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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
Form 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2022
OR

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

For the transition period from to
Commission file number: 001-38940
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 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 Global Market

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (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 October 31, 2022 was 38,552,521.

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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)

	September 30, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 84,961	$ 171,434
Marketable securities	286,799	236,701
Accounts receivable	662	2,307
Prepaid expenses and other current assets	9,988	7,892
Total current assets	382,410	418,334
Operating lease right-of-use assets	3,845	4,806
Property and equipment, net	2,170	2,583
Restricted cash	560	560
Other assets	196	7
Total assets	$ 389,181	$ 426,290
Liabilities		
Current liabilities:		
Accounts payable	$ 4,367	$ 4,798
Accrued expenses	10,874	12,838
Deferred revenue, current portion	3,345	20,628
Total current liabilities	18,586	38,264
Long-term liabilities:		
Operating lease liability, net of current portion	2,730	3,838
Deferred revenue, net of current portion	2,804	47,489
Total liabilities	24,120	89,591
Commitments and contingencies (Note 9)		
Stockholders' Equity		
Preferred shares, $0.0001 par value, 10,000,000 shares authorized, no shares issued and outstanding as of September 30, 2022 and December 31, 2021	—	—
Common shares, $0.0001 par value, 400,000,000 shares authorized, 38,532,370 shares issued and outstanding as of September 30, 2022 and 37,085,397 shares issued and outstanding as of December 31, 2021	4	4
Additional paid-in capital	641,872	575,231
Accumulated deficit	(272,718)	(238,054)
Accumulated other comprehensive loss	(4,097)	(482)
Total stockholders' equity	365,061	336,699
Total liabilities and stockholders' equity	$ 389,181	$ 426,290

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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Collaboration revenue	$ 2,055	$ 3,124	$ 64,673	$ 10,238
Operating expenses:				
Research and development	25,245	20,966	77,360	64,131
General and administrative	8,303	7,276	24,128	20,367
Total operating expenses	33,548	28,242	101,488	84,498
Loss from operations	(31,493)	(25,118)	(36,815)	(74,260)
Other income:				
Interest income, net	1,657	77	2,326	140
Other expense, net	(156)	—	(144)	(20)
Total other income, net	1,501	77	2,182	120
Loss before provision for income taxes	(29,992)	(25,041)	(34,633)	(74,140)
Provision for income taxes	(29)	—	(31)	—
Net loss	$ (30,021)	$ (25,041)	$ (34,664)	$ (74,140)
Net loss per share, basic and diluted	$ (0.78)	$ (0.69)	$ (0.91)	$ (2.09)
Weighted average common shares outstanding, basic and diluted	38,490,910	36,547,222	37,961,262	35,392,153
Comprehensive loss:				
Net loss	$ (30,021)	$ (25,041)	$ (34,664)	$ (74,140)
Other comprehensive loss:				
Unrealized holding losses on marketable securities, net of tax	(1,680)	(73)	(3,615)	(72)
Total other comprehensive loss	(1,680)	(73)	(3,615)	(72)
Comprehensive loss	$ (31,701)	$ (25,114)	$ (38,279)	$ (74,212)

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		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2021	**37,085,397**	**$ 4**	**$ 575,231**	**$ (238,054)**	**$ (482)**	**$ 336,699**
Equity-based compensation expense	—	—	6,765	—	—	6,765
Vesting of restricted shares	1,990	—	—	—	—	—
Issuance of common shares upon stock option exercises	146,237	—	2,127	—	—	2,127
Issuance of common shares under the Employee Stock Purchase Plan	16,845	—	571	—	—	571
Unrealized holding losses on marketable securities	—	—	—	—	(1,310)	(1,310)
Net loss	—	—	—	(31,484)	—	(31,484)
Balance at March 31, 2022	**37,250,469**	**$ 4**	**$ 584,694**	**$ (269,538)**	**$ (1,792)**	**$ 313,368**
Equity-based compensation expense	—	—	7,623	—	—	7,623
Vesting of restricted shares	3,681	—	—	—	—	—
Issuance of common shares upon stock option exercises	194,442	—	1,573	—	—	1,573
Issuance of common shares through at-the-market offering, net of issuance costs of $1.3 million	1,000,000	—	39,210	—	—	39,210
Unrealized holding losses on marketable securities	—	—	—	—	(625)	(625)
Net income	—	—	—	26,841	—	26,841
Balance at June 30, 2022	**38,448,592**	**$ 4**	**$ 633,100**	**$ (242,697)**	**$ (2,417)**	**$ 387,990**
Equity-based compensation expense	—	—	7,537	—	—	7,537
Issuance of common shares upon stock option exercises	70,352	—	921	—	—	921
Issuance of common stock under the Employee Stock Purchase Plan	13,426	—	314	—	—	314
Unrealized holding losses on marketable securities	—	—	—	—	(1,680)	(1,680)
Net loss	—	—	—	(30,021)	—	(30,021)
Balance at September 30, 2022	**38,532,370**	**$ 4**	**$ 641,872**	**$ (272,718)**	**$ (4,097)**	**$ 365,061**

	Common Shares		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2020	**32,037,686**	**$ 3**	**$ 287,727**	**$ (142,512)**	**$ (21)**	**$ 145,197**
Equity-based compensation expense	—	—	4,442	—	—	4,442
Vesting of restricted shares	46,893	—	—	—	—	—
Issuance of common shares upon stock option exercises	279,431	—	2,657	—	—	2,657
Issuance of common stock under the Employee Stock Purchase Plan	26,561	—	613	—	—	613
Issuance of common shares through at-the-market offering, net of issuance costs of $0.2 million	240,704	—	7,231	—	—	7,231
Issuance of common shares in secondary offering, net of offering costs of $15.0 million	3,500,000	1	230,030	—	—	230,031
Unrealized holding gains on marketable securities	—	—	—	—	5	5
Net loss	—	—	—	(21,284)	—	(21,284)
Balance at March 31, 2021	**36,131,275**	**$ 4**	**$ 532,700**	**$ (163,796)**	**$ (16)**	**$ 368,892**
Equity-based compensation expense	—	—	5,308	—	—	5,308
Vesting of restricted shares	24,080	—	—	—	—	—
Issuance of common shares upon stock option exercises	122,156	—	1,577	—	—	1,577
Unrealized holding losses on marketable securities	—	—	—	—	(4)	(4)
Offering costs incurred	—	—	(49)	—	—	(49)
Net loss	—	—	—	(27,815)	—	(27,815)
Balance at June 30, 2021	**36,277,511**	**$ 4**	**$ 539,536**	**$ (191,611)**	**$ (20)**	**$ 347,909**
Equity-based compensation expense	—	—	5,791	—	—	5,791
Vesting of restricted shares	34,204	—	—	—	—	—
Issuance of common shares upon stock option exercises	273,624	—	3,683	—	—	3,683
Issuance of common stock under the Employee Stock Purchase Plan	9,002	—	482	—	—	482
Issuance of common shares through at-the-market offering, net of issuance costs of $0.9 million	298,070	—	17,414	—	—	17,414
Unrealized holding losses on marketable securities	—	—	—	—	(73)	(73)
Net loss	—	—	—	(25,041)	—	(25,041)
Balance at September 30, 2021	**36,892,411**	**$ 4**	**$ 566,906**	**$ (216,652)**	**$ (93)**	**$ 350,165**

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)

	Nine Months Ended September 30,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (34,664)	$ (74,140)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	762	754
Premium amortization and discount accretion on marketable securities	1,137	531
Equity-based compensation	21,925	15,541
Loss on sale of marketable securities	154	—
Loss on disposal of equipment	—	4
Change in operating assets and liabilities:		
Accounts receivable	1,645	4,696
Prepaid expenses and other current assets	(2,031)	(1,353)
Other assets	(189)	51
Operating lease right-of-use assets	961	785
Accounts payable	(519)	(842)
Accrued expenses	(2,215)	(1,743)
Deferred revenue	(61,968)	(6,295)
Operating lease liabilities	(857)	(865)
Net cash used in operating activities	(75,859)	(62,876)
Cash flows from investing activities:		
Purchases of marketable securities	(235,773)	(223,803)
Proceeds from maturities of marketable securities	173,623	106,000
Proceeds from sale of marketable securities	7,146	—
Purchase of property and equipment	(301)	(563)
Net cash used in investing activities	(55,305)	(118,366)
Cash flows from financing activities:		
Proceeds from issuance of common shares under Employee Stock Purchase Plan	885	1,095
Proceeds from at-the-market offering, net of issuance costs	39,250	24,645
Proceeds from secondary offering, net of issuance costs	—	229,982
Proceeds from issuance of common shares upon stock option exercises	4,556	7,917
Net cash provided by financing activities	44,691	263,639
Net (decrease) increase in cash, cash equivalents and restricted cash	(86,473)	82,397
Cash and cash equivalents and restricted cash, beginning of period	171,994	102,322
Cash and cash equivalents and restricted cash, end of period	$ 85,521	$ 184,719
Non-cash activities:		
Purchases of property and equipment included in accounts payable and accrued expenses	$ 48	$ 173
Amounts from exercise of stock options included in prepaid expenses and other current assets	$ 65	$ —
Unpaid issuance costs for at-the-market offering included in accounts payable and accrued expenses	$ 40	$ —
Right-of-use assets obtained in exchange for operating lease liabilities	$ —	$ 4,434

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

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 first-in-class oral small molecule integrin therapeutics. Integrins are a validated target class with multiple approved drugs for the treatment of serious chronic diseases. Despite significant biopharmaceutical industry investment, no oral integrin therapies have been approved. The Company has created the Morphic integrin technology platform, or MInT Platform, by leveraging its unique understanding of integrin structure and biology, to develop a pipeline of novel product candidates designed to achieve potency, high selectivity, and the pharmaceutical properties required for oral administration.

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") with Jefferies LLC ("Jefferies") with respect to an at-the-market offering program (the "Previous ATM") under which the Company could offer and sell, from time to time at its sole discretion, shares of our common stock, having an aggregate offering amount of up to $75.0 million, referred to as Placement Shares, through Jefferies as its sales agent. The Company paid Jefferies a commission equal to 3.0% of the gross sales proceeds of any Placement Shares sold through Jefferies under the Original Agreement, and also provided Jefferies with customary indemnification and contribution rights. On August 11, 2021, the Company entered into an Amendment No. 1 to the Open Market Sale Agreement with Jefferies, establishing a new at-the-market offering program (the "New ATM") with an aggregate offering amount of up to $150.0 million, also subject to a commission equal to 3.0% of gross sales proceeds from Placement Shares sold through Jefferies. Under the New ATM, the Company may offer and sell, from time to time at its sole discretion, shares of its common stock, referred to as Placement Shares, through Jefferies as its sales agent.

During the nine months ended September 30, 2022, the Company issued and sold 1,000,000 shares under the New ATM for net proceeds of approximately $39.2 million after deducting offering commissions and expenses. As of September 30, 2022, the Company had approximately $97.2 million of common stock remaining available for sale under the New ATM.

In March 2021, the Company completed an underwritten follow-on public offering of 3,500,000 shares of its common stock at a price to the public of $70.00 per share. Gross proceeds from the secondary offering were approximately $245.0 million, before deducting underwriting discounts, commissions and other offering expenses of approximately $15.0 million, paid by the Company, resulting in net proceeds of approximately $230.0 million.

On March 2, 2022, the Company incorporated Morphic Therapeutic UK Ltd in London, United Kingdom (the "U.K."), to support Company functions outside of the United States.

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 a Massachusetts Security Corporation, organized in December 2019. 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 September 30, 2022 and 2021.

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, 2021, and the notes thereto, which are included in the Company's Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on February 24, 2022.

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 revenue recognition, accrued research and development expenses, the valuation of equity-based compensation, and income taxes. 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 nine months ended September 30, 2022 are consistent with those discussed in Note 2 to the consolidated financial statements in the Company's 2021 Annual Report on Form 10-K, except as described below.

As disclosed in Note 1, on March 2, 2022, the Company incorporated Morphic Therapeutic UK Ltd in London, U.K., to support Company functions outside of the United States. The geographic location of all long-lived assets of the Company continues to be the United States.

The functional reporting currency of Morphic Therapeutic UK Ltd is the United States Dollar. Foreign currency remeasurement is included in other income (expense) in the Company's consolidated statements of operations.

Reclassification

Certain amounts have been reclassified for the nine months ended September 30, 2021 in the current Form 10-Q to conform with current year presentation. As disclosed in Note 2 to the Company's 2021 Annual Report on Form 10-K, in February 2016, the FASB issued ASU 2016-02, Leases (Topic 842), with guidance regarding the accounting for and disclosure of leases. As the Company adopted Topic 842 in the annual period ended December 31, 2021 effective January 1, 2021, the Company reclassified certain amounts in the Company's cash flows from operating activities in the current Form 10-Q. Amounts for the nine months ended September 30, 2021 from the change in deferred rent were reclassified as changes in operating lease right-of-use assets and changes in operating lease liabilities. There were no changes to total cash flows or to cash flows from operating activities, investing activities or financing activities as a result of this reclassification.

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 September 30, 2022, investments include U.S. Treasury securities, U.S. government-sponsored enterprise securities and corporate debt securities, including corporate bonds and commercial paper, 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 tables below present information about the Company's financial assets that are measured at fair value on a recurring basis as of September 30, 2022 and December 31, 2021 (in thousands) and indicate the level within the fair value hierarchy where each measurement is classified.

	Fair Value Measurements at September 30, 2022			
	Total	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 84,314	$ 44,484	$ 39,830	$ —
Marketable securities:				
U.S. Treasury securities	177,220	—	177,220	—
U.S. government-sponsored enterprise securities	9,919	—	9,919	—
Commercial paper	9,767	—	9,767	—
Corporate bonds	89,893	—	89,893	—
Total assets	$ 371,113	$ 44,484	$ 326,629	$ —

	Fair Value Measurements at December 31, 2021			
	Total	Level 1	Level 2	Level 3
Assets:				
Cash equivalents	$ 171,142	$ 171,142	$ —	$ —
Marketable securities:				
U.S. Treasury securities	16,212	—	16,212	—
Commercial paper	99,898	—	99,898	—
Corporate bonds	120,591	—	120,591	—
Total assets	$ 407,843	$ 171,142	$ 236,701	$ —

Cash equivalents consist of money market funds and U.S. Treasury securities as of September 30, 2022 and money market funds as of December 31, 2021. 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 September 30, 2022 and December 31, 2021. The U.S. Treasury securities included in cash equivalents as of September 30, 2022 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, U.S. government-sponsored enterprise securities, commercial paper and corporate bonds, and these securities are categorized as Level 2 as of September 30, 2022 and December 31, 2021. The Company had no liabilities measured at fair value on a recurring basis at September 30, 2022 and December 31, 2021.

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.

4. Marketable securities

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

	As of September 30, 2022				
	Maturity	Amortized cost	Gross unrealized holding gains	Gross unrealized holding losses	Aggregate estimated fair value
Marketable securities:					
U.S. Treasury securities	within 2 years	$ 179,332	$ —	$ (2,112)	$ 177,220
U.S. government-sponsored enterprise securities	within 2 years	10,000	—	(81)	9,919
Commercial paper	less than 1 year	9,767	—	—	9,767
Corporate bonds	within 2 years	91,772	—	(1,879)	89,893
Total marketable securities		$ 290,871	$ —	$ (4,072)	$ 286,799

	As of December 31, 2021				
	Maturity	Amortized cost	Gross unrealized holding gains	Gross unrealized holding losses	Aggregate estimated fair value
Marketable securities:					
U.S. Treasury securities	less than 1 year	$ 16,224	$ —	$ (12)	$ 16,212
Commercial paper	less than 1 year	99,900	—	(2)	99,898
Corporate bonds	within 2 years	121,034	—	(443)	120,591
Total marketable securities		$ 237,158	$ —	$ (457)	$ 236,701

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 investments during the three and nine months ended September 30, 2022. As such, an allowance for credit losses was not recognized. As of September 30, 2022, 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 $1.2 million as of September 30, 2022 and December 31, 2021.

5. Cash, Cash Equivalents and Restricted Cash

Restricted cash consists of cash collateralizing a letter of credit in the amount of $560,000 issued to the landlord of the Company's facility lease. The letter of credit and cash collateralizing it increased from $275,000 in August 2021 due to the operating lease extension. The terms of the letter 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):

	September 30, 2022	December 31, 2021	September 30, 2021	December 31, 2020
Cash and cash equivalents	$ 84,961	$ 171,434	$ 184,159	$ 102,047
Restricted cash	560	560	560	275
Total cash, cash equivalents, and restricted cash	$ 85,521	$ 171,994	$ 184,719	$ 102,322

6. Accrued Expenses

At September 30, 2022 and December 31, 2021 accrued expenses consisted of the following (in thousands):

	September 30, 2022	December 31, 2021
Payroll and related expenses	$ 4,645	$ 6,396
Research and development activities	3,985	4,268
Current portion of operating lease liability	1,462	1,211
Other expenses	782	963
Total	$ 10,874	$ 12,838

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 2019 Plan, the number of shares of common stock available for issuance under the A&R 2019 Plan increased by 1.5 million shares in January 2022. As of September 30, 2022, there were a total of 1.7 million shares available for future award grants under the A&R 2019 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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Stock options	$ 6,674	$ 5,403	$ 19,459	$ 14,448
Restricted common stock	—	71	5	224
Restricted stock units	756	163	2,151	385
Employee Stock Purchase Plan	107	154	310	484
Total	$ 7,537	$ 5,791	$ 21,925	$ 15,541

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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Research and development expense	$ 3,423	$ 2,599	$ 10,316	$ 7,406
General and administrative expense	4,114	3,192	11,609	8,135
Total	$ 7,537	$ 5,791	$ 21,925	$ 15,541

Stock Options

The following table summarizes the Company's stock option activity during the nine months ended September 30, 2022:

	Number of Shares	Weighted Average Exercise Price
Outstanding as of December 31, 2021	4,781,565	$ 20.03
Granted	1,470,368	39.94
Exercised	(411,031)	11.24
Forfeited or expired	(441,934)	33.35
Outstanding as of September 30, 2022	5,398,968	$ 25.04
Options exercisable as of September 30, 2022	2,704,979	$ 18.64

Restricted Stock Units

The following table summarizes the restricted stock units activity during the nine months ended September 30, 2022:

	Number of Shares	Weighted Average Fair Value per Share at Issuance
Unvested restricted stock units as of December 31, 2021	7,000	$ 57.73
Granted	291,970	43.98
Vested	(3,500)	57.73
Forfeited	(32,200)	44.75
Unvested restricted stock units as of September 30, 2022	263,270	$ 44.07

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.

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, or the 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 September 30, 2022, the Company forecasts an ordinary pre-tax loss for the year ended December 31, 2022 and, since it maintains a full valuation allowance on its deferred tax assets, the Company did not record an income tax benefit in 2022.

On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (the "Inflation Act") into law. The Inflation Act contains certain tax measures, including a corporate alternative minimum tax of 15% on some large corporations and an excise tax of 1% on corporate stock buy-backs. The various provisions of the Inflation Act do not have a material impact on the Company's condensed consolidated financial statements.

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 September 30, 2022, 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.

During the nine months ended September 30, 2022, there were no material changes to our 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, 2021, filed with the SEC on February 24, 2022.

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 agreements 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, 2021 filed with the SEC on February 24, 2022.

AbbVie Agreement

During the three and nine months ended September 30, 2022 the Company continued to perform under its agreement with AbbVie, (the "AbbVie Agreement") pursuant to which the Company recognizes revenues in proportion to the costs incurred. In June 2022, AbbVie informed the Company that it had decided to exercise its right to terminate the AbbVie Agreement for convenience, subject to a 180 day notification period. The AbbVie Agreement will terminate effective December 2022 or earlier if agreed to by the Company and AbbVie.

The Company recognizes the $100.0 million up-front payment paid to the Company under the AbbVie Agreement as revenue as work is performed in proportion to the costs incurred. Upon receipt of notification of the exercise of the right to terminate the AbbVie Agreement, the Company concluded that there was a contract modification to an existing contract under ASC 606 because the notification of termination of the AbbVie Agreement resulted in a reduction in scope of the Company's responsibilities for the three remaining research programs thereunder. The terms of the AbbVie Agreement termination notification did not include any additional promised goods or services. As a result of the notification from AbbVie, the Company recognized revenue of $57.7 million on a cumulative catch-up basis during the three months ended June 30, 2022 using an updated measure of progress towards satisfying the research and development services performance obligations thereunder. These research and development performance obligations will be completed through the effective date of the termination in December 2022.

The following table summarizes research and development costs incurred and revenue recognized in connection with Company's performance under the AbbVie Agreement during the three and nine months ended September 30, 2022 and 2021 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Revenue recognized	$ 890	$ 1,476	$ 60,140	$ 5,043
Costs incurred	30	1,206	631	4,374

In August 2020, pursuant to the AbbVie Agreement, AbbVie exercised its option to exclusively license and control further development and commercialization of the Company's αvβ6–specific integrin program for the treatment of fibrotic diseases including IPF and additional fibrosis-related indications. In connection with the exercise of the option, AbbVie paid the Company $20.0 million. Under this license, AbbVie controls and is responsible for the development and commercialization of this program. AbbVie has informed the Company that it does not intend to advance any of its selective oral αvβ6-specific integrin inhibitors due to a suspected on-target / αvβ6-mediated safety signal that has been observed in pre-clinical testing. Details about these observations are planned to be released in an upcoming scientific publication. As a result, the Company does not expect to receive additional payments for this program under the AbbVie Agreement.

As of September 30, 2022, the Company had $0.4 million of remaining deferred revenue, which is classified as current deferred revenue in the accompanying condensed consolidated balance sheets based on the period over which the revenue is expected to be recognized. This deferred revenue balance represents the aggregate amount of the transaction price allocated to the performance obligations that are partially unsatisfied as of September 30, 2022.

Janssen Agreement

During the three and nine months ended September 30, 2022, the Company continued to perform under its agreement with Janssen (the "Janssen Agreement"), pursuant to which the Company recognizes revenue in proportion to the costs incurred to date.

Under the terms of the Janssen Agreement, Janssen paid the Company an upfront fee of $10.0 million for the first two research programs in 2019 and in December 2020 the Company reached an agreement with Janssen to commence work on the third research program, and Janssen paid the Company $5.0 million for the third research program commencement fee in February 2021. The Company expects to provide research services and recognize revenue under the Janssen Agreement through 2024.

In December 2021, Janssen informed the Company that it had decided not to exercise its options on the first two integrin targets, thus also discontinuing those two research programs. The Company has focused efforts on the third integrin research program which includes the potential development of integrin antibody activators.

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 and nine months ended September 30, 2022 and 2021 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Reimbursement revenue	$ 662	$ 1,276	$ 2,704	$ 3,914
Upfront payment revenue	503	372	1,829	1,281
Total revenue recognized	$ 1,165	$ 1,648	$ 4,533	$ 5,195
Costs incurred	$ 530	$ 1,118	$ 2,258	$ 3,388

The Company had $0.7 million and $2.3 million due from Janssen included in accounts receivable on the condensed consolidated balance sheets as of September 30, 2022 and December 31, 2021, respectively.

As of September 30, 2022, $5.8 million of deferred revenue is classified as either current or long-term deferred revenue in the accompanying condensed consolidated balance sheet based on the period over which the revenue is expected to be recognized. This deferred revenue balance represents the portion of the upfront payment received allocated to the performance obligations that are partially unsatisfied as of September 30, 2022.

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 September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Net loss	$ (30,021)	$ (25,041)	$ (34,664)	$ (74,140)
Weighted average common shares outstanding, basic and diluted	38,490,910	36,547,222	37,961,262	35,392,153
Net loss per share, basic and diluted	$ (0.78)	$ (0.69)	$ (0.91)	$ (2.09)

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 and Nine Months Ended September 30,	
	2022	2021
Restricted common stock	—	24,393
Restricted stock units	263,270	41,095
Stock options	5,398,968	5,086,495
	5,662,238	5,151,983

In addition to the securities listed in the table above, as of September 30, 2022 the Company had reserved 1,142,204 shares of common stock for sale under the Company's Employee Stock Purchase Plan (the "ESPP"), which, if issued, would be anti-dilutive if included in calculation of diluted net loss per share for the three and nine months ended September 30, 2022.

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, 2021, filed with the SEC on February 24, 2022.

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 below. These forward-looking statements may include, but are not limited to, statements regarding our future results of operations and financial position, the impact of the COVID-19 pandemic, our business strategy, market size, potential growth opportunities, our preclinical and clinical development activities, the efficacy and safety profile of our product candidates, use of net proceeds from our offerings, our ability to maintain and recognize the benefits of certain designations received by product candidates, the timing and results of preclinical studies and clinical trials, commercial collaborations with third parties and the receipt and timing of potential regulatory designations, approvals and commercialization of product candidates. 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.

Overview

We are a biopharmaceutical company applying our proprietary insights into integrins to discover and develop a pipeline **o**f 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, or FDA. Despite this, 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, or MInT Platform, was created 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 α4β7-specific integrin inhibitor affecting inflammation, into clinical development for the treatment of inflammatory bowel disease, or IBD. We submitted an investigational new drug application, or 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 comprised of single-ascending dose, or SAD, food effect, or FE, and multiple-ascending dose, or MAD, cohorts to establish our clinical program and select doses for our Phase 2 program in IBD with an initial focus on ulcerative colitis, or UC.

The MORF-057 Phase 1 study included SAD, MAD, and FE cohorts evaluating MORF-057 safety, pharmacokinetics, or PK, and pharmacodynamics, or 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 (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 impact on trough MORF-057 levels and that MORF-057 can be administered without regard to food in planned studies in patients.

α4β7 receptor occupancy 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 the MORF-057 Phase 1 study, subjects receiving MORF-057 at 200 mg BID twice daily 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 pharmacodynamic measures. All doses were well tolerated, no safety signals were identified, and a favorable pharmacokinetic 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 C_{trough}. 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 trial of MORF-057 in March 2022. EMERALD-1 (MORF-057-201), which is an open-label 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. Additional patients that were undergoing screening at the time the study completed enrollment are eligible to enter the study if they meet the study criteria. Enrollment of an exploratory cohort of up to ten patients who have previously failed treatment with advanced UC therapies is ongoing. Patients enrolled in the EMERALD-1 study are being treated with 100 mg BID (twice daily) at sites in the United States and Poland. The primary endpoint of the trial is the change in Robarts Histopathology Index (RHI), a validated instrument that measures histological disease activity in ulcerative colitis at 12 weeks compared to baseline. Patients will then continue for an additional 40 weeks of maintenance therapy followed by a 52-week assessment. Secondary and additional outcome measures in the EMERALD-1 study include change in the modified Mayo clinic score, safety, PK parameters and key PD measures including α4β7 receptor occupancy and lymphocyte subset trafficking. We expect that primary endpoint data from the main cohort of the EMERALD-1 Phase 2a trial of MORF-057 in patients with moderate to severe UC will report in the second quarter of 2023. EMERALD-2 (MORF-057-202) which is a global Phase 2b randomized controlled trial of MORF-057 is expected to begin in the fourth quarter of 2022. Patients enrolled in the EMERALD-2 study will be randomized to receive one of three active arms or a placebo arm: 100 mg BID (twice daily), 200 mg BID, and a QD (once daily) arm, or a placebo arm which will cross 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 modified Mayo score at 12 weeks. The secondary endpoints will include the change in RHI, pharmacokinetic and pharmacodynamic 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 completion of 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. Given the progress achieved with MORF-057, we will pause and not advance a second generation development candidate into clinical studies during 2022, focusing on the advancement of MORF-057 through Phase 2 clinical programs. We have positioned additional next generation α4β7 small molecule development candidates for clinical studies in eosinophilic diseases.

In August 2020, AbbVie exercised its option under the AbbVie Agreement to license certain product candidates and now controls and is responsible for the development and commercialization of our αvβ6-specific integrin inhibitor program. In connection with the option exercise, AbbVie made a one-time $20.0 million payment to us. Under this license, AbbVie controls and is responsible for the development and commercialization of this program. AbbVie has informed us that it does not intend to advance any of our selective oral αvβ6-specific integrin inhibitors due to a suspected on-target/ αvβ6-mediated safety signal that has been observed in pre-clinical testing. Details about these observations are planned to be released in an upcoming scientific publication. As a result, we do not expect to receive additional payments for this program under the AbbVie Agreement. In June 2022, AbbVie informed us that it had decided to exercise its right to terminate the AbbVie Agreement for convenience, subject to a 180-day notification period. The AbbVie Agreement will terminate effective December 2022 or earlier if agreed to by us and AbbVie. We continue to advance additional discovery programs with AbbVie as a part of this collaboration through the effective date of the AbbVie Agreement's termination.

In February 2019, we entered into an agreement with Janssen Pharmaceuticals, Inc., or Janssen, to develop novel integrin therapeutics, or the Janssen Agreement. In February 2021 Janssen paid us $5.0 million to commence work on a third research program. We are entitled to additional payments upon the achievement of certain milestones and royalties in accordance with the Janssen Agreement. In December 2021, Janssen informed us that they have decided not to exercise the options on the first two integrin targets. We have focused efforts on the third integrin research program which includes the potential development of integrin antibody activators. The first two integrin targets have been returned to us due to a lack of target validation in the specific disease of Janssen's interest.

Beyond these lead targets, 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 near to or into 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, demonstrating anti-tumor activity in checkpoint refractory cancer models and continue our focus on advancing our αvβ8 program. We also

have additional research stage programs ongoing against integrin targets in pulmonary arterial hypertension (PAH) and other therapeutic areas. Integrins are known to promote cell proliferation, survival, hypertrophic growth and fibrosis, which are key elements in the progression of PAH.

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, or the Original Agreement, with Jefferies LLC, or Jefferies, with respect to an at-the-market offering program, or the Previous ATM, under which we may offer and sell, from time to time at our sole discretion, shares of our common stock, having an aggregate offering amount of up to $75,000,000, referred to as Placement Shares, through Jefferies as sales agent. In August 2021, we entered into Amendment No. 1 to the Original Agreement with Jefferies with respect to an at-the-market offering program, or the New ATM, increasing the amount of Placement Shares, under the Original Agreement, which we may offer and sell, from time to time at its sole discretion, through Jefferies as sales agent, up to an aggregate offering amount of up to $150,000,000. We refer to the Previous ATM and the New ATM, collectively, as the ATM. During the three months ended September 30, 2022, 1,000,000 shares were issued under the New ATM for net proceeds of $39.2 million, after deducting offering commissions and expenses. As of September 30, 2022, we had approximately $97.2 million of common stock remaining available for sale under the New ATM. We may not sell any Placement Shares under the Previous ATM.

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 and Janssen, discussed further in Note 10 of the accompanying 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 September 30, 2022, we raised an aggregate of approximately $742.4 million of gross proceeds primarily through the issuance of equity, including our convertible preferred equity securities, our initial public offering, our underwritten public offering in March 2021, and sales of shares of our common stock pursuant to the ATM, along with payments received under our collaboration agreements.

Since inception, we have incurred significant operating losses. As of September 30, 2022, we had an accumulated deficit of $272.7 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.

We have updated our current operating plan as a result of: the receipt of significant cash proceeds raised under the New ATM; the reduction in the scope of our partnered programs; a proactive pipeline prioritization and the implementation of increased operational efficiencies. As of September 30, 2022, we had cash, cash equivalents, and marketable securities of $371.8 million. We believe that our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2025.

Impact of the COVID-19 Pandemic

The current COVID-19 pandemic continues to present a substantial public health and economic challenge around the world and is affecting our employees, patients, communities and business operations, as well as the U.S. economy and financial markets. The extent of the ongoing impact of the novel strain of coronavirus, SARS-CoV-2, or COVID-19, on our operational and financial performance will depend on certain developments, including the duration and spread of the outbreak, the rise of variants that may be less responsive to existing vaccines, the impact on our clinical and preclinical studies, employee or industry events, and the effect on our suppliers and manufacturers, all of which are uncertain and cannot be predicted. Although we currently have not experienced much of an impact on our business, excluding minor changes to our development timelines,

if there are closures or other restrictions in places where we or our vendors work or transport supply that may result in constrained supply of our product candidates or delays in our clinical and preclinical studies or planned clinical trials, our business, results of operations and overall financial performance in future periods could be materially adversely impacted. In addition, we have experienced impacts from changes in how we and companies worldwide conduct business due to the COVID-19 pandemic, including but not limited to restrictions on travel and in-person meetings, delays in future site activations and future enrollment of clinical trials, prioritization of hospital resources toward the COVID-19 pandemic effort, and delays in review by the FDA and comparable foreign regulatory agencies. As of the filing date of this Form 10-Q, the extent to which COVID-19 may impact our financial condition, results of operations or guidance is uncertain. The effects of the COVID-19 pandemic will not be fully reflected in our results of operations and overall financial performance until future periods. See "Risk Factors" included elsewhere in this Quarterly Report on Form 10-Q for further discussion of the possible impact of the COVID-19 pandemic on our business.

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 our agreements with AbbVie and Janssen. We expect that our revenue, until we have a marketed product, will be derived primarily from payments under our collaboration and option agreements with AbbVie and Janssen or other collaboration and license agreements that we may enter into in the future, if any.

Collaboration Revenue — AbbVie

In October 2018, we entered into a collaboration with AbbVie, an investor that held approximately 5% of our common stock at the time of the agreement, designed to advance a number of our oral integrin therapeutics for fibrosis-related indications. Under the terms of the AbbVie Agreement, AbbVie paid us an upfront payment of $100.0 million for research and development activities, and we provided to AbbVie exclusive license options on product candidates directed at multiple targets. In August 2020, AbbVie exercised its option to license the selective αvβ6-specific integrin inhibitors program and paid us a one-time payment of $20.0 million.

For each lead compound against a target under the AbbVie Agreement, we conduct research and development activities through the completion of IND-enabling studies, at which point AbbVie may pay a license fee of $20.0 million, on a target-by-target basis, to exercise its exclusive license option and assume responsibility for global development and commercialization. We are also eligible for clinical and commercial milestone payments and tiered royalties from high single digit to low teens on worldwide net sales for each licensed product. AbbVie has informed us that it does not intend to advance any of our selective oral αvβ6-specific integrin inhibitors due to a suspected on-target/ αvβ6-mediated safety signal that has been observed in pre-clinical testing. Details about these observations are planned to be released in an upcoming scientific publication. As a result, we do not expect to receive additional payments for this program under the AbbVie Agreement. In June 2022, AbbVie informed us that it had decided to exercise its right to terminate the AbbVie Agreement for convenience, subject to a 180 day notification period. The AbbVie Agreement will terminate effective December 2022 or earlier if agreed to by us and AbbVie.

Collaboration Revenue — Janssen

In February 2019, we entered into the Janssen Agreement to discover and develop novel integrin therapeutics for patients with conditions not adequately addressed by current therapies. The Janssen Agreement focuses on three integrin targets, each target the subject of a research program, with the ability to substitute up to two integrin targets not explored by us. Upon completing IND-enabling studies, on a research program-by-research program basis, Janssen may exercise an exclusive option to obtain an exclusive license with respect to the target that is the subject of the research program, including all licensed compounds that are the subject of the applicable research program, and then Janssen will be responsible for global clinical development and commercialization. In consideration of the rights granted, during 2019, Janssen paid us an upfront fee of $10.0 million for each of the first two research programs, and in December 2020 we agreed with Janssen to commence work on the third research program, and in February 2021 Janssen paid us $5.0 million for the third research program commencement fee. Janssen also funds research activities at agreed upon rates, pursuant to the terms of the agreement, and we are also eligible to receive additional milestone and royalty payments. In December 2021, Janssen informed us that they have decided not to exercise the options on the first two integrin targets which resulted in a reduction in scope of our responsibilities under the Janssen Agreement.

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. Significant judgment 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 our future 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, 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, and 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.

Results of Operations

Comparison of the Three Months Ended September 30, 2022 and 2021

The following table summarizes our results of operations for the three months ended September 30, 2022 and 2021:

	Three Months Ended September 30,		Change	
	2022	2021	$	%
	(in thousands, except percentages)			
Collaboration revenue	$ 2,055	$ 3,124	$ (1,069)	(34)%
Operating expenses:				
Research and development	25,245	20,966	4,279	20 %
General and administrative	8,303	7,276	1,027	14 %
Total operating expenses	33,548	28,242	5,306	19 %
Loss from operations	(31,493)	(25,118)	(6,375)	25 %
Other income:				
Interest income, net	1,657	77	1,580	2,052 %
Other expense, net	(156)	—	(156)	*
Total other income, net	1,501	77	1,424	1,849 %
Loss before provision for income taxes	(29,992)	(25,041)	(4,951)	20 %
Provision for income taxes	(29)	—	(29)	*
Net loss	$ (30,021)	$ (25,041)	$ (4,980)	20 %

*Percentage not meaningful

Collaboration Revenue

The decrease in collaboration revenue of $1.1 million is attributable to a decrease in activity under the AbbVie Agreement and the Janssen Agreement. In Q2 2022, we decreased our estimates to complete the remaining performance obligations under the AbbVie Agreement based on AbbVie's notification of exercise of their option to terminate the AbbVie Agreement effective December 2022 or earlier if agreed to by us and AbbVie. Commencing after Janssen informed us in December 2021 that they have decided not to exercise the options on the first two integrin targets identified under the Janssen Agreement, we have focused efforts on the third integrin research program thereunder. The revenue for our collaborations fluctuates based on the timing and magnitude of costs incurred under the collaboration programs, as well as changes to our estimates to complete the remaining performance obligations.

Research and Development Expenses

Research and development expense increased by $4.3 million, or 20%, from $21.0 million for the three months ended September 30, 2021 to $25.2 million for the three months ended September 30, 2022. 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 September 30, 2022 and 2021:

	Three Months Ended September 30,		Change	
	2022	2021	$	%
	(in thousands, except percentages)			
External costs by program:				
MORF-057	$ 9,245	$ 7,200	$ 2,045	28 %
αvβ8 Program	3,038	2,407	631	26 %
Janssen Agreement programs	180	525	(345)	(66)%
AbbVie Agreement programs	22	597	(575)	(96)%
Other early development candidates and unallocated costs	2,356	1,161	1,195	103 %
Total external costs	14,841	11,890	2,951	25 %
Internal costs:				
Employee compensation and benefits	9,422	8,071	1,351	17 %
Facility and other	982	1,005	(23)	(2)%
Total internal costs	10,404	9,076	1,328	15 %
Total research and development expense	$ 25,245	$ 20,966	$ 4,279	20 %

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

- The $3.0 million increase in external costs from the three months ended September 30, 2021 to the three months ended September 30, 2022 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, including αvβ8. These increases were partially offset by decreases in activity under the AbbVie Agreement and the Janssen Agreement.
- The $1.3 million increase in internal costs from the three months ended September 30, 2021 to the three months ended September 30, 2022 was primarily driven by an increase in headcount and non-cash equity-based compensation expense 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 $1.0 million, or 14%, from $7.3 million for the three months ended September 30, 2021 to $8.3 million for the three months ended September 30, 2022. The increase in general and administrative expense was primarily attributable to a $0.9 million increase in non-cash equity-based compensation expense and a $0.5 million increase

in legal expenses related to regulatory and patent costs, partially offset by a $0.3 million decrease in consulting expenses, a $0.1 million decrease in corporate insurance expense and a $0.1 million decrease in other professional services fees.

Interest Income, Net

Interest income increased by $1.6 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 September 30, 2022 compared to the three months ended September 30, 2021.

Comparison of the Nine Months Ended September 30, 2022 and 2021

The following table summarizes our results of operations for the nine months ended September 30, 2022 and 2021:

	Nine Months Ended September 30,		Change	
	2022	2021	$	%
	(in thousands, except percentages)			
Collaboration revenue	$ 64,673	$ 10,238	$ 54,435	532 %
Operating expenses:				
Research and development	77,360	64,131	13,229	21 %
General and administrative	24,128	20,367	3,761	18 %
Total operating expenses	101,488	84,498	16,990	20 %
Loss from operations	(36,815)	(74,260)	37,445	(50)%
Other income:				
Interest income, net	2,326	140	2,186	1,561 %
Other expense, net	(144)	(20)	(124)	620 %
Total other income, net	2,182	120	2,062	1,718 %
Loss before provision for income taxes	(34,633)	(74,140)	39,507	(53)%
Provision for income taxes	(31)	—	(31)	*
Net loss	$ (34,664)	$ (74,140)	$ 39,476	(53)%

*Percentage not meaningful

Collaboration Revenue

The increase in collaboration revenue of $54.4 million is attributable to a reduction in the scope of the AbbVie Agreement. In Q2 2022, we decreased our estimates to complete the remaining performance obligations under the AbbVie Agreement and recorded a cumulative catch-up to revenue based on AbbVie's notification of exercise of their option to terminate the AbbVie Agreement effective December 2022 or earlier if agreed to by us and AbbVie. Offsetting the increase in collaboration revenue is a decrease in collaboration revenue is attributable to the decreased activity under the Janssen Agreement. Commencing after Janssen informed us in December 2021 that they have decided not to exercise the options on the first two integrin targets identified under the Janssen Agreement, we have focused efforts on the third integrin research program thereunder. The revenue for our collaborations fluctuates based on the timing and magnitude of costs incurred under the collaboration programs, as well as changes to our estimates to complete the remaining performance obligations.

Research and Development Expenses

Research and development expense increased by $13.2 million, or 21%, from $64.1 million for the nine months ended September 30, 2021 to $77.4 million for the nine months ended September 30, 2022. A significant portion of our research and development costs have been external clinical and preclinical contract research organization (“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 nine months ended September 30, 2022 and 2021:

	Nine Months Ended September 30,		Change	
	2022	2021	$	%
	(in thousands, except percentages)			
External costs by program:				
MORF-057	$ 26,141	$ 22,946	$ 3,195	14 %
αvβ8 Program	10,552	5,794	4,758	82 %
Janssen Agreement programs	1,090	1,378	(288)	(21)%
AbbVie Agreement programs	155	2,518	(2,363)	(94)%
Other early development candidates and unallocated costs	6,990	4,673	2,317	50 %
Total external costs	44,928	37,309	7,619	20 %
Internal costs:				
Employee compensation and benefits	29,389	23,749	5,640	24 %
Facility and other	3,043	3,073	(30)	(1)%
Total internal costs	32,432	26,822	5,610	21 %
Total research and development expense	$ 77,360	$ 64,131	$ 13,229	21 %

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

- The $7.6 million increase in external costs from the nine months ended September 30, 2021 to the nine months ended September 30, 2022 primarily related to costs associated with the ongoing Phase 2 clinical studies and other development activities for MORF-057 and development milestone fees due to our collaborators as well as other external research costs to support our early development candidates, including αvβ8. These increases were partially offset by decreases in activity under the AbbVie Agreement and the Janssen Agreement.
- The $5.6 million increase in internal costs from the nine months ended September 30, 2021 to the nine months ended September 30, 2022 was primarily driven by an increase in headcount and non-cash equity-based compensation expense 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 $3.8 million, or 18%, from $20.4 million for the nine months ended September 30, 2021 to $24.1 million for the nine months ended September 30, 2022. The increase in general and administrative expense was primarily attributable to a $3.5 million increase in non-cash equity-based compensation expense, a $0.3 million increase in personnel costs and a $0.3 million increase in professional services fees, corporate insurance expense and IT system costs, partially offset by a $0.3 million decrease in consulting expenses.

Interest Income, Net

Interest income increased by $2.2 million due to an increase in effective interest rates on cash equivalents and marketable securities and an increase in invested marketable securities during the nine months ended September 30, 2022 compared to the nine months ended September 30, 2021.

Liquidity and Capital Resources

Sources of Liquidity

From inception through September 30, 2022, we raised an aggregate of approximately $742.4 million of gross proceeds primarily through the issuance of equity, including our convertible preferred equity securities, our initial public offering and follow-on equity offering, and sales of shares of our common stock under the ATM, 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 September 30, 2022 and December 31, 2021:

	September 30, 2022	December 31, 2021
	(in thousands)	
Cash	$ 647	$ 292
Cash equivalents	84,314	171,142
Marketable securities	286,799	236,701
Total cash, cash equivalents and marketable securities	$ 371,760	$ 408,135

Cash Flows

The following table provides information regarding our cash flows for the nine months ended September 30, 2022 and 2021:

	Nine Months Ended September 30,	
	2022	2021
	(in thousands)	
Net cash used in operating activities	$ (75,859)	$ (62,876)
Net cash used in investing activities	(55,305)	(118,366)
Net cash provided by financing activities	44,691	263,639
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (86,473)	$ 82,397

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 $75.9 million for the nine months ended September 30, 2022 compared to $62.9 million in cash used in operating activities for the nine months ended September 30, 2021. The increase in cash used in operating activities was primarily driven by an $17.0 million increase in operating expenses and an increase in cash outflows from changes in operating assets and liabilities in 2022, offset by an increase in non-cash items recorded as operating expenses.

Net Cash Used in Investing Activities

Net cash used in investing activities was $55.3 million for the nine months ended September 30, 2022 compared to $118.4 million used in investing activities for the nine months ended September 30, 2021. The change in cash used in investing activities is primarily based on the timing of purchases or maturities in marketable securities in the period. During the nine months ended September 30, 2022, cash used in investing activities primarily resulted from purchases of marketable securities exceeding maturities and sales of marketable securities. During the nine months ended September 30, 2021, the increase in cash used in investing activities was due to an increase in investments in marketable securities with proceeds from the underwritten public offering completed in March 2021.

Net Cash Provided by Financing Activities

Net cash provided by financing activities of $44.7 million for the nine months ended September 30, 2022 resulted from $39.2 million in net proceeds received from sales of shares of common stock under the ATM and $5.4 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 nine months ended September 30, 2021 of $263.6 million primarily resulted from $230.0 million in net proceeds received from the underwritten public offering completed in March 2021, $24.6 million in net proceeds received from sales of shares of common stock under the ATM, and $9.0 million in proceeds received from 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 or on acceptable terms, including, but not limited to, as a result of COVID-19, the ongoing conflict in the Ukraine, inflation, or rising interest rates, we

would be forced to delay, reduce, or eliminate our research and development programs or future commercialization efforts. We expect our existing cash, cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2025.

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:

- 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;
- the potential delays in our preclinical studies, our development programs and our current and planned clinical trials due to the effects of the COVID-19 pandemic or geo-political actions, including war (such as the current armed conflict in Ukraine);
- general economic conditions and trends, including inflation, rising interest rates, and the ongoing labor shortage; 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.

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 September 30, 2022, 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, 2021, which was filed with the SEC on February 24, 2022.

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.

Contractual Obligations

In August 2021, the Company exercised its one-time extension right for its existing lease for 32,405 square feet of office and laboratory space through May 2025, as provided for under the terms of the lease, and with future rent payments of $4.6 million at September 30, 2022. As of September 30, 2022, our contractual obligations remain consistent with those disclosed in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, filed with the SEC on February 24, 2022.

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

There were no material changes in our exposure to market risk from December 31, 2021 to September 30, 2022.

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 September 30, 2022. 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 September 30, 2022 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 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.

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:

- We are a clinical stage biopharmaceutical company with a limited operating history, no product candidates approved for commercial sale, and a history of significant losses. We expect to continue to incur significant losses for the foreseeable future and we may never achieve profitability.
- We will require substantial additional funding to pursue our business objectives. If we are unable to raise capital when needed or on terms acceptable to us, we could be forced to delay, reduce or eliminate our research or drug development programs or any future commercialization efforts or other operations.
- Raising additional equity capital may cause dilution to our stockholders.
- Obtaining debt financing may restrict our operations or require us to relinquish rights to our technologies or product candidates.
- Our product candidates are in early-stages of development. We and our partners may not obtain regulatory approvals for or successfully commercialize our product candidates, including our lead product candidate MORF-057.
- Our ongoing and future clinical trials may reveal significant adverse events not seen in our preclinical studies, and there is no guarantee that successful results in preclinical studies will lead to successful results in clinical trials. In addition, significant adverse events or other side effects may lead to difficulty in recruiting patients to our clinical trials, and we may be required to abandon our development efforts of our product candidates, which will adversely affect our business and financial condition.
- We currently have collaborations with AbbVie and Janssen, from which we have derived a substantial portion of our revenue and such revenue is expected to decrease in the future.
- Our product candidates are subject to extensive governmental regulations, and we and/or our collaborators may be unable to obtain, or may be delayed in obtaining, U.S. or foreign regulatory approval. If we do not receive regulatory approval, we may be unable to commercialize our product candidates. We do not have prior experience in managing the clinical trials necessary to obtain such regulatory approvals.
- If we are not able to obtain, maintain and enforce patent protection for our technologies or our product candidates, the development and commercialization of our product candidates may be adversely affected.
- Our success largely depends on the continued service of our key management, advisors and other specialized technical personnel involved with the crystallization of integrins.
- A sale of a substantial number of shares of our common stock, including under our "at-the-market" offering with Jefferies LLC, or Jefferies, or other equity or debt offering of our securities, may cause the price of our common stock to decline.

- Our executive officers, directors and certain of our stockholders and their affiliates beneficially own approximately 50% of our outstanding voting stock. As a result, these stockholders have substantial control over our company and their interests may not be aligned with the interests of our other stockholders.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- The COVID-19 pandemic could adversely impact our business, including our clinical trials and clinical trial operations.
- Delaware law and provisions in our restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer, or proxy contest difficult, thereby depressing the market price of our common stock.
- The exclusive forum provision in our organizational documents 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 Relating to our Business and Operations

The outbreak of COVID-19, or a similar pandemic, epidemic or outbreak of an infectious disease in the United States or elsewhere, could have a material adverse impact on our business, financial condition and results of operations, including the execution of our preclinical studies and clinical trials and the use and sufficiency of our existing cash.

The extent to which the ongoing COVID-19 pandemic impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19 and its variants, the continued effectiveness of available vaccines, and the actions taken to contain the virus or treat its impact, among others. Many countries around the world continue to impose quarantines and restrictions on travel and mass gatherings to slow the spread of the virus.

The spread of an infectious disease, including COVID-19, may also result in the inability of our suppliers to deliver supplies to us on a timely basis. We currently utilize third parties to, among other things, manufacture components of our product candidates and, in the future, intend to utilize third parties to conduct our preclinical studies and clinical trials. If either we or any third-party parties in the supply chain for materials used in the production of our product candidates are adversely impacted by restrictions resulting from the COVID-19 pandemic, our supply chain may be disrupted, limiting our ability to manufacture our product candidates for our preclinical studies and clinical trials.

The COVID-19 pandemic has in the past affected the business of the FDA, EMA and other health authorities, and if these impacts are ongoing or recur, they could result in delays in meetings related to current and planned clinical trials and ultimately of reviews and approvals of our product candidates. Infections and deaths related to COVID-19 are disrupting certain healthcare and healthcare regulatory systems worldwide. The ongoing effects of COVID-19 may also slow potential enrollment of current and planned clinical trials, reduce the number of eligible patients for our current and planned clinical trials, create difficulties in recruiting clinical site investigators and staff, divert healthcare resources away from the conduct of clinical trials, delay receiving approval from local authorities to initiate our current and planned clinical trials, delay necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees, interrupt key clinical trial activities (like site monitoring) due to travel limitations imposed by authorities, and create difficulties in data collection and analysis, among other things. It is unknown how long these disruptions could continue, were they to occur. Any elongation or de-prioritization of our preclinical or clinical studies or delay in regulatory review resulting from such disruptions could materially affect the development and study of our product candidates. Any delays to our current and planned timelines could also impact the use and sufficiency of our existing cash reserves, and we may be required to raise additional capital earlier than we had previously planned. We may be unable to raise additional capital if and when needed, which may result in further delays or suspension of our development plans. If we are able to raise additional capital, challenging and uncertain economic conditions can make capital raising costly and dilutive.

In response to the COVID-19 pandemic, during 2020, 2021 and part of 2022 we limited our office access to only those employees completing laboratory-based tasks essential to the development efforts, and allowed other employees to work outside of our office with certain precautions in place that we believed would ensure our employees' safety and well being. In early 2022, we reopened our office to all employees.

We have implemented appropriate safety measures, including increased sanitation standards. We have also suspended any requirement for an employee to obtain a doctor's note to be absent from or return to the workplace, and are following guidance from the Center for Disease Control and the Occupational Safety and Health Administration regarding suspension of nonessential travel, self-isolation recommendations for employees returning from certain geographic areas, confirmed reports of any COVID-19 diagnosis among our employees, and the return of such employees to our workplace. Pursuant to updated guidance from the Equal Employment Opportunity Commission, we are engaging in limited and appropriate inquiries of employees regarding potential COVID-19 exposure, based on the direct threat that such exposure may present to our workforce. We continue to address other unique situations that arise among our workforce due to the COVID-19 pandemic on a case-by-case basis. While we believe that we have taken appropriate measures to ensure the health and well-being of our employees, there can be no assurances that our measures will be sufficient to protect our employees in our workplace or that they may otherwise be exposed to COVID-19 outside of our workplace. If a number of our "essential" employees become ill, incapacitated or are otherwise unable to continue working during the current or any future epidemic, our operations may be adversely impacted.

In the event of shelter-in-place orders or other mandated local travel restrictions or quarantines, and in particular if there are additional reclosures in locations where we do business, including with our collaborators, partners and contractors, our collaborators, partners and contractors conducting preclinical, clinical, research or manufacturing activities may not be able to access laboratory or manufacturing space, and our core activities may be significantly limited or curtailed, possibly for an extended period of time. In the first quarter of 2022, some of our partners and contractors operating in China faced temporary closures in compliance with local containment measures enacted in response to local COVID-19 resurgences. Furthermore, to the extent the pandemic is ongoing and there are outbreaks in the laboratory space or office space, we may be subject to risk of liability should any employee allege we failed to adequately mitigate the risk of exposure to COVID-19. The spread of COVID-19, which has caused a broad impact globally, including restrictions on travel and quarantine policies put into place by businesses and governments, may have a material economic effect on our business. While the potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict, it has already caused, and is likely to result in further, significant disruption of global financial markets and the trading prices for our common stock and the common stock of other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic, which may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the global effort to control COVID-19 infections could materially and adversely affect our business and the value of our common stock.

The COVID-19 pandemic and mitigation measures also have had, and may continue to have, an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed. The extent to which the COVID-19 pandemic impacts our business and operations will depend on future developments that are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of the virus and the actions to contain its impact.

Such events may result in a period of business disruption, and in reduced operations, any of which could materially affect our business, financial condition and results of operations. We do not yet know the full extent of potential delays or impacts on our business, our preclinical studies and clinical trials, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the situation closely, although, as of the date of this Quarterly Report on Form 10-Q, we do not expect any material impact on our long-term activity. The extent to which COVID-19 impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of COVID-19 and the actions to contain COVID-19 or treat its impact, among others.

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 September 30, 2022, we had 103 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, other key employees and advisors. We currently do not maintain key person insurance on these individuals. The loss of one or more members of our management team or other key employees or advisors, including due to illness resulting from COVID-19, 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, in particular, personnel involved with crystallization of integrins, 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 also 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 and success at 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 collaboration 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 our product candidates, 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 and 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, if 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 our ability to obtain sufficient insurance coverage could have a material and adverse effect on our business, financial condition, results of operations and prospects.

When we conduct clinical trials of our product candidates, we may be exposed to significant product liability risks inherent in the development, testing, manufacturing and marketing 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 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 decreased demand for our products, 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 similar 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 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, loss of data, and other disruptions could compromise sensitive information related to our business or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, results of operations, financial condition and prospects.

We collect and maintain information in digital form that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal data. It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We have established physical, electronic and organizational measures to safeguard and secure our systems to prevent a data compromise, and rely on commercially available systems, software, tools, and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. Our internal information technology systems and infrastructure, and those of our current and any future collaborators, contractors and consultants and other third parties on which we rely, are vulnerable to damage from cyber incidents such as third parties getting access to employee accounts using

stolen or inferred credentials, computer viruses, phishing attacks, spamming, malware, cyber-attacks or cyber-intrusions over the Internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization, and attempts to gain unauthorized access to computer systems and networks. Our internal information technology systems and infrastructure is also vulnerable to damage from natural disasters, terrorism, war, telecommunication and electrical failures. System failures or outages, including any potential disruptions due to significantly increased global demand on certain cloud-based systems during the COVID-19 pandemic, could compromise our ability to perform these functions in a timely manner, which could harm our ability to conduct business or delay our financial reporting. Such failures could materially adversely affect our operating results and financial condition.

The risk of a security breach or disruption or data loss, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. The occurrence of these and other more sophisticated or state-supported attack campaigns may increase as geopolitical tensions and intermittent warfare continue or escalate outside of the U.S., including, for example, due to the Russia-Ukraine conflict. In addition, the prevalent use of mobile devices that access confidential information increases the risk of data security breaches, which could lead to the loss of confidential information or other intellectual property. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. 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, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing rules and regulations, 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.

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

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. We believe our procedures for storing, handling and disposing these materials in our facilities comply with the relevant guidelines of Middlesex County, Massachusetts. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards mandated by applicable regulations, 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 to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of these materials, this insurance may not provide adequate coverage against potential liabilities. We may incur substantial costs to comply with, and substantial fines or penalties if we violate, any of these laws or regulations.

Our current operations are concentrated in one location, and we or the third parties upon whom we depend may be adversely affected by a heavy snowstorm 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 located in our facilities in Waltham, Massachusetts. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemic, including the COVID-19 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. For example, our operations are concentrated primarily on the east coast of the United States, and any adverse weather event or natural disaster, such as a hurricane or heavy snowstorm, could have a material adverse effect on a substantial portion of our operations. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Extreme weather conditions or other natural disasters could further disrupt our operations, and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted 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 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, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other 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, 2021, we had net operating loss, or NOL, carryforwards for federal and state income tax purposes of $159.6 million and $170.2 million, respectively, which begin to expire in 2037. As of December 31, 2021, we also had available tax credit carryforwards for federal and state income tax purposes of $8.6 million and $2.8 million, respectively, which begin to expire in 2034. 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, 2018 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, 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 Internal Revenue 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 may trigger 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, 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. On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security ("CARES Act"), was signed into law. The CARES Act changes certain provisions of the Tax Cuts and Jobs Act of 2017 ("Tax Act").

Under the Tax Act, as modified by the CARES Act, NOLs from tax years that began after December 31, 2017 may offset no more than 80% of current taxable income annually for taxable years beginning after December 31, 2020. Accordingly, if we generate NOLs after the tax year ended December 31, 2017, we might have to pay more federal income taxes in a subsequent year as a result of the 80% taxable income limitation than we would have had to pay under the law in effect before the Tax Act as modified by the CARES Act.

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 Act eliminates the currently available option to deduct research and development expenditures and requires taxpayers to amortize them over five years. The U.S. Congress is considering legislation that would defer the amortization requirement to future periods, however, we have no assurance that the provision will be repealed or otherwise modified.

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 and we have initiated a Phase 2 program initially in ulcerative colitis. We have no products approved for commercial sale and have not generated any revenue from commercial product sales, and we will continue to incur significant research and development and other expenses related to our clinical development and ongoing operations. For the nine months ended September 30, 2022, we reported a net loss of $34.7 million. As of September 30, 2022, we had an accumulated deficit of approximately $272.7 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;
- 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 regulatory approval for our product candidates due to the impacts of COVID-19 or supply chain disruptions (whether as a result of the impact of the COVID-19 pandemic, the ongoing conflict in the Ukraine, inflation, rising interest rates, the ongoing labor shortage or 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 revenues, 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. If 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 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. In addition, we expect to incur increased costs associated with operating as a public company.

Since our inception, we have invested a significant portion of our efforts and financial resources in research and development activities. As of September 30, 2022, we had $371.8 million in cash, cash equivalents and marketable securities. Based on our current operating plan, we believe that our available cash, cash equivalents and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements into the second half of 2025. However, our future capital requirements and the period for which we expect our existing resources to support our operations, fund expansion, develop new or enhanced products, or otherwise respond to competitive

pressures, 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 our 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 potential worsening global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide, including as a result of the COVID-19 pandemic, increase in inflation, rising interest rates, the ongoing labor shortage, disruptions to global supply chains, and the ongoing conflict in the Ukraine and the global sanctions imposed in response thereto. 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-3, our stockholders will 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 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, or 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, or 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.

Our product candidates are in early 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 all of our product candidates are in early 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 an 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 technology in particular or as a result of the impacts of COVID-19; or
- varying interpretations of our data by the FDA and similar foreign regulatory agencies.

We or 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. 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 has informed us that it does not intend to advance any of its selective oral αvβ6-specific integrin inhibitors due to a suspected on-target / αvβ6-mediated safety signal that has been observed in pre-clinical testing. In June 2022, AbbVie informed us that they had decided to exercise their right to terminate the AbbVie Agreement for convenience, subject to a 180 day notification period. The AbbVie Agreement will terminate effective December 2022 or earlier if agreed to by us and AbbVie.

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 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 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. 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, or 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 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 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, or 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. 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 changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes 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 topline or preliminary data from our anticipated clinical trials. Interim data 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 data should be viewed with caution until the final data are available. Adverse differences between interim or 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, 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, or 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 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 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 are well-capitalized and, in contrast to us, have significant clinical experience, and may include our existing or future collaborators. In addition, these companies 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.

Our α4β7 clinical program, initially under development for treatment of IBD, if approved would face competition from approved IBD treatments marketed by AbbVie, Johnson & Johnson, UCB, Biogen Inc., Pfizer Inc., and Bristol-Myers Squibb Company, in addition to other major pharmaceutical companies, against which our product candidate may compete, if approved. Further, Takeda Pharmaceutical Company Ltd. currently markets Entyvio, which is an α4β7 monoclonal antibody to treat ulcerative colitis and Crohn's disease. In addition, we are aware of IBD treatments in clinical development by AbbVie, Johnson & Johnson, Pfizer Inc., Gilead Sciences, Inc., Eli Lilly and Company, Bristol-Myers Squibb Company, Boehringer Ingelheim, and Protagonist Therapeutics, Inc., 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 our product candidates, we may not be successful in commercializing our product candidates if they are approved and we 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 must 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 will be expensive and time consuming and will 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 all or certain of our product candidates, 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 cannot continue to supply their products on commercially reasonable terms, 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 entered into collaborations with AbbVie and Janssen and may, in the future, seek to enter into collaborations with other third parties for the discovery, development and commercialization of our product candidates. If our collaborators cease development efforts under our collaboration agreements, if their scope will be reduced or if any of those agreements are terminated, these collaborations may fail to lead to commercial products and we may never receive milestone payments or future royalties under these agreements.

We have entered into collaborations with AbbVie and Janssen to discover or develop certain integrin-based therapeutics, and such collaborations could represent a significant portion of our product pipeline. In both collaborations, we agreed to conduct research and development activities through the completion of IND-enabling studies, upon which AbbVie and Janssen can exercise their options to develop and commercialize a successful product candidate. We have derived substantially all of our revenue to date from these collaboration agreements, and we may derive a portion of our future revenue from these 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, revenue and cash resources from milestone payments under our collaboration agreements will be substantially less than expected. AbbVie has informed us that it does not intend to advance any of its selective oral αvβ6-specific integrin inhibitors due to a suspected on-target / αvβ6-mediated safety signal that has been observed in pre-clinical testing, and in June 2022, informed us that they had decided to exercise their right to terminate the AbbVie Agreement for convenience, subject to a 180 day notification period. The AbbVie Agreement will terminate effective December 2022 or earlier if agreed to by us and AbbVie. In addition, in December 2021, Janssen informed us that they have decided not to exercise the options on the first two integrin targets under the Janssen Agreement, and we have focused efforts on the third integrin research program which 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, including the recent termination of the AbbVie Agreement, 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 our existing collaboration agreements, and what we expect will be the case with any future collaboration agreements, we have and expect to continue to have 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, including the termination of the AbbVie 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, or the Schrödinger Agreement. Under the collaboration, Schrödinger will use its technology platform to perform virtual screens of members of the target class of human integrins, and we and Schrödinger will 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 delays 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 any additional collaborations we seek, 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 additional collaborations, 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 additional collaborations, 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. Under the terms of the Janssen Agreement, Janssen will assume responsibility for the manufacturing for licensed products. 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. In particular, any replacement of our manufacturer 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 by restrictions resulting from the COVID-19 pandemic, 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, or 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, or medical pandemics such as the COVID-19 pandemic. 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, or 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, or TCA, which was provisionally applicable since January 1, 2021 and has been formally applicable since May 1, 2021. 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. 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). The regulatory regime in Great Britain therefore currently aligns in the most part with EU regulations, however 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 and other outbreaks, including the COVID-19 pandemic, which could significantly disrupt our operations.

Our business could be adversely impacted by the effects of the COVID-19 pandemic or other epidemics or pandemics. If there are closures or other restrictions in places where we or our vendors work or transport supply, we may experience disruptions to our operations. We have and may continue to experience impacts to certain of our suppliers as a result of the COVID-19 pandemic or other health epidemic or outbreak 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 and may continue to experience disruptions, such as temporary closure of the offices of our suppliers and suspension of services, 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 small 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 our 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 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 September 30, 2022, 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, or 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, or 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 inflammatory bowel disease 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, or 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 to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once granted. 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. Further, infections and deaths related to COVID-19 are disrupting certain healthcare and healthcare regulatory systems globally. 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 plan 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. 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 similar 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. For example, in December 2016, the 21st Century Cures Act, or Cures Act, was signed into law. The Cures Act, among other things, is intended to modernize the regulation of drugs and biologics and to spur innovation. 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 prevent, limit or delay regulatory approval of our product candidates. 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, or together, the ACA, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, (i) subjected therapeutic biologics to potential competition by lower-cost biosimilars by creating a licensure framework for follow on biologic products, (ii) proscribed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs and therapeutic biologics that are inhaled, infused, instilled, implanted or injected, (iii) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, (iv) established annual non-deductible fees and taxes on manufacturers of certain branded prescription drugs and therapeutic biologics apportioned among these entities according to their market share in certain government healthcare programs, (v) established a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70% point-of-sale discounts off negotiated prices of applicable brand drugs and therapeutic biologics to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs and therapeutic biologics to be covered under Medicare Part D, (vi) expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals and by adding new mandatory eligibility categories for individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability, (vii) expanded the entities eligible for discounts under the Public Health program, (viii) created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research and (ix) established a Center for Medicare Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

There have been legislative and judicial efforts to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA, including measures taken during the Trump administration. The Tax Act, among other things, includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." In November 2020, the United States Supreme Court held oral arguments on the Fifth Circuit U.S. Court of Appeals decision that held that the individual mandate is unconstitutional. On June 17, 2021, the U.S. Supreme Court dismissed the challenge to the ACA without specifically ruling on the constitutionality of the ACA. Thus, the ACA will remain in effect in its current form. Further, prior to the U.S. Supreme Court ruling, President Biden issued an Executive Order to initiate a special enrollment period from February 15, 2021, through August 15, 2021, for purposes of obtaining health insurance coverage through the ACA marketplace. The Executive Order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is possible that the ACA will be subject to further 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, and the healthcare reform measures of the Biden administration will impact the ACA or our business. Additionally, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on certain

high cost employer-sponsored insurance plans and the medical device excise tax on non-exempt medical devices, and effective January 1, 2021, also eliminates the health insurer tax. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amended the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In addition, CMS published a final rule that would give states greater flexibility, effective January 1, 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted to reduce healthcare expenditures. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect on April 1, 2013 and will remain in effect through 2030 unless additional Congressional action is taken. The CARES Act, which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. The Consolidated Appropriations Act, 2021 extended the suspension of the 2% Medicare sequester through March 31, 2021. 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.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or MMA, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician-administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class. While the MMA only applies to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the MMA may result in a similar reduction in payments from private payors.

Recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several 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. At the federal level, the former Trump administration's budget proposal for fiscal year 2021 included a $135 billion allowance to support legislative proposals seeking to reduce drug process, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower cost generic and biosimilar drugs. In particular, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. The FDA also released a final rule in September 2020 providing guidance for states to build and submit importation plans for drugs from Canada. In July 2021, President Biden issued an executive order supporting the importation of drugs from Canada as an effort to reduce prescription drug costs, requesting that the Department of Health and Human Services develop a plan to address drug pricing by the end of the summer of 2021 and encouraging the Federal Trade Commission to use its rulemaking authority to combat unfair anticompetitive conduct related to the introduction of generic drugs and biosimilars to the market.

Further, in November 2020, 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 CMS also issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest

price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the United States District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. 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. On September 9, 2021, the Biden Administration published a wide-ranging list of policy proposals, most of which would need to be carried out by Congress, to reduce drug prices and drug payment. The HHS plan includes, among other reform measures, proposals to lower prescription drug prices, including by allowing Medicare to negotiate prices and disincentivizing price increases, and to support market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase price transparency. These initiatives recently culminated in the enactment of the Inflation Reduction Act, or IRA, in August 2022, which will, among other things, allow HHS to negotiate the selling price of certain drugs and biologics that CMS reimburses under Medicare Part B and Part D, although this will only apply to high-expenditure single-source drugs that have been approved for at least 7 years (11 years for biologics). The negotiated prices, which will first become effective in 2026, will be capped at a statutory ceiling price beginning in October 2023, penalize drug manufacturers that increase prices of Medicare Part B and Part D drugs at a rate greater than the rate of inflation. 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, 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 will take effect progressively starting in 2023, although they may be subject to legal challenges. It is unclear to what extent these new regulations 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.

At the state level, legislatures are increasingly passing legislation 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. We expect that additional state and federal healthcare reform measures will 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, 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 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, as amended by HITECH, and their 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) 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, such as those of California and Massachusetts, that impose restrictive requirements regulating the use and disclosure of health information and other personally identifiable information (for example, in June 2018, California enacted the California Consumer Privacy Act, which became effective on January 1, 2020, and the California Privacy Rights Act, or CPRA, which modifies the CCPA and creates additional obligations beginning on January 1, 2022) that gives California residents expanded rights to access and delete their 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 for data breaches that is expected to increase data breach litigation; resulting in increased compliance costs and potential liability);
- 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 programs are in the early 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 some 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 opportunities for grant funding toward clinical trial costs, 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%. Thus, further limiting 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, or 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. In addition, as a result of Brexit, there will be a transition period until a comprehensive trade agreement between the U.K. and EU is negotiated by year-end 2020. Beginning in 2021, the U.K. became a "third country" under the GDPR. We may, however, incur liabilities, expenses, costs, and other operational losses under GDPR and applicable EU Member States and the U.K. privacy laws in connection with any measures we take to comply with them.

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 provisions of the Data Protection Directive, and as of May 2018, the General Data Protection Regulation, or GDPR. These directives impose 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. The Data Protection Directive and GDPR also impose strict rules on the transfer of personal data out of the EU to the United States. In addition, the GDPR increases the scrutiny

of transfers of personal data from clinical trial sites located in the European Economic Area to the United States and other jurisdictions that the European Commission does not recognize as having "adequate" data protection laws. For example, following a decision of the Court of Justice of the EU in October 2015, the transfer of personal data to U.S. companies that had certified as members of the U.S. Safe Harbor Scheme, was declared invalid. In July 2016, the European Commission adopted the EU-U.S. Privacy Shield Framework, or the Privacy Shield Framework, which replaced the U.S. Safe Harbor Scheme. On July 16, 2020, the Court of Justice of the European Union issued a decision that declared the Privacy Shield Framework invalid, and will also result in additional compliance obligations for companies that implement standard contractual clauses to ensure a valid basis for the transfer of personal data outside of Europe. On November 10, 2020, the European Data Protection Board issued recommendations on the additional safeguards required for standard contractual clauses to be valid. It is possible that the ability to transfer personal data from the European Union to the United States will be 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 Data Protection Directive, the GDPR, and the related national data protection laws of the EU Member States 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. The 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 is significant uncertainty related to the manner in which data protection authorities will seek to enforce compliance with GDPR is not yet clear. 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. Further, Brexit has created uncertainty with regard to data protection regulation in the U.K. The U.K. enacted the Data Protection Act 2018 to directly enforce the GDPR.

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.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, 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 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 global pandemics such as COVID-19, the ongoing conflict in the Ukraine, inflation, rising interest rates, and the ongoing labor shortage.

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 may be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. The trading prices for our common stock and the common stock of other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic among other factors. 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:

- 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, such as the ongoing conflict in the Ukraine;
- natural disasters and other calamities, including global pandemics, such as COVID-19; and
- general economic, industry and market conditions, including inflation, rising interest rates, and the ongoing labor shortage.

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, including as a result of the COVID-19 pandemic, increase in inflation, rising interest rates, disruptions to global supply chains, and the ongoing conflict in the Ukraine and the global sanctions imposed in response thereto, 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. Additionally, market volatility arising from the COVID-19 pandemic 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 warrant or 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 to 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 after delivering 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 at this stage to predict the number of shares that will be ultimately issued, if any. 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 shelf registration statement on Form S-3, 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 September 30, 2022, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 50% 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 restated bylaws, as amended, 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 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, or the DGCL, our restated certificate of incorporation, or our 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, or 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. Section 404 of the Sarbanes-Oxley Act also generally requires an attestation from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting.

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, or 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 Securities Exchange Act of 1934, as amended, or 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.

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***

None

Item 6. ***Exhibits***

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

Exhibit Number	Description	Form	File No.	Exhibit Filing Date	Filed/Furnished Herewith
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.

November 2, 2022 By: /s/ Praveen P. Tipirneni
Praveen P. Tipirneni, M.D.
Chief Executive Officer and Director
(Principal Executive Officer)

November 2, 2022 By: /s/ Marc Schegerin
Marc Schegerin, M.D.
Chief Financial Officer and Chief Operating Officer
(Principal Financial Officer)

November 2, 2022 By: /s/ Robert E. Farrell, Jr.
Robert E. Farrell, Jr., CPA
Chief Accounting Officer and Assistant Treasurer
(Principal Accounting Officer)

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: November 2, 2022

/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: November 2, 2022

/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 September 30, 2022 (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: November 2, 2022

/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 September 30, 2022 (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: November 2, 2022

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