforwards that could be utilized annually to offset our future taxable income, if any. This limitation would generally apply in the event of a cumulative change in ownership of our company of more than 50% within a three-year period. We have not performed an analysis to determine whether there has been an ownership change pursuant to Section 382 of the Code. Any such limitation may significantly reduce our ability to utilize our net operating loss carryforwards and tax credit carryforwards before they expire. Private placements, our IPO and other transactions that have occurred since our inception or that may occur in the future could result in such an ownership change pursuant to Section 382 of the Internal Revenue Code. Any such limitation, whether as the result of our IPO, prior private placements, sales of our common stock by our existing stockholders or additional sales of our common stock by us, could have a material adverse effect on our results of operations in future years. There is also a risk that due to regulatory changes at the state level, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise be unavailable to offset future income tax liabilities.

***We may be subject to adverse legislative or regulatory tax changes that could negatively impact our financial condition.***

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect our stockholders or us. We assess the impact of various tax reform proposals and modifications to existing tax treaties in all jurisdictions where we have operations to determine the potential effect on our business and any assumptions we have made about our future taxable income. We cannot predict whether any specific proposals will be enacted, the terms of any such proposals or what effect, if any, such proposals would have on our business if they were to be enacted. Beginning in 2022, the Tax Cuts and Jobs Act of 2017 eliminates the currently available option to deduct research and development expenditures and requires taxpayers to amortize them generally over five years. The U.S. Congress is considering legislation that would restore the current deductibility of research and development expenditures, however, we have no assurance that the provision will be repealed or otherwise modified.

**Risks Related to Intellectual Property**

***If we are not able to obtain, maintain, and enforce patent protection for our technologies or product candidates, development and commercialization of our product candidates may be adversely affected.***

Our success depends in part on our ability to obtain and maintain patents and other forms of intellectual property rights, including in-licenses of intellectual property rights of others, for our product candidates, as well as our ability to preserve our trade secrets, to prevent third parties from infringing upon our proprietary rights and to operate without infringing upon the proprietary rights of others. As of March 31, 2024 June 30, 2024, we solely owned various issued patents and pending patent applications protecting our integrin therapeutic compounds across multiple programs (including our product candidates) in the U.S. and many other major jurisdictions worldwide, including Europe, Japan and China. In addition, we hold an exclusive, worldwide license agreement with the Children's Medical Center Corporation (the "CMCC Agreement") to certain U.S. patents and related pending U.S. patent application(s) relating to modified integrin polypeptides, crystallizable dimers comprising a modified integrin polypeptide, and related methods. We may not be able to apply for patents on certain aspects of our product candidates in a timely fashion or at all. Further, we may not be able to prosecute all necessary or desirable patent applications, or maintain, enforce and license any patents that may issue from such patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. We may not have the right to control the preparation, filing and prosecution of all patent applications that we license from third parties, or to maintain the rights to patents licensed to third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. Future patents we obtain may not be sufficiently broad to prevent others from using our technology or from developing competing products and technology. There is no guarantee that any of our pending patent applications will result in issued or granted patents, that any of our future issued or granted patents will not later be found to be invalid or unenforceable or that any future issued or granted patents will include claims that are sufficiently broad to cover our product candidates or to provide meaningful protection from our competitors. Moreover, the patent position of biotechnology and biopharmaceutical companies can be highly uncertain because it involves complex legal and factual questions. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our current and future proprietary technology and product candidates are covered by valid and enforceable patents, or are effectively maintained as trade secrets. If third parties disclose or misappropriate our proprietary rights, it may materially and adversely affect our position in the market.

Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first inventor to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent the claimed invention was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we, our licensors or collaborators, or any future strategic partners were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we, our licensors or collaborators, or any future strategic partners were the first to file for patent protection of such inventions.

The U.S. Patent and Trademark Office ("USPTO") and various foreign governmental patent agencies require compliance with a large number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case. The standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biotechnology and biopharmaceutical patents. As such, we do not know the degree of future protection that we will have on our proprietary products and technology. The process of obtaining patents is time consuming, expensive and sometimes unpredictable.

Once granted, for a given period after allowance or grant patents may remain open to opposition, interference, re-examination, post-grant review, *inter partes* review, nullification, or derivation action in court or before patent offices or similar proceedings, during which time third parties can raise objections against such initial grant. Such proceedings may continue for a protracted period of time and an adverse determination in any such proceedings could reduce the scope of the allowed or granted claims thus attacked, or could result in our patents being invalidated in whole or in part, or being held unenforceable, which could allow third parties to commercialize our product candidates and compete directly with us without payment to us. In addition, there can be no assurance that:

- others will not or may not be able to make, use or sell compounds that are the same as or similar to our product candidates but that are not covered by the claims of the patents that we own or license;
- we or our licensors, or our existing or future collaborators are the first to make the inventions covered by each of our issued patents and pending patent applications that we own or license;
- we or our licensors, or our existing or future collaborators are the first to file patent applications covering certain aspects of our inventions;
- others will not independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- a third party may not challenge our patents and, if challenged, a court would hold that our patents are valid, enforceable and infringed;
- any issued patents that we own or have licensed or that we may license in the future will provide us with any competitive advantages, or will not be challenged by third parties;
- we may develop additional proprietary technologies that are patentable;
- the patents of others will not have a material or adverse effect on our business, financial condition, results of operations and prospects; and
- our competitors do not conduct research and development activities in countries where we do not have enforceable patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.

If we or our licensors or collaborators fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which could have a material and adverse effect on our business, financial condition, results of operations and prospects. In addition, if the breadth or strength of protection

provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

***If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.***

In addition to seeking patent protection for certain aspects of our product candidates, we also consider trade secrets, including confidential and unpatented know-how, important to the maintenance of our competitive position. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. We seek to protect trade secrets and confidential and unpatented know-how, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to such knowledge, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants that obligate them to maintain confidentiality and assign their inventions to us. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts in the United States and certain foreign jurisdictions are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent them from using that technology or information to compete with us. Furthermore, we expect that, over time, our trade secrets, know-how and proprietary information may be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel to and from academic and industry scientific positions. Consequently, without costly efforts to protect our proprietary technology, we may be unable to prevent others from exploiting that technology, which could affect our ability to expand in domestic and international markets. If any of our trade secrets were to be disclosed to or independently developed by a competitor, our competitive position would be harmed which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***Other companies or organizations may challenge our or our licensors' patent rights or may assert patent rights that prevent us from developing and commercializing our products, if approved.***

Oral integrin therapies in fibrosis and IBD or other disease areas are a relatively new scientific field. We have applied for and have obtained a license from a third party on an exclusive basis to U.S. patent filings related to our MInT

Platform. Other pending patent applications in the United States and in key markets around the world that we own or license claim many different methods, compositions and processes relating to the discovery, development, and manufacture of small-molecule integrin inhibitor-based and other therapeutics.

As the field of small-molecule integrin inhibitor-based therapeutics continues to mature, patent applications are being processed by national patent offices around the world. There is uncertainty about which patents will issue and, if they do, as to when, to whom, and with what claims. In addition, third parties may attempt to invalidate our intellectual property rights. Even if our rights are not directly challenged, disputes could lead to the weakening of our intellectual property rights. Our defense against any attempt by third parties to circumvent or invalidate our intellectual property rights could be costly to us, could require significant time and attention of our management and could have a material and adverse effect on our business, financial condition, results of operations and prospects or our ability to successfully compete. If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product.

***We may not be able to protect our intellectual property rights throughout the world.***

Filing, prosecuting, defending and enforcing patents covering our technology in the United States and in other jurisdictions worldwide would be extremely costly, and our or our licensors' or collaborators' intellectual property rights may not exist in some countries outside the United States or may be less extensive in some countries than in the United States. In jurisdictions where we or our licensors or collaborators have not obtained patent protection, competitors may seek to use our or our licensors' or collaborators' technology to develop competing products and further, may export otherwise infringing products to territories where we have patent protection, but where it is more difficult to enforce a patent as compared to the United States. Competitor products may compete with our future products in jurisdictions where we do not have issued or granted patents or where our or our licensors' or collaborators' issued or granted patent claims or other intellectual property rights are not sufficient to prevent competitor activities in these jurisdictions. The legal systems of certain countries, particularly certain developing countries, make it difficult to enforce patents and such countries may not recognize other types of intellectual property protection, particularly relating to pharmaceuticals or biopharmaceuticals. This could make it difficult for us or our licensors or collaborators to prevent the infringement of our or their patents or marketing of competing products in violation of our or their proprietary rights generally in certain jurisdictions. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our and our licensors' or collaborators' efforts and attention from other aspects of our business, could put our and our licensors' or collaborators' patents at risk of being invalidated or interpreted narrowly and our and our licensors' or collaborators' patent applications at risk of not issuing and could provoke third parties to assert claims against us or our licensors or collaborators. We or our licensors or collaborators may not prevail in any lawsuits that we or our licensors or collaborators initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

When we elect to pursue patent protection on an invention, we generally first file a U.S. provisional patent application (a priority filing) at the USPTO. An international patent application under the Patent Cooperation Treaty ("PCT") and/or a national application in a non-PCT country may then be filed within twelve months after the priority filing. Based on the PCT filing, national and regional patent applications may be filed in one or more PCT member countries. We have thus far not filed for patent protection in all national and regional jurisdictions where such protection may be available. In addition, we may decide to abandon national and regional patent applications before grant. Finally, the grant proceeding of each national or regional patent office is an independent proceeding, which may lead to situations in which patent applications might in some jurisdictions be refused by the relevant registration authorities, while granted by others. It is also quite common that, depending on the country, different scopes of patent protection may be granted on the same product candidate or technology.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in the United States, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. If we or our licensors or collaborators encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such a patent. If we or any of our licensors or collaborators are forced to grant a license to third parties with respect to any

patents relevant to our business, our competitive position in the relevant jurisdiction may be impaired and our business, financial condition, results of operations and prospects may be adversely affected.

***If we fail to comply with our obligations under any license, collaboration or other agreements, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our product candidates or we could lose certain rights to grant sublicenses.***

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others. Any termination of our licenses could result in the loss of significant rights and could harm our ability to develop our product candidates. Our current licenses impose, and any future licenses we enter into are likely to impose, various development, commercialization, funding, milestone, royalty, diligence, sublicensing, insurance, patent prosecution and enforcement and/or other obligations on us. If we breach any of these obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture and sell any future products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating a licensor's rights. In addition, while we cannot determine currently the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

***We, our licensors or collaborators, or any future strategic partners may need to resort to litigation to protect or enforce our patents, if and when granted, or other proprietary rights, all of which could be costly and time consuming, delay or prevent the development and commercialization of our product candidates, or put our patents, if and when granted, patent applications and other proprietary rights at risk.***

Competitors may infringe our owned or licensed patents, if and when granted, patent applications or other intellectual property. If we were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates or our technology, the defendant could counterclaim that our patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, lack of adequate written description, obviousness or non-enablement. Grounds for an unenforceability assertion could be an allegation that an individual connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. The outcome following legal assertions of invalidity or unenforceability during patent litigation is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on one or more of our product candidates or certain aspects of our platform technology. Such a loss of patent protection could have a material and adverse effect on our business, financial condition, results of operations and prospects. Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the inventorship or priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring our product candidates to market. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. Patents and other intellectual property rights will not protect our technology if competitors design around our protected technology without legally infringing our patents or other intellectual property rights.

***Intellectual property rights of third parties could adversely affect our ability to commercialize our product candidates, and we, our licensors or collaborators, or any future strategic partners may become subject to third party claims or litigation alleging infringement of patents or other proprietary rights or seeking to invalidate patents or other proprietary rights. We might be required to litigate or obtain licenses from third parties in order to develop or market our product candidates. Such litigation or licenses could be costly or not available on commercially reasonable terms.***

We, our licensors or collaborators, or any future strategic partners, may be subject to third-party claims for infringement or misappropriation of patent or other proprietary rights. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and

pharmaceutical industries, including patent infringement lawsuits, interferences, derivations, oppositions and *inter partes* review proceedings before the USPTO, and corresponding foreign patent offices. There may be issued patents and pending patent applications that claim aspects of our targets, our MInT Platform, or our product candidates and modifications that we may need to apply to our product candidates. There may be issued patents that claim integrin inhibitors which may be relevant to the products we wish to develop. Thus, it is possible that one or more organizations will hold patent rights to which we will need a license. If those organizations refuse to grant us a license to such patent rights on reasonable terms, we may not be able to market products or perform research and development or other activities covered by these patents, which could have a material and adverse effect on our business, financial condition, results of operations and prospects. If we, our licensors or collaborators, or any future strategic partners are found to infringe a third-party patent or other intellectual property rights, we could be required to pay damages, potentially including treble damages and attorneys' fees if we or they are found to have infringed willfully. In addition, we, our licensors or collaborators, or any future strategic partners may choose to seek, or be required to seek, a license from a third party, which may not be available on acceptable terms, if at all. Even if a license can be obtained on acceptable terms, the rights may be non-exclusive, which could give our competitors access to the same technology or intellectual property rights licensed to us. If we fail to obtain a required license, we or our existing or future collaborators may be unable to effectively market product candidates based on our technology, which could limit our ability to generate revenue or achieve profitability and possibly prevent us from generating revenue sufficient to sustain our operations. In addition, we may find it necessary to pursue claims or initiate lawsuits to protect or enforce our patent or other intellectual property rights. The cost to us in defending or initiating any litigation or other proceeding relating to patent or other proprietary rights, even if resolved in our favor, could be substantial, and litigation could divert our management's attention. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could delay our research and development efforts and limit our ability to continue our operations.

Because the integrin-based therapeutics landscape is still evolving, it is difficult to conclusively assess our freedom to operate without infringing on third-party rights. There are numerous companies that have pending patent applications and issued patents broadly covering integrins generally, covering integrins directed against the same targets as, or targets similar to, those we are pursuing, or covering compounds similar to our product candidates. Failure to receive a license could delay commercialization of our product candidates. Our competitive position may suffer if patents issued to third parties or other third-party intellectual property rights cover our products, if approved, or product candidates or elements thereof, or our manufacture or uses relevant to our development plans. In such cases, we may not be in a position to develop or commercialize products or product candidates until such patents expire or unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned, or enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms. There may be issued patents of which we are not aware, held by third parties that, if found to be valid and enforceable, could be alleged to be infringed by our MInT Platform and product candidates. There also may be pending patent applications of which we are not aware that may result in issued patents, which could be alleged to be infringed by our MInT Platform and product candidates. If such an infringement claim should be brought and be successful, we may be required to pay substantial damages, including potentially treble damages and attorneys' fees for willful infringement, and we may be forced to abandon our product candidates or seek a license from any patent holders. No assurances can be given that a license will be available on commercially reasonable terms, if at all.

It is also possible that we have failed to identify relevant third-party patents or applications. For example, U.S. applications filed before November 29, 2000, and certain U.S. applications filed after that date that will not be filed outside the United States remain confidential unless and until corresponding patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our product candidates or MInT Platform could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our MInT Platform, our product candidates or the use of our product candidates. Third-party intellectual property right holders may also actively bring infringement claims against us. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in marketing our products, if approved. Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our product candidates that are held to be infringing. We might, if possible, also be forced to redesign product candidates so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business and could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities.***

Litigation and other legal proceedings relating to intellectual property claims, with or without merit, are unpredictable and generally expensive and time consuming and are likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Moreover, such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities.

We may not have sufficient financial or other resources to adequately conduct such litigation or proceedings. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

***We may be subject to claims that we or our employees or consultants have wrongfully used or disclosed alleged trade secrets of our employees' or consultants' former employers or their clients. These claims may be costly to defend and if we do not successfully do so, we may be required to pay monetary damages and may lose valuable intellectual property rights or personnel.***

Many of our employees, including our management, were previously employed at universities or biotechnology or biopharmaceutical companies, including our competitors or potential competitors. Some of these employees executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment.

Although no claims against us are currently pending, we may be subject to claims that these employees, employees of our licensors or collaborators or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we or our licensors or collaborators fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. A loss of key research personnel or their work product could hamper our ability to develop and ultimately commercialize, or prevent us from developing and commercializing, our product candidates, which could severely harm our business. Even if we or our licensors or collaborators are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

***Patent terms may be insufficient to protect our competitive position on our product candidates for an adequate amount of time.***

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various patent term adjustments or extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to be paid to the USPTO and various governmental patent agencies outside of the United States in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ consultants and an outside firm and/or rely on our outside counsel to pay these fees due to the USPTO and non-U.S. patent agencies. The USPTO and various non-U.S. governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. However, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors might be able to enter the market and this circumstance would have a material adverse effect on our business.

***Changes in U.S. patent and ex-U.S. patent laws could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.***

Changes in either the patent laws or interpretation of the patent laws in the United States or in other jurisdictions could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. In the United States, numerous recent changes to the patent laws and proposed changes to the rules of the USPTO may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. We cannot assure you that subsequent rulings will not adversely impact our patents or patent applications. In addition to increasing uncertainty regarding our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once granted. For example, the U.S. Supreme Court, in the case Amgen v. Sanofi, held that broad functional antibody claims are invalid for lack of enablement. In addition, in Juno v. Kite, the Federal Circuit held broad antibody and chimeric antigen receptor claims supported by few examples invalid for lack of written description. Recently, the Federal Circuit issued a precedential decision in In re Cellect (No. 22-1293) that could shorten or eliminate extended patent term awarded under Patent Term Adjustment if challenged on the basis of Obvious-Type Double Patenting. Depending on decisions by the U.S. Congress, the federal courts and the USPTO, and similar legislative and regulatory bodies in other countries in which may pursue patent protection, the laws and regulations governing patents could change in unpredictable ways,

particularly with respect to pharmaceutical patent protection, that would weaken our ability to obtain new patents or to enforce our or our licensors' or collaborators' existing patents and patents that we might obtain in the future.

***If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.***

Our common law trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively which could have a material and adverse effect on our business, financial condition, results of operations and prospects.

**Risks Related to Government Regulation**

***We and/or our collaborators may be unable to obtain, or may be delayed in obtaining, U.S. or foreign regulatory approval and, as a result, unable to commercialize our product candidates.***

Our product candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, post-approval monitoring, marketing and distribution of drugs. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process are required to be completed successfully in the United States and in many foreign jurisdictions before a new drug can be marketed. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. It is possible that none of the product candidates we may develop, either alone or with our collaborators, will obtain the regulatory approvals necessary for us or our existing or future collaborators to begin selling them.

We have no prior experience in conducting and managing the clinical trials necessary to obtain regulatory approvals, including approval by the FDA. The time required to obtain FDA and other approvals is unpredictable but typically takes many years following the commencement of clinical trials, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when regulating us require judgment and can change, which makes it difficult to predict with certainty their application. Any analysis we perform of data from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We or our collaborators may also encounter unexpected delays or increased costs due to new government regulations, for

example, from future legislation or administrative action, or from changes in FDA policy during the period of product development, clinical trials and FDA regulatory review. Such disruptions could divert healthcare resources away from, or materially delay review by, the FDA and comparable foreign regulatory agencies. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of preclinical studies or clinical trials or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates. It is impossible to predict whether additional legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or the impact of such changes, if any.

Given that the product candidates we are developing, either alone or with our collaborators, represent a new therapeutic approach, the FDA and its foreign counterparts may not have established any definitive policies, practices or guidelines in relation to these product candidates. Moreover, the FDA may respond to any NDA that we may submit by defining requirements that we do not anticipate. Such responses could delay clinical development of our product candidates. In addition, because there may be approved treatments for some of the diseases for which we may seek approval, in order to receive regulatory approval, we may need to demonstrate through clinical trials that the product candidates we develop to treat these diseases, if any, are not only safe and effective, but safer or more effective than existing products. Furthermore, in recent years, there has been increased public and political pressure on the FDA with respect to the approval process for new drugs, and FDA standards, especially regarding product safety.

Any delay or failure in obtaining required approvals could have a material and adverse effect on our ability to generate revenues from the particular product candidate for which we are seeking approval. Furthermore, any regulatory approval to market a product may be subject to limitations on the approved uses for which we may market the product or on the labeling or other restrictions.

We are also subject to or may in the future become subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with the FDA approval process described above, as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval. FDA approval does not ensure approval by regulatory authorities outside the United States and vice versa. Any delay or failure to obtain U.S. or foreign regulatory approval for a product candidate could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***Even if we receive regulatory approval for any of our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal. We may also be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.***

Any regulatory approvals that we or our existing or future collaborators obtain for our product candidates may also be subject to limitations on the approved indicated uses for which a product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the product candidate.

In addition, if the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, labeling, packaging, distribution, post-approval monitoring and adverse event reporting, storage, import, export, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. The FDA has significant post-market authority, including the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials to evaluate safety risks related to the use of a product or to require withdrawal of the product from the market. The FDA also has the authority to require a REMS after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. The manufacturing facilities we use to make a future product, if any, will also be subject to periodic review and inspection by the FDA and other regulatory agencies, including for continued compliance with cGMP requirements. The discovery of any new or previously unknown problems with our third-party manufacturers, manufacturing processes or facilities may result in restrictions on the product, manufacturer or facility, including withdrawal of the product from the market. If we rely on third-party manufacturers, we will not have control over compliance with applicable rules and regulations by such manufacturers. Any product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review. The FDA imposes stringent restrictions on manufacturers' communications regarding use of their products. If we promote our product candidates in a manner inconsistent with FDA-approved labeling or otherwise not in compliance with FDA regulations, we may be subject to enforcement action. In addition, unless we conduct head-to-head comparative clinical trials for our product candidates, we will be unable to make comparative claims regarding any other products in the promotional materials for our product candidates. If we or our existing or future collaborators, manufacturers or service providers fail to comply with applicable continuing regulatory requirements in the United States or foreign jurisdictions in which we seek to market our products, we or they may be subject to, among other things, fines, warning letters, holds on clinical trials, delay of approval or refusal by the FDA or comparable foreign regulatory bodies to approve pending applications or supplements to approved applications, suspension or withdrawal of regulatory approval, product recalls and seizures, administrative detention of products, refusal to permit the import or export of products, operating restrictions, injunction, civil penalties and criminal prosecution.

Subsequent discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls;
- fines, warning or untitled letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our strategic partners;
- suspension or revocation of product license approvals;
- product seizure or detention or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance,

we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would adversely affect our business.

We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. Changes in FDA staffing could result in delays in the FDA's responsiveness or in its ability to review submissions or applications, issue regulations or

guidance, or implement or enforce regulatory requirements in a timely fashion or at all. Similar consequences would also result in the event of another significant shutdown of the federal government such as the one that occurred from December 22, 2018 through January 25, 2019. It is difficult to predict how these requirements will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If any legislation, executive orders, or lapses in agency funding impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

***We may face difficulties from healthcare legislative reform measures.***

Existing regulatory policies may change and additional government regulations may be enacted that could affect pricing and third-party payment for our product candidates, which could negatively affect our business, financial condition and prospects. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Healthcare and Education Reconciliation Act (together, the "ACA") was enacted, which was intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for health care and health insurance industries, impose new taxes and fees on the health industry and impose additional health policy.

While there have been legislative and judicial efforts to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA, the ACA remains in effect in its current form. It is possible that the ACA will be subject to judicial or congressional challenges in the future. It is unclear how any such efforts to repeal, replace, amend or invalidate the ACA or its implementing regulations, or portions thereof, will impact the ACA or our business. There have also been and continue to be a number of initiatives at the United States federal and state levels that seek to reduce healthcare costs, including the Budget Control Act (which, subject to certain temporary suspension periods, imposed 2% reductions in Medicare payments to providers per fiscal year starting April 1, 2013 and, due to subsequent legislative amendments to the statute, that will remain in effect through 2031, unless additional Congressional action is taken). Moreover, the American Taxpayer Relief Act of 2012 among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. If federal spending is further reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA or the National Institutes of Health to continue to function at current levels. Amounts allocated to federal grants and contracts may be reduced or eliminated. These reductions may also impact the ability of relevant agencies to timely review and approve research and development, manufacturing, and marketing activities, which may delay our ability to develop, market and sell any products we may develop.

Further, in November 2020, the U.S. Department of Health and Human Services ("HHS"), finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. The implementation of this final rule was delayed by the Biden administration until January 1, 2023 and subsequently delayed by the Inflation Reduction Act ("IRA") until January 1, 2032. In December 2020, CMS issued a final rule implementing significant manufacturer price reporting changes under the Medicaid Drug Rebate Program, including regulations that affect manufacturer-sponsored patient assistance programs subject to pharmacy benefit manager accumulator programs and Best Price reporting related to certain value-based purchasing arrangements. Under the American Rescue Plan Act of 2021, effective January 1, 2024, the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs is eliminated. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than they receive on the sale of products. It is unclear to what extent these new requirements will be

implemented and to what extent these regulations or any future legislation or regulations by the Biden administration will have on our business, including our ability to generate revenue and achieve profitability.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives.

There has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several presidential executive orders, Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare, and reform government program reimbursement methodologies for drug products.

Recently, several healthcare reform initiatives culminated in the enactment of the IRA in August 2022, which allows, among other things, the HHS to negotiate the selling price of a statutorily specified number of drugs and biologics each year that CMS reimburses under Medicare Part B and Part D. Only high-expenditure single-source drugs that have been approved for at least 7 years (11 years for single-source biologics) can qualify for negotiation, with the negotiated price taking effect two years after the selection year. Negotiations for Medicare Part D products begin in 2024 with the negotiated price taking effect in 2026, and negotiations for Medicare Part B products begin in 2026 with the negotiated price taking effect in 2028. In August 2023, HHS announced the ten Medicare Part D drugs and biologics that it selected for negotiations, and by October 1, 2023, each manufacturer of the selected drugs signed a manufacturer agreement to participate in the negotiations. HHS will announce the negotiated maximum fair price by September 1, 2024, and this price cap, which cannot exceed a statutory ceiling price, will come into effect on January 1, 2026. A drug or biological product that has an orphan drug designation for only one rare disease or condition will be excluded from the IRA's price negotiations requirements, but loses that exclusion if it has designations for more than one rare disease or condition, or if is approved for an indication that is not within that single designated rare disease or condition, unless such additional designation or such disqualifying approvals are withdrawn by the time CMS evaluates the drug for selection for negotiation. The IRA also penalizes drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation and eliminates the "donut hole" under Medicare Part D beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program, which requires manufacturers that wish for their drugs to be covered by Medicare Part D to provide statutorily defined discounts to Part D enrollees. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. Manufacturers that fail to comply with the IRA may be subject to various penalties, some significant, including civil monetary penalties. The IRA also extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. These provisions are began taking effect progressively starting in 2023, although they may be subject to legal challenges. For example, the provisions related to the negotiation of selling prices of high-expenditure single-source drugs and biologics have been challenged in multiple lawsuits. Thus, while it is unclear how the IRA will be implemented, it will likely have a significant impact on the pharmaceutical industry and the pricing of our products and product candidates. The adoption of restrictive price controls in new jurisdictions, more

restrictive controls in existing jurisdictions or the failure to obtain or maintain timely or adequate pricing could also adversely impact revenue. We expect pricing pressures will continue globally.

At the state level, legislatures are increasingly enacting laws and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Additional state and federal healthcare reform measures may be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or companion diagnostics or additional pricing pressures.

We expect that the ACA and IRA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

***Our operations and relationships with healthcare providers, healthcare organizations, customers and third-party payors will be subject to applicable anti-bribery, anti-kickback, fraud and abuse, transparency and other healthcare and privacy laws and regulations, which could expose us to, among other things, enforcement actions, criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.***

Our current and future arrangements with healthcare providers, healthcare organizations, third-party payors and customers expose us to broadly applicable anti-bribery, fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our product candidates. In addition, we may be subject to patient data privacy and security regulation by the U.S. federal government and the states and the foreign governments of countries in which we conduct our business. Restrictions under applicable federal and state anti-bribery and healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal and state healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal criminal and civil false claims and civil monetary penalties laws, including the federal False Claims Act, which can be enforced through civil whistleblower or qui tam actions against individuals or entities, prohibits, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Moreover, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;
- HIPAA, which imposes criminal and civil liability, prohibits, among other things, knowingly and willfully executing, or attempting to execute a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA and its respective implementing regulations, including the Final Omnibus Rule published on January 25, 2013, which impose obligations on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services involving the storage, use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information; the federal legislation commonly referred to as Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of covered drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with certain exceptions, to report annually to CMS information related to certain payments and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), physician assistants, certain types of advance practice nurses and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members, with the information made publicly available on a searchable website;
- state privacy laws and regulations that impose restrictive requirements regulating the use and disclosure of health information and other sensitive personal information that is not subject to HIPAA. For example, in June 2018, California enacted the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 ("CPRA") which gives California residents expanded rights to access and delete their personal information, restrict processing of sensitive personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used, and provides for civil penalties for violations, as well as a private right of action that may lead to an increased probability for data breach litigation, all of which will result in increased compliance costs and potential liability. The CPRA also created a new privacy regulator called the California Privacy Protection Agency, which is charged with enforcement as well as drafting and promulgating new privacy regulations. Following California's lead, several other state states enacted privacy laws that took have taken effect in 2023: 2023 and 2024 to date: the Colorado Privacy Act, the Connecticut Personal Data Privacy and Online Monitoring Act, the Utah Consumer Privacy Act, and the Virginia Consumer Data Protection Act, the Florida Digital Bill of Rights, Oregon's protections for the personal data of consumers enacted through SB 619, and the Texas Data Privacy and Security Act. Additional state privacy laws are to take effect in 2024: the Florida Digital Bill second half of Rights (July 1, 2024), Montana's Consumer Data Privacy Act (October 1, 2024), Oregon's protections 2024 and beyond. In addition, a comprehensive federal privacy bill, which includes a private right of action for violations, has been proposed and is under review by the personal data House of consumer enacted through SB 619 (July 1, 2024), and the Texas Data Privacy and Security Act (July 1, 2024); Representatives;
- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public

international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof;

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and
- certain state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures and drug pricing information, state and local laws that require the registration of pharmaceutical sales representatives, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

If we or our collaborators, manufacturers or service providers fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions, which could affect our ability to develop, market and sell our products successfully and could harm our reputation and lead to reduced acceptance of our products by the market. These enforcement actions include, among others:

- exclusion from participation in government-funded healthcare programs; and
- exclusion from eligibility for the award of government contracts for our products.

Privacy laws, rules and regulations evolve frequently, and their scope may continually change through new legislation, amendments to existing legislation, and changes in enforcement, and may be inconsistent from one jurisdiction to another. The interpretation and application of consumer, health-related and data protection laws, especially with respect to genetic samples and data, in the United States, the European Union and elsewhere, are often uncertain, contradictory and in flux. As a result, implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot determine the impact such future laws, regulations and standards may have on our business. We cannot provide assurance that current or future legislation will not prevent us from generating or maintaining personal data or that patients will consent to the use of their personal data (as necessary); either of these circumstances may prevent us from undertaking or publishing essential research and development, manufacturing, and commercialization, which could have a material adverse effect on our business, results of operations, financial condition and prospects.

Efforts to ensure that our current and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any such requirements, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, integrity oversight and reporting obligations, or reputational harm, any of which could adversely affect our financial results.

These risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

***Even if we are able to commercialize any product candidate, such product candidate may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.***

The regulations that govern regulatory approvals, pricing and reimbursement for new drugs vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription biopharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if our product candidates obtain regulatory approval.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from third-party payors including government authorities, such as Medicare and Medicaid, private health insurers and other organizations. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from third-party payors are critical to new product acceptance. Even if we succeed in bringing one or more products to the market, these products may not be considered cost-effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis. Because our products remain in various stages of development, we are unable at this time to determine their cost effectiveness or the likely level or method of coverage and reimbursement. Increasingly, the third-party payors who reimburse patients or healthcare providers, such as government and private insurance plans, are requiring that drug companies provide them with predetermined discounts from list prices, and are seeking to reduce the prices charged or the amounts reimbursed for biopharmaceutical products. If the price we are able to charge for any products we develop, or the coverage and reimbursement provided for such products, is inadequate in light of our development and other costs, our return on investment could be affected adversely.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug or therapeutic biologic will be reimbursed in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution.

Interim reimbursement levels for new drugs, if applicable, may also be insufficient to cover our costs and may not be made permanent. Reimbursement rates may be based on payments allowed for lower cost drugs that are already reimbursed, may be incorporated into existing payments for other services and may reflect budgetary constraints or imperfections in Medicare data. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Further, no uniform policy for coverage and reimbursement exists in the United States, and coverage and reimbursement can differ significantly from payor to payor. As a result, obtaining coverage and reimbursement approval of a product from a third-party payor is a time consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost effectiveness data for the use of our products on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates, but also have their own methods and approval process apart from Medicare determinations. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for new drugs that we develop and for which we obtain regulatory approval could have a material and adverse effect on our business, financial condition, results of operations and prospects.

***If we decide to pursue a Fast Track Designation by the FDA, it may not lead to a faster development or regulatory review or approval process.***

We may seek Fast Track Designation for one or more of our product candidates. If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the product sponsor may apply for FDA Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even if we do receive Fast Track Designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program.

***If we decide to seek Orphan Drug Designation for one or more of our product candidates, we may be unsuccessful or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for supplemental market exclusivity.***

As part of our business strategy, we may seek Orphan Drug Designation for one or more of our product candidates, and we may be unsuccessful. Regulatory authorities in some jurisdictions, including the United States and Europe,

may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, Orphan Drug Designation entitles a party to financial incentives such as tax advantages and user fee waivers. In addition, if a product that has Orphan Drug Designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or where the manufacturer is unable to assure sufficient product quantity.

Even if we obtain Orphan Drug Designation for our product candidates in specific indications, we may not be the first to obtain marketing approval of these product candidates for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moiety can be approved for the same condition. Even after an orphan product is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. In addition, while we may seek Orphan Drug Designation for our product candidates, we may never receive such designations.

Tax reform legislation, which was signed into law on December 22, 2017, reduced the amount of the qualified clinical research costs for a designated orphan product that a sponsor may claim as a credit from 50% to 25%. This may further limit the advantage and may impact our future business strategy of seeking the Orphan Drug Designation.

***We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.***

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended ("FCPA"), the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other collaborators from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products sell our products outside the United States, to conduct clinical trials, and/or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences.

***Governments outside the United States tend to impose strict price controls, which may adversely affect our revenue, if any.***

In some countries, particularly member states of the EU the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution,

or arbitrage between low-priced and high-priced member states, can further reduce prices. To obtain coverage and reimbursement or pricing approvals in some countries, we or current or future collaborators may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our therapeutic candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of any product candidate approved for marketing is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business, financial condition, results of operations or prospects could be materially and adversely affected.

***European data collection is governed by restrictive regulations governing the use, processing, and cross-border transfer of personal information.***

The collection and use of personal health data in the EU is governed by the General Data Protection Regulation ("GDPR"). The GDPR imposes several requirements relating to the consent of the individuals to whom the personal data relates, the information provided to the individuals, notification of data processing obligations to the competent national data protection authorities and the security and confidentiality of the personal data. Additionally, the United Kingdom (the "U.K.") implemented its own Data Protection Act, effective in May 2018 and statutorily amended in 2019, that is further supplemented by the U.K. GDPR which took effect on January 1, 2021. The U.K. GDPR is based on the GDPR that had applied previously in the U.K. but with changes, including its own derogations, for how the GDPR is applied in the U.K. From the beginning of 2021 (when the transitional period following Brexit expired), we have had to continue to comply with the GDPR as well as the U.K.'s Data Protection Act and the U.K. GDPR. The GDPR and U.K. GDPR also impose strict rules on the transfer of personal data out of the EU to the United States. These laws increase the scrutiny of transfers of personal data, such as from clinical trial sites, located in the European Economic Area, the United Kingdom, and Switzerland to jurisdictions that the European Commission does not recognize as having "adequate" data protection laws, such as the United States. On June 4, 2021, the European Commission finalized revised versions of the Standard Contractual Clauses that can be used to transfer personal data out of the EU to the United States. The U.K. Information Commissioner's Office of the Data Protection Authority published the U.K. version of the Standard Contractual Clauses, which we will be required to use for transfers of U.K. residents' personal data to a foreign country that does not have adequate data protection. Also, effective July 10, 2023, the new EU-U.S. Data Privacy Framework ("DPF"), has been recognized as adequate under EU law to allow transfers of personal data from the EU (as well as the U.K. and Switzerland) to certified companies in the U.S. However, the DPF is likely subject to face legal challenge at the Court of Justice of the European Union which could cause the legal requirements for personal data transfers from the Europe to the U.S. to become uncertain once again. EU data protection authorities have and may again block the use of certain U.S.-based services that involve the transfer of personal data to the U.S. In the EU and other markets, potential new rules and restrictions on the flow of data across borders could increase the cost and complexity of doing business in those regions, thus it is possible that the ability to transfer personal data from the European Union to the United States may become restricted. We and many other companies may be required to adopt additional measures to accomplish and maintain legitimate means for the transfer and receipt of personal data from the European Union to the United States and other third-party countries. Failure to comply with the requirements of the GDPR, the U.K. GDPR, and the related national data protection laws of the EU Member States and the United Kingdom may result in fines (for example, of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year (whichever is higher)) and other administrative penalties. Future GDPR regulations may impose additional responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. This may be onerous and adversely affect our business, financial condition, results of operations and prospects. As a result of the implementation of the GDPR, we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules. There remains uncertainty related to the manner in which data protection authorities will seek to enforce compliance with GDPR. For example, it is not clear if the authorities will conduct random audits of companies doing business in the EU, or if the authorities will wait for complaints to be filed by individuals who claim their rights have been violated. Enforcement uncertainty and the costs associated with ensuring GDPR compliance be onerous and adversely affect our business, financial condition, results of operations and prospects.

**Risks Related to Ownership of Our Common Stock**

***Our quarterly operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.***

Our quarterly and annual operating results, including our collaboration revenue, net loss and cash flow, may fluctuate significantly from period to period, which makes it difficult for us to predict our future operating results. Our operating results are and will be affected by numerous factors, many of which are outside of our control including:

- variations in the level of expense related to the ongoing development of our MInT Platform, product candidates or future development programs;
- results of preclinical and clinical trials, or the addition or termination of existing or future clinical trials or funding support by us, or existing or future collaborators or licensing partners;
- our execution of any additional collaboration, licensing or similar arrangements, and the timing of payments we may make or receive under existing or future arrangements or the termination or modification of any such existing or future arrangements;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- additions and departures, or leaves of absences, of key personnel;
- strategic decisions by us, our collaborators or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- if any of our product candidates receives regulatory approval, the terms of such approval and market acceptance and demand for such product candidates;
- regulatory developments affecting our product candidates or those of our competitors; and
- changes in general market and economic conditions, including due to regional conflicts around the world, instability in the banking sector, inflation and market volatility, interest rate fluctuations, uncertainty with respect to the federal debt ceiling and budget and the related potential for government shutdowns, cybersecurity events, the ongoing labor shortage, global supply chain disruptions, the weakening of the global and U.S. economies, or otherwise.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our common stock to fluctuate substantially. We believe that quarterly comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

***The market price of our stock may be volatile, and you could lose all or part of your investment.***

The trading price of our common stock and the common stock of other biopharmaceutical companies have been and may continue to be highly volatile and subject to wide fluctuations in response to various factors, many of which we cannot control. The market price for our common stock may be influenced by many factors, including the other risks described in this section and elsewhere in this report and the following:

- the Offer, the Merger, the pendency of the Merger, perceptions regarding the Merger, or failure to complete the Offer or the Merger;
- results of preclinical studies and clinical trials of our product candidates, or those of our competitors or our existing or future collaborators;
- regulatory or legal developments in the United States and other countries, especially changes in laws or regulations applicable to our product candidates;
- the success of competitive products or technologies;
- introductions and announcements of new products by us, our future commercialization partners, or our competitors, and the timing of these introductions or announcements;
- actions taken by regulatory agencies with respect to our products, clinical studies, manufacturing process or sales and marketing terms;
- actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us;
- the success of our efforts to acquire or in-license additional technologies, products or product candidates;
- developments concerning any future collaborations, including but not limited to those with development and commercialization partners;
- market conditions in the pharmaceutical and biotechnology sectors;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures or capital commitments;
- developments or disputes concerning patents or other proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our product candidates and products;
- our ability or inability to raise additional capital and the terms on which we raise it;
- the recruitment or departure of key personnel;
- changes in the structure of healthcare payment systems;
- actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- announcement and expectation of additional financing efforts;
- speculation in the press or investment community;
- share price and fluctuations of trading volume of our common stock, which may affect our trading liquidity and public float;
- sales of our common stock by us, insiders or our stockholders;
- the concentrated ownership of our common stock;
- changes in accounting principles;
- actions instituted by activist shareholders or others;
- terrorist acts, acts of war or periods of widespread civil unrest, and regional conflicts around the world;
- natural disasters and other calamities, including global pandemics;
- cybersecurity events; and
- general economic, industry and market conditions, including instability in the banking sector, inflation and market volatility, interest rate fluctuations, uncertainty with respect to the federal debt ceiling and budget and the related potential for government shutdowns, and the ongoing labor shortage, global supply chain disruptions, the weakening of the global and U.S. economies, or otherwise.

In addition, the stock market in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme price and volume fluctuations that have been often unrelated or disproportionate to the operating performance of the issuer. These broad market and industry factors may seriously harm the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and adverse impact on the market price of our common stock. In addition, it may be more difficult for stockholders to sell a substantial number of shares for the same price at which stockholders could sell a smaller number of shares.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for biopharmaceutical companies, which have experienced significant stock price volatility in recent years. Market volatility may lead to increased shareholder activism if we experience a market valuation that they believe are not reflective of our stock's intrinsic value. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition.

***A sale of a substantial number of shares of our common stock may cause the price of our common stock to decline.***

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our stockholders sell, or the market perceives that our stockholders intend to sell, substantial amounts of our common stock in the public market the market price of our common stock could decline significantly.

We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of our outstanding options, or the perception that such sales may occur, could adversely affect the market price of our common stock.

We also expect that significant additional capital may be needed in the future to continue our planned operations. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner that we determine from time to time. To the extent that additional capital is raised through the sale and issuance of shares or other securities convertible into shares, our stockholders will be diluted. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

We are party to an "at-the-market" offering of our common stock pursuant to a sales agreement, as amended from time to time, between us and Jefferies. Subject to certain limitations in the sales agreement and compliance with applicable law, we may, in our sole discretion, deliver a placement notice to Jefferies at any time throughout the term of the sales agreement. The number of shares that are sold by Jefferies upon our delivery of a placement notice will fluctuate based on the market price of our common stock during the sales period and limits we set with Jefferies. Because the price per share of each share sold will fluctuate based on the market price of our common stock during the sales period, it is not possible to predict the number of shares that will be ultimately issued, if any, pursuant to the sales agreement. Issuances of any shares sold pursuant to the sales agreement will have a dilutive effect on our existing stockholders. Further, if we sell common stock, preferred stock, convertible securities and other equity securities in other transactions pursuant to our currently effective shelf registration statement on Form S-3ASR or any shelf registration statement on Form S-3ASR that we may file in the future, existing investors may be materially diluted by such subsequent sales and new investors could gain rights superior to our existing stockholders.

***Our principal stockholders and management own a significant percentage of our stock and will be able to control matters subject to stockholder approval.***

Based on the beneficial ownership of our common stock as of March 31, 2024 June 30, 2024, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 64% 81% of our outstanding voting stock. As a result, these stockholders, if acting together, will continue to have control over the outcome of corporate actions requiring stockholder approval, including the election of directors, amendment of our organizational documents, any merger, consolidation or sale of all or substantially all of our assets and any other significant corporate transaction. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

***Anti-takeover provisions in our charter documents and under Delaware law could prevent or delay an acquisition of us, which may be beneficial to our stockholders, and may prevent attempts by our stockholders to replace or remove our current management.***

Our restated certificate of incorporation and our amended and restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions could also make it difficult for stockholders to elect directors who are not nominated by current members of our board of directors or take other corporate actions, including effecting changes in our management. These provisions:

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- provide that directors may only be removed "for cause" and only with the approval of two-thirds of our stockholders;
- require super-majority voting to amend some provisions in our restated certificate of incorporation and amended and restated bylaws;
- authorize the issuance of "blank check" preferred stock that our board could use to implement a stockholder rights plan;
- eliminate the ability of our stockholders to call special meetings of stockholders;

- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting; and
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

***The exclusive forum provision in our restated certificate of incorporation may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims.***

Our restated certificate of incorporation, to the fullest extent permitted by law, provides that the Court of Chancery of the State of Delaware is the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the Delaware General Corporation Law (the "DGCL"), DGCL, our restated certificate of incorporation, or our amended and restated bylaws; or any action asserting a claim against us that is governed by the internal affairs doctrine. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act. It could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provisions contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, results of operations and financial condition.

In addition, Section 203 of the DGCL may discourage, delay or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15% or more of our common stock.

Section 22 of the Securities Act of 1933, as amended (the "Securities Act"), creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. In March 2020, we amended and restated our restated bylaws to provide that the federal district courts of the United States of America will, to the fullest extent permitted by law, be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, or a Federal Forum Provision. Our decision to adopt a Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. While there can be no assurance that federal or state courts will follow the holding of the Delaware Supreme Court or determine that the Federal Forum Provision should be enforced in a particular case, application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court.

Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. In addition, neither the exclusive forum provision nor the Federal Forum Provision applies to suits brought to enforce any duty or liability created by the Exchange Act. Accordingly, actions by our stockholders to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder must be brought in federal court.

Our stockholders will not be deemed to have waived our compliance with the federal securities laws and the regulations promulgated thereunder.

Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to our exclusive forum provisions, including the Federal Forum Provision. These provisions may limit a stockholders' ability to bring a claim in a judicial forum of their choosing for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers, and other employees.

***Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.***

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

**General Risk Factors**

***If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.***

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. We do not have any control over the industry or securities analysts, or the content and opinions included in their reports. If any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our preclinical studies and clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of such analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause a decline in our stock price or trading volume.

***If we fail to maintain an effective system of internal control over financial reporting in the future, we may not be able to accurately report our business, results of operations, financial condition and cash flows and future prospects, which may adversely affect investor confidence in us and, as a result, the value of our common stock.***

The Sarbanes-Oxley Act requires, among other things, that we maintain effective internal controls for financial reporting and disclosure controls and procedures and that we furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment needs to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting that results in more than a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented or detected on a timely basis.

Our compliance with Section 404 will require that we incur substantial accounting expense and expend significant management efforts. We currently do not have an internal audit group and we rely on limited accounting and finance staff to compile the system and process documentation necessary to perform the annual evaluation needed to comply with Section 404. We may not be able to complete our annual evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we fail to identify and to remediate any significant deficiencies or material weaknesses that may be identified, or encounter problems or delays in the evaluation of internal control over financial reporting, we will be unable to assert that our internal control over financial reporting is effective. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by the Nasdaq Stock Market LLC ("NASDAQ"), the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

***Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.***

We are subject to the periodic reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly,

because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

***ESG factors may impose additional costs and expose us to new risks.***

There is an increasing focus from certain investors, regulators, employees, customers and other stakeholders concerning corporate responsibility, specifically related to environmental, social, and governance ("ESG") matters. Some investors may use these non-financial performance factors to guide their investment strategies and, in some cases, may choose not to invest in us if they believe our policies and actions relating to corporate responsibility are inadequate. The growing investor demand for measurement of non-financial performance is addressed by third-party providers of sustainability assessment and ratings on companies. The criteria by which our corporate responsibility practices are assessed may change due to the constant evolution of the sustainability landscape, which could result in greater expectations of us and cause us to undertake costly initiatives to satisfy such new criteria. If we elect not to or are unable to satisfy such new criteria, investors may conclude that our policies and/or actions with respect to corporate social responsibility are inadequate. We may face reputational damage in the event that we do not meet the ESG standards set by various constituencies. In addition, the SEC has proposed new rules that, if adopted in their current form, would impose new disclosure requirements regarding, among other ESG topics, climate-related risks, greenhouse gas emissions data and any publicly set climate-related targets or goals. Efforts to comply with these or any additional new regulatory requirements, or our failure to do so, could have adverse impacts on our business, operating results and financial condition.

Furthermore, in the event that we communicate certain initiatives and goals regarding ESG matters, we could fail, or be perceived to fail, in our achievement of such initiatives or goals, or we could be criticized for the scope, target and timelines of such initiatives or goals. If we fail to satisfy the expectations of investors, regulators, customers, employees and other stakeholders, if our initiatives are not executed as planned, or if we fail to implement sufficient oversight or accurately capture and disclose ESG matters, our reputation and business, operating results and financial condition could be adversely impacted.

**Item 2.** ***Unregistered Sales of Equity Securities and Use of Proceeds***

None

***Item 3. Defaults Upon Senior Securities***

None

**Item 4.** ***Mine Safety Disclosures***

Not Applicable

**Item 5.** ***Other Information***

During the three months ended March 31, 2024 June 30, 2024, except as noted below none the Company's directors or executive officers adopted a Rule 10b5-1 trading plan, terminated a Rule 10b5-1 trading plan or adopted or terminated a non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K).

On February 23, 2024, Robert E. Farrell, Jr., CPA, the Senior Vice President of Finance and Chief Accounting Officer of the Company, adopted a trading arrangement for the sale of shares of the Company's common stock that is intended to satisfy the affirmative defense conditions of Securities Exchange Act Rule 10b5-1(c) (the "Farrell Plan"). The Farrell Plan, which is scheduled to expire on February 25, 2025, provides for the sale of up to 90,272 shares of common stock pursuant to the terms thereof.

On February 29, 2024, Marc Schegerin, M.D., the Chief Financial Officer and Chief Operating Officer of the Company, terminated an existing trading arrangement for the sale of shares of the Company's common stock (the "Terminated Schegerin Plan") and adopted a trading arrangement for the sale of shares of the Company's common stock that is intended to satisfy the affirmative defense conditions of Securities Exchange Act Rule 10b5-1(c) (the "New Schegerin Plan"). The Terminated Schegerin Plan was adopted on May 5, 2023, was scheduled to expire on August 30, 2024 and provided for the sale of up to 112,322 shares of common stock pursuant to the terms thereof. As of the date of termination of the Terminated Schegerin Plan, Dr. Schegerin had sold 20,000 shares of common stock thereunder. The New Schegerin Plan, which is scheduled to expire on December 31, 2025, provides for the sale of up to 208,506 shares of common stock pursuant to the terms thereof.

**Item 6. *Exhibits***

Furnish the exhibits required by Item 601 of Regulation S-K (§ 229.601 of this chapter).

| Exhibit Number | Description | Exhibit Filing Form | File No. | Date | Filed/Furnished Herewith |
|---|---|---|---|---|---|
| 10.1 | Sixth Amendment of Lease, dated March 29, 2024, between ARE-MA Region No. 110, LLC and Morphic Therapeutic, Inc. | | | | X |
| 31.1 | Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. | | | | X |
| 31.2 | Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002. | | | | X |
| 32.1* | Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. | | | | X |
| 32.2* | Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. | | | | X |
| 101.INS | Inline XBRL Instance Document. | | | | X |
| 101.SCH | Inline XBRL Taxonomy Extension Schema Document. | | | | X |
| 101.CAL | Inline XBRL Taxonomy Extension Calculation Linkbase Document. | | | | X |
| 101.DEF | Inline XBRL Taxonomy Extension Definition Linkbase Document. | | | | X |
| 101.LAB | Inline XBRL Taxonomy Extension Label Linkbase Document. | | | | X |
| 101.PRE | Inline XBRL Taxonomy Extension Presentation Linkbase Document. | | | | X |
| 104 | Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101) | | | | X |

* *The certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-Q and are not deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liability of that section, nor shall they be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.*

**SIGNATURES**

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

MORPHIC HOLDING, INC.

April July 25, 2024 By: /s/ Praveen P. Tipirneni

Praveen P. Tipirneni, M.D.

Chief Executive Officer and Director
(Principal Executive Officer)

By: /s/ Marc Schegerin

April July 25, 2024

Marc Schegerin, M.D.

Chief Financial Officer and Chief Operating Officer
(Principal Financial Officer)

April July 25, 2024 By: /s/ Robert E. Farrell, Jr.

Robert E. Farrell, Jr., CPA

Chief Accounting Officer and Assistant Treasurer
(Principal Accounting Officer)

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**Exhibit 10.1**

**SIXTH AMENDMENT OF LEASE**

THIS SIXTH AMENDMENT OF LEASE (this "**Sixth Amendment**") is made as of March 29, 2024, by and between **ARE-MA REGION NO. 110, LLC**, a Delaware limited liability company ("**Landlord**"), and **MORPHIC THERAPEUTIC, INC.**, a Delaware corporation ("**Tenant**"), formerly known as Morphic Rock Therapeutic, Inc.

**RECITALS**

A. Landlord (as successor-in-interest to Astrazeneca Pharmaceuticals LP) and Tenant are now parties to that certain Lease dated as of August 5, 2015, as amended by that certain First Amendment of Lease dated as of November 8, 2016, as further amended by that certain Second Amendment of Lease dated as of June 1, 2017, as further amended by that certain Third Amendment of Lease dated as of April 20, 2018, as further amended by that certain Fourth Amendment of Lease dated as of February 14, 2020, and as further amended by that certain Fifth Amendment of Lease dated as of August 17, 2021 (the "**Fifth Amendment**")(as amended, the "**Existing Lease**") whereby Tenant leases certain space in the buildings and facilities commonly known as 35 Gatehouse Drive, Waltham, Massachusetts, which leased space currently consists of approximately 11,166 square feet of rentable space located on Level 2 of Building A (the "**A2 Premises**"), 12,147 square feet of rentable office space located on Level 2 of Building D (the "**D2 Premises**") and 9,092 square feet of rentable laboratory space located on Level 3 of Building C (the "**C3 Premises**", and together with the A2 Premises and the D2 Premises, the "**Premises**"), all as more particularly set forth in the Existing Lease.

B. The Lease Term of the Existing Lease is scheduled to expire on May 31, 2025.

C. Landlord and Tenant desire, subject to the terms and conditions set forth below, to amend the Existing Lease to extend the Lease Term through December 31, 2025 (the "**Sixth Amendment Expiration Date**").

**NOW, THEREFORE**, in consideration of the foregoing Recitals, which are incorporated herein by this reference, the mutual promises and conditions contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, Landlord and Tenant hereby agree as follows:

1. **Extension of Lease Term**. The Lease Term is hereby extended through the Sixth Amendment Expiration Date. Tenant's occupancy of the Premises through the Sixth Amendment Expiration Date shall be on an "as-is" basis, and Landlord shall have no obligation to provide any tenant improvement allowance or to make any alterations to the Premises. Tenant shall have no further right to extend the Lease Term.

2. **Base Rent**. Tenant shall continue to pay Base Rent as provided in the Fifth Amendment through May 31, 2025. Commencing on June 1, 2025, Tenant shall commence paying Base Rent:

a. for the A2 Premises and the C3 Premises in the amount of $62.50 per rentable square foot per year; and

a. for the D2 Premises in the amount of $35.00 per rentable square foot per year.

3. **Security Deposit**. Landlord holds a Security Deposit in the amount of $560,393.33 in the form of a Letter of Credit. Prior to the date of this Sixth Amendment, Tenant delivered to Landlord an amendment to the Letter of Credit extending the expiration date of the Letter of Credit until March 31, 2026.



4. **Brokers**. Landlord and Tenant each represents and warrants that it has not dealt with any broker, agent or other person (collectively, "**Broker**") in connection with the transaction reflected in this Sixth Amendment and that no Broker, other than CBRE, brought about this transaction. Landlord and Tenant each hereby agree to indemnify and hold the other harmless from and against any claims by any Broker, other than CBRE, claiming a commission or other form of compensation by virtue of having dealt with Tenant or Landlord, as applicable, with regard to this leasing transaction. Landlord shall be responsible for all commissions due to CBRE arising out of the execution of this Sixth Amendment in accordance with the terms of a separate written agreement between Landlord and Broker.

5. **OFAC**. Tenant is currently (a) in compliance with and shall at all times during the term of the Lease remain in compliance with the regulations of the Office of Foreign Assets Control ("**OFAC**") of the U.S. Department of Treasury and any statute, executive order, or regulation relating thereto (collectively, the "**OFAC Rules**"), (b) not listed on, and shall not during the term of the Lease be listed on, the Specially Designated Nationals and Blocked Persons List, Foreign Sanctions Evaders List or the Sectoral Sanctions Identifications List, which are all maintained by OFAC and/or on any other similar list maintained by OFAC or other governmental authority pursuant to any authorizing statute, executive order, or regulation, and (c) not a person or entity with whom a U.S. person is prohibited from conducting business under the OFAC Rules.

6. **Miscellaneous**.

a. This Sixth Amendment is the entire agreement between the parties with respect to the subject matter hereof and supersedes all prior and contemporaneous oral and written agreements and discussions. This Sixth Amendment may be amended only by an agreement in writing, signed by the parties hereto.

b. This Sixth Amendment is binding upon and shall inure to the benefit of the parties hereto, and their respective successors and assigns.

c. This Sixth Amendment may be executed in 2 or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature process complying with the U.S. federal ESIGN Act of 2000) or other transmission method and any counterpart so delivered shall be deemed to have been duly and validly delivered and be valid and effective for all purposes. Electronic signatures shall be deemed original signatures for purposes of this Sixth Amendment and all matters related thereto, with such electronic signatures having the same legal effect as original signatures.

d. Except as amended and/or modified by this Sixth Amendment, the Lease is hereby ratified and confirmed and all other terms of the Lease shall remain in full force and effect, unaltered and unchanged by this Sixth Amendment. Each of the parties hereto represents and warrants to the other that the person executing this Sixth Amendment on behalf of such party has the full right, power and authority to enter into and execute this Sixth Amendment on such party's behalf and that no consent from any other person or entity is necessary as a condition precedent to the legal effect of this Sixth Amendment. In the event of any conflict between the provisions of this Sixth Amendment and the provisions of the Lease, the provisions of this Sixth Amendment shall prevail. Whether or not specifically amended by this Sixth Amendment, all of the terms and provisions of the Lease are hereby amended to the extent necessary to give effect to the purpose and intent of this Sixth Amendment.

e. Tenant acknowledges that Landlord's business operations are proprietary to Landlord. Absent prior written consent from Landlord, Tenant shall hold confidential and will not disclose to third parties, and shall require Tenant's Invitees to hold confidential and not disclose to third

parties, information regarding the systems, controls, equipment, programming, vendors, tenants, and specialized amenities of Landlord. Tenant shall notify Landlord immediately if Tenant becomes aware of any third party contacting Tenant or any Tenant's Invitees requesting information regarding Landlord's business operations.

f. Each signatory of this Sixth Amendment represents hereby that he or she has the authority to execute and deliver this Sixth Amendment on behalf of the party hereto for which such signatory is acting.

**[Signatures are on the next page]**



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**IN WITNESS WHEREOF**, the parties hereto have executed this Sixth Amendment as of the day and year first above written.

**TENANT:**

**MORPHIC THERAPEUTIC, INC.**

/s/ Robert Farrell
By: Robert E. Farrell Jr. CPA
Title: SVP Finance & Operations & Chief Accounting Officer

**LANDLORD:**

**ARE-MA REGION NO. 110, LLC,**
a Delaware limited liability company

/s/ ARE-QRS CORP.,
a Maryland corporation general partner

By: Scott Sherwood
Title: VP - Real Estate Legal Affairs



**Exhibit 31.1**

**CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF
THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Praveen P. Tipirneni, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Morphic Holding, 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 the 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.

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: April 25, 2024 July 25, 2024

/s/ Praveen P. Tipirneni

Praveen P. Tipirneni, M.D.
Chief Executive Officer and Director
(Principal Executive Officer)

**Exhibit 31.2**

**CERTIFICATION PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Marc Schegerin, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Morphic Holding, 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 the 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.

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: April 25, 2024 July 25, 2024

/s/ Marc Schegerin

Marc Schegerin, M.D.
Chief Financial Officer and Chief Operating Officer
(Principal Financial Officer)

**Exhibit 32.1**

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

I, Praveen P. Tipirneni, Chief Executive Officer of Morphic Holding, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. the Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended March 31, 2024 June 30, 2024 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 25, 2024 July 25, 2024

/s/ Praveen P. Tipirneni

Praveen P. Tipirneni, M.D.
Chief Executive Officer and Director
(Principal Executive Officer)

**Exhibit 32.2**

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

I, Marc Schegerin, Chief Financial Officer and Chief Operating Officer of Morphic Holding, Inc. (the "Company"), do hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. the Quarterly Report on Form 10-Q of the Company for the fiscal quarter ended March 31, 2024 June 30, 2024 (the “Report”) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 25, 2024 July 25, 2024

/s/ Marc Schegerin

Marc Schegerin, M.D.

Chief Financial Officer and Chief Operating Officer

(Principal Financial Officer)

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