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, 2019
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** (Address of Principal Executive Offices)	**02451** (Zip Code)

Registrant's telephone number, including area code: **(781) 996-0955**

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 November 11, 2019 was 30,483,521.

MORPHIC HOLDING, INC.
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FOR THE QUARTER ENDED September 30, 2019

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, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 159,807	$ 185,901
Marketable securities	91,939	—
Accounts receivable	2,364	—
Prepaid expenses and other current assets	2,926	1,222
Total current assets	257,036	187,123
Property and equipment, net	2,716	1,843
Restricted cash	275	275
Other assets	52	64
Total assets	$ 260,079	$ 189,305
Liabilities		
Current liabilities:		
Accounts payable	$ 3,285	$ 1,745
Accrued expenses	5,051	3,239
Deferred revenue, current portion	18,063	29,862
Deferred rent, current portion	80	57
Total current liabilities	26,479	34,903
Long-term liabilities:		
Deferred revenue, net of current portion	74,010	66,781
Deferred rent, net of current portion	242	306
Other long-term liabilities	—	58
Total liabilities	100,731	102,048
Commitments and contingencies (Note 9)	—	—
Preferred shares:		
Series Seed preferred shares, $0.0001 par value, no shares authorized, issued, and outstanding as of September 30, 2019, and 11,967,689 shares authorized, 2,045,556 shares issued and outstanding as of December 31, 2018 (aggregate liquidation preference of $8,980 at December 31, 2018)	—	8,658
Series A preferred shares, $0.0001 par value, no shares authorized, issued, and outstanding as of September 30, 2019 and 49,047,619 shares authorized, 8,411,368 shares issued and outstanding as of December 31, 2018 (liquidation preference of $51,500 as of December 31, 2018)	—	51,320
Series B preferred shares, $0.0001 par value, no shares authorized, issued, and outstanding as of September 30, 2019 and 61,538,454 shares authorized, 10,553,483 shares issued and outstanding as of December 31, 2018 (liquidation preference of $80,000 as of December 31, 2018)	—	79,831
Stockholders' Equity (Deficit)		
Preferred shares, $0.0001 par value, 10,000,000 shares authorized, no shares issued and outstanding as of September 30, 2019 and December 31, 2018	—	—
Common shares, $0.0001 par value, 400,000,000 shares authorized, 30,034,268 shares issued and outstanding as of September 30, 2019 and 151,000,000 shares authorized and 1,832,923 shares issued and outstanding as of December 31, 2018	3	—
Additional paid-in capital	236,980	1,633
Accumulated deficit	(77,682)	(54,185)
Accumulated other comprehensive income	47	—
Total stockholders' equity (deficit)	159,348	(52,552)
Total liabilities, preferred shares, and stockholders' equity (deficit)	$ 260,079	$ 189,305

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 unit, share, per unit, and per share data)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Collaboration revenue - related party	$ 3,772	$ —	$ 13,736	$ —
Collaboration revenue - other	1,903	—	3,575	—
	5,675	—	17,311	—
Operating expenses:				
Research and development	12,635	5,767	36,912	15,344
General and administrative	2,898	1,405	6,807	3,311
Total operating expenses	15,533	7,172	43,719	18,655
Loss from operations	(9,858)	(7,172)	(26,408)	(18,655)
Other income:				
Interest income, net	1,392	111	3,574	214
Other expense, net	(94)	(16)	(94)	(46)
Total other income, net	1,298	95	3,480	168
Loss before provision for income taxes	(8,560)	(7,077)	(22,928)	(18,487)
Provision for income taxes	(304)	—	(569)	—
Net loss	$ (8,864)	$ (7,077)	$ (23,497)	$ (18,487)
Net loss per share, basic and diluted	$ (0.30)		$ (2.06)	
Net loss per unit, basic and diluted		$ (7.00)		$ (18.28)
Weighted average common shares outstanding, basic and diluted	29,999,170		11,393,192	
Weighted average common units outstanding, basic and diluted		1,011,227		1,011,227
Comprehensive loss:				
Net loss	$ (8,864)	$ (7,077)	$ (23,497)	$ (18,487)
Other comprehensive income (loss):				
Unrealized holding gains on marketable securities, net of tax	6	—	47	—
Comprehensive loss	$ (8,858)	$ (7,077)	$ (23,450)	$ (18,487)

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

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

	Series Seed Convertible Preferred Units		Series A Convertible Preferred Units		Series B Convertible Preferred Units		Common Units		Additional Paid-in	Accumulated	Total Stockholders'
	Units	Amount	Units	Amount	Units	Amount	Units	Amount	Capital	Deficit	Deficit
Balance at December 31, 2017	**2,045,556**	**$ 8,658**	**6,729,096**	**$ 41,029**	**—**	**$ —**	**1,011,227**	**$ —**	**$ 661**	**$ (30,354)**	**$ (29,693)**
Equity-based compensation expense	—	—	—	—	—		—	—	123	—	123
Net Loss	—	—	—	—	—		—	—	—	(5,179)	(5,179)
Balance at March 31, 2018	**2,045,556**	**8,658**	**6,729,096**	**41,029**	**—**	**$ —**	**1,011,227**	**—**	**784**	**(35,533)**	**(34,749)**
Equity-based compensation expense	—	—	—	—	—	—	—	—	135	—	135
Net Loss	—	—	—	—	—	—	—	—	—	(6,231)	(6,231)
Balance at June 30, 2018	**2,045,556**	**8,658**	**6,729,096**	**41,029**	**—**	**—**	**1,011,227**	**—**	**919**	**(41,764)**	**(40,845)**
Equity-based compensation expense	—	—	—	—	—	—	—	—	136	—	136
Net Loss	—	—	—	—	—	—	—	—	—	(7,077)	(7,077)
Issuance of Series A Preferred Units August 10, 2018, net of offering costs of $9	—	—	1,682,272	10,291	—	—	—	—	—	—	
Issuance of Series B Preferred Units September 25, 2018, net of offering costs of $169	—	—	—	—	10,553,483	79,831	—	—	—	—	—
Balance at September 30, 2018	**2,045,556**	**$ 8,658**	**8,411,368**	**$ 51,320**	**10,553,483**	**$ 79,831**	**1,011,227**	**$ —**	**$ 1,055**	**$ (48,841)**	**$ (47,786)**

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

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

	Series Seed Convertible Preferred Shares		Series A Convertible Preferred Shares		Series B Convertible Preferred Shares		Common Shares		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income	Total Stockholders' (Deficit)/Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2018	**2,045,556**	**$ 8,658**	**8,411,368**	**$ 51,320**	**10,553,483**	**$ 79,831**	**1,832,923**	**$ —**	**$ 1,633**	**$ (54,185)**	**$ —**	**$ (52,552)**
Vesting of restricted shares	—	—	—	—	—	—	99,911	—	—	—	—	—
Equity-based compensation expense	—	—	—	—	—	—	—	—	499	—	—	499
Unrealized holding gains on marketable securities, net of tax	—	—	—	—	—	—	—	—	—	—	25	25
Net loss	—	—	—	—	—	—	—	—	—	(5,200)	—	(5,200)
Balance at March 31, 2019	**2,045,556**	**8,658**	**8,411,368**	**51,320**	**10,553,483**	**79,831**	**1,932,834**	**—**	**2,132**	**(59,385)**	**25**	**(57,228)**
Vesting of restricted shares	—	—	—	—	—	—	112,165	—		—	—	
Equity-based compensation expense	—	—	—	—	—	—		—	667	—	—	667
Unrealized holding gains on marketable securities, net of tax	—	—	—	—	—	—		—	—	—	16	16
Net loss	—	—	—	—	—	—	—	—	—	(9,433)	—	(9,433)
Balance at June 30, 2019	**2,045,556**	**8,658**	**8,411,368**	**51,320**	**10,553,483**	**79,831**	**2,044,999**	**—**	**2,799**	**(68,818)**	**41**	**(65,978)**
Conversion of convertible preferred stock into common stock	(2,045,556)	(8,658)	(8,411,368)	(51,320)	(10,553,483)	(79,831)	21,010,407	2	139,807	—	—	139,809
Reclassification of warrants to purchase preferred shares to stockholders' equity	—	—	—	—	—	—	—	—	118	—	—	118
Issuance of common shares at initial public offering, net of offering costs of $10.2 million	—	—	—	—	—	—	6,900,000	1	93,267	—	—	93,268
Issuance of common shares upon warrants exercise	—	—	—	—	—	—	5,766	—	—	—	—	—
Vesting of restricted shares	—	—	—	—	—	—	73,096	—	—	—	—	—
Equity-based compensation expense	—	—	—	—	—	—	—	—	989	—	—	989
Unrealized holding gains on marketable securities, net of tax	—	—	—	—	—	—	—	—	—	—	6	6
Net loss	—	—	—	—	—	—	—	—	—	(8,864)	—	(8,864)
Balance at September 30, 2019	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**30,034,268**	**$ 3**	**$ 236,980**	**$ (77,682)**	**$ 47**	**$ 159,348**

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

	Nine Months Ended September 30,	
	2019	2018
Cash flows from operating activities:		
Net loss	$ (23,497)	$ (18,487)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	576	395
Premium amortization and discount accretion on marketable securities	(1,556)	—
Equity-based compensation	2,155	394
Non-cash interest expense	—	26
Change in fair value of warrants	94	—
Change in operating assets and liabilities:		
Accounts receivable	(2,364)	—
Prepaid expenses and other current assets	(1,704)	8
Other assets	12	(9)
Accounts payable	1,540	864
Accrued expenses	1,812	591
Deferred revenue	(4,570)	—
Deferred rent	(41)	(17)
Other long-term liabilities	(33)	13
Net cash used in operating activities	(27,576)	(16,222)
Cash flows from investing activities:		
Purchases of marketable securities	(225,836)	—
Proceeds from maturities of marketable securities	135,500	—
Purchase of property and equipment	(1,449)	(492)
Net cash used in investing activities	(91,785)	(492)
Cash flows from financing activities:		
Repayment of debt	—	(247)
Proceeds from issuance of Common Stock, net	93,267	—
Proceeds from issuance of Preferred Stock, net	—	90,122
Net cash provided by financing activities	93,267	89,875
Net (decrease) increase in cash and cash equivalents and restricted cash	(26,094)	73,161
Cash and cash equivalents and restricted cash, beginning of period	186,176	21,025
Cash and cash equivalents and restricted cash, end of period	$ 160,082	$ 94,186
Non-cash financing activities:		
Reclassification of warrants to additional paid-in capital	118	—
Conversion of preferred shares to common stock	$ 139,807	$ —
Supplemental cash flow information:		
Cash paid for taxes	550	—
Cash paid for interest	$ —	$ 19

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

Morphic Holding, Inc. was formed under the laws of the State of Delaware in August 2014 under the name Integrin Rock, LLC. The Company subsequently changed its name to Morphic Rock Holding, LLC in October 2014 and then to Morphic Holding, LLC in June 2016. On December 5, 2018, the Company completed a series of transactions (the "Reorganization") pursuant to which Morphic Holding, LLC was converted in a tax free reorganization into Morphic Holding, Inc. and three wholly-owned subsidiaries, namely Lazuli, Inc., Tourmaline, Inc, and Phyllite, Inc, were merged with and into another wholly-owned subsidiary, Morphic Therapeutic, Inc. As part of the Reorganization, all convertible preferred units and common units of Morphic Holding, LLC issued and outstanding immediately prior to the Reorganization were exchanged for shares of Morphic Holding Inc. capital stock of the same class or series on a one-for-one basis. Previously outstanding vested and unvested incentive units, irrespective of threshold amounts (defined as the fair value of common unit on the date the incentive unit award is granted) or voting rights, were exchanged for an equal number of shares of common stock or restricted common stock, respectively. The restricted common stock was issued with the same vesting terms as the unvested incentive units held immediately prior to the Reorganization.

Upon consummation of the Reorganization, the historical consolidated financial statements of Morphic Holding, LLC became the historical consolidated financial statements of Morphic Holding Inc. Except as otherwise indicated or the context otherwise requires, all information included in this filing is presented giving effect to the Reorganization. At the time of the Reorganization, the Company created a Massachusetts Securities Corporation (the "Security Corporation") to take advantage of the favorable tax treatment of income earned on securities held within such entity. As of September 30, 2019, all of the Company's excess funds were invested through the Security Corporation.

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 our 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 and 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.

On July 1, 2019, the Company completed an IPO, in which the Company issued and sold 6,900,000 shares of its common stock at a public offering price of $15.00 per share, including 900,000 shares of common stock sold pursuant to the underwriters' exercise of their option to purchase additional shares of common stock, for aggregate gross proceeds of $103.5 million. The Company raised approximately $93.3 million in net proceeds after deducting underwriting discounts and commissions and offering expenses payable by the Company. Upon the closing of the IPO, all of the outstanding shares of convertible preferred stock automatically converted into 21,010,407 shares of common stock; the warrants to purchase 6,825 convertible preferred shares automatically converted in to warrants to purchase 6,825 common shares. Subsequent to the closing of the IPO, there were no shares of preferred stock outstanding. In connection with the closing

of the IPO, the Company amended and restated its Fourth Amended and Restated Certificate of Incorporation to change the authorized capital stock to 400,000,000 shares designated as common stock, and 10,000,000 shares designated as preferred stock, all with a par value of $0.0001 per share.

Basis of Presentation

The consolidated financial statements include the accounts of Morphic Holding, Inc. and its wholly owned subsidiaries described above. All intercompany balances have been eliminated in consolidation.

These condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative United States generally accepted accounting principles as found in the Accounting Standards Codification ("ASC") and Accounting Standards Update ("ASU") of the Financial Accounting Standards Board ("FASB").

The unaudited interim financial statements have been prepared on the same basis as the audited annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary for the fair presentation of the Company's financial position as of September 30, 2019 and the results of its operations for the three and nine months ended September 30, 2019 and 2018 and its cash flows for the nine months ended September 30, 2019 and 2018. Financial statement disclosures for the nine months ended September 30, 2019 and 2018 are condensed and do not include all disclosures required for an annual set of financial statements in accordance with GAAP and should be read in conjunction with the Company's audited financial statements and notes in the prospectus filed with the Securities and Exchange Commission on June 27, 2019. The results for the three and nine months ended September 30, 2019 are not necessarily indicative of results to be expected for the year ended December 31, 2019, any other interim periods, or any future year or period.

2. Summary of Significant Accounting Policies

Use of Estimates and Judgements

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, including incentive units, restricted common stock, and stock options, and income taxes. Actual results could differ from those estimates.

Concentration of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash and cash equivalents, marketable securities, and accounts receivable under Janssen agreement. The Company has all cash and cash equivalents at one accredited financial institution, in amounts that exceed federally insured limits. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The primary objectives for the Company's investment portfolio are the preservation of capital and maintenance of liquidity. In 2019, the Company adopted its investment policy which allows funds to be held outside bank accounts, but to be invested only in readily marketable fixed income instruments with readily ascertainable market values, denominated and payable in U.S. dollars including obligations of the U.S. government and its agencies and money market funds registered according to Rule 2a-7 of the Investment Company Act of 1940. Investments in the money market fund shall be consistent with approved instruments and assets under management must be at least $1 billion.

The Company has no off-balance sheet risk, such as foreign exchange contracts, option contracts, or other foreign-hedging arrangements.

Cash and Cash Equivalents and Restricted Cash

The Company considers highly liquid investments with a maturity of three months or less when purchased to be cash equivalents. At September 30, 2019, cash and cash equivalents include bank demand deposits and money market funds that invest primarily in U.S. government-backed securities and treasuries. Cash equivalents are stated at fair value.

Restricted cash consists of a letter of credit in the amount of $275,000 issued to the landlord of the Company's facility lease. The terms of the letter of credit extend beyond one year. The following table reconciles cash and cash equivalents and restricted cash per the balance sheet to the statements of cash flows:

	September 30, 2019	December 31, 2018	September 30, 2018	December 31, 2017
Cash and cash equivalents	$ 159,807	$ 185,901	$ 93,911	$ 20,750
Restricted cash	275	275	275	275
	$ 160,082	$ 186,176	$ 94,186	$ 21,025

Marketable securities

The Company invests funds in the United States Treasury securities; those securities are included in the current assets based on their contractual maturities, classified as available-for-sale, and carried at fair value. Changes in fair value of marketable securities are recorded in other comprehensive income (loss) as net unrealized gains (losses) on marketable securities. The Company recognized $6,000 and $47,000 in unrealized gains, net for the three and nine months ended September 30, 2019, respectively. The Company held no marketable securities prior to 2019.

Interest income on investments

The Company recognizes interest income from investments in money market funds and available-for-sale securities, including amortization of premium/accretion of discount, on an accrual basis. For the three and nine months ended September 30, 2019**,** the Company recognized $1.4 million and $3.6 million in interest income, respectively. For the three and nine months ended September 30, 2018, the Company recognized $111,000 and $214,000 in interest income, respectively.

Interest income is included with other income on the condensed consolidated statements of operations and comprehensive loss.

Fair Value Measurements

ASC Topic 820, *Fair Value Measurement* ("ASC 820"), establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. ASC 820 identifies fair value as the exchange price, or exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a three-tier fair value hierarchy that distinguishes between the following:

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.

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

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

Comprehensive Loss

Comprehensive loss is the change in equity of a business enterprise during a period from transactions and other events and circumstances from non-owner sources. Comprehensive loss includes net loss and the change in accumulated other comprehensive loss for the period. For the three and nine months ended September 30, 2019, comprehensive loss included $6,000 and $47,000 in unrealized holding gains on marketable securities, respectively; for the three and nine months ended September 30, 2018, comprehensive loss equaled net loss.

Recently Adopted Accounting Pronouncements

In January 2016, the FASB issued ASU 2016-01, Financial Instruments — Overall (Subtopic 825-10): Recognition and Measurement of Financial Assets and Financial Liabilities ("ASU 2016-01), which amended the guidance on the recognition and measurement of financial assets and financial liabilities. The new guidance requires that equity investments (except those accounted for under the equity method of accounting, or those that result in consolidation of the investee) are measured at fair value with changes in fair value recognized in net income. The guidance also requires the use of an exit price when measuring the fair value of financial instruments for disclosure purposes, eliminates the requirement to disclose the methods and significant assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at amortized cost and requires separate presentation of financial assets and financial liabilities by measurement category and form of financial asset. The guidance became effective for the Company for the fiscal year beginning January 1, 2019, including interim periods within that fiscal year. Adoption of ASU 2016-01 did not have a material impact on the Company's consolidated financial statements.

Recently Issued Accounting Pronouncements not yet Adopted

As an "emerging growth company," or EGC, under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, the Company has made an election under Section 107 of the JOBS Act to take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. Thus, the Company follows requirements applicable to the private companies for adopting new and updated accounting standards.

In April 2019, the FASB issued ASU 2019-04, *Financial Instruments-Credit Losses*, Topic 815, *Derivatives and Hedging*, and Topic 825, *Financial Instruments* ("ASU 2019-04"). Certain provisions of ASU 2019-04 amend the guidance of ASU 2016-13, are applicable to the Company's investments portfolio, and allow the Company to make certain accounting policy elections regarding establishing allowance for credit losses for the accrued interest receivable and the corresponding disclosures. The guidance is effective for the fiscal year beginning January 1, 2021, and interim periods within the fiscal year beginning January 2022 and will be adopted using the modified retrospective approach. The Company is currently evaluating the impact of ASU 2019-04 on the consolidated financial statements, including the impact of the available accounting policy elections.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments Credit Losses* (Topic 326) ("ASU 2016-13"), which requires consideration of a broader range of reasonable and supportable information in developing credit loss estimates. The guidance is effective for the fiscal year beginning January 1, 2021, and interim periods within the fiscal year beginning January 2022 and will be adopted using modified-retrospective approach. The Company is currently evaluating the impact of ASU 2016-13, as amended by ASU 2019-04 described above, on its consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases* (Topic 842), with guidance regarding the accounting for and disclosure of leases. This standard is effective for public companies for annual and interim periods beginning after December 15, 2018. For all other entities, this standard is effective for annual reporting periods beginning after December 15, 2019, and interim periods within annual periods beginning after December 15, 2020.

In general, for lease arrangements exceeding a twelve-month term, these arrangements must now be recognized as assets and liabilities on the balance sheet of the lessee. Under ASU 2016-02, a right-of-use asset and lease obligation will be recorded for all leases, whether operating or financing, while the income statement will reflect lease expense for operating leases and amortization/interest expense for financing leases. The balance sheet amount recorded for existing leases at the date of adoption of ASU 2016-02 must be calculated using the applicable incremental borrowing rate at the date of adoption. This update also requires lessees and lessors to disclose key information about their leasing transactions.

The Company currently expects to elect the available package of practical expedients which allows the Company to not reassess previous accounting conclusions around whether arrangements are or contain leases, the classification of leases, and the treatment of initial direct costs. The Company also expects it will make an accounting policy election to keep leases with an initial term of 12 months or less off of the balance sheet.

In July 2018, the FASB issued ASU 2018-11, *Leases - Targeted Improvements*, intended to ease the implementation of the new lease standard for financial statement preparers by, among other things, allowing for an additional transition method. In lieu of presenting transition requirements to comparative periods, as previously required, an entity may now elect to show a cumulative effect adjustment on the date of adoption without the requirement to recast prior period financial statements or disclosures presented in accordance with ASU 2016-02. The Company expects to adopt the new standard and elect to use the optional transition method, resulting in no retrospective adjustment to the prior period financial information, effective January 1, 2020, which will be the initial date of application. The Company is in the process of assessing the impact of the standard and while not complete, it expects that it will record a material asset and liability related to its current operating lease, however, the full impact of adoption to the Company's financial statements is yet to be determined.

The Company has considered other recent accounting pronouncements and concluded that they are either not applicable to the business, or that the effect is not expected to be material to the consolidated financial statements as a result of future adoption.

3. Fair Value of Financial Assets and Liabilities

The following tables summarize the assets and liabilities measured at fair value on a recurring basis at September 30, 2019 and December 31, 2018 (in thousands):

	Fair Value Measurements at September 30, 2019			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds, included in cash and cash equivalents	$ 159,583	$ 159,583	$ —	$ —
U.S. Treasury obligations	91,939	—	91,939	—
Total assets	$ 251,522	$ 159,583	$ 91,939	$ —

	Fair Value Measurements at December 31, 2018			
	Total	Level 1	Level 2	Level 3
Assets:				
Money market funds, included in cash and cash equivalents	$ 185,676	$ 185,676	$ —	$ —
Total assets	$ 185,676	$ 185,676	$ —	$ —

The money market funds included in the table 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, 2019 and December 31, 2018. Marketable securities, included in the table above, consist exclusively of U.S. Treasury securities that are valued using matrix pricing compiled by third party pricing vendors, using observable market inputs such as interest rates, yield curves, and credit risk. Accordingly, these securities are categorized as Level 2 as of September 30, 2019. The Company held no marketable securities as of December 31, 2018.

4. Marketable securities

As of September 30, 2019, the Company had the following investments in marketable securities classified as available for sale (in thousands):

	Maturity	Amortized cost	Gross unrealized holding gains	Gross unrealized holding losses	Aggregate estimated fair value
U.S. Treasury securities	less than 1 year	$ 91,879	$ 60	$ -	$ 91,939

As of September 30, 2019, the Company held no marketable securities in an unrealized loss position. The Company did not have any investments in marketable securities at December 31, 2018.

5. Accrued Expenses

At September 30, 2019 and December 31, 2018 accrued expenses consist of the following (in thousands):

	September 30, 2019	December 31, 2018
Payroll and related expenses	2,099	2,012
Research and development activities	1,785	512
Other expenses	1,167	715
	$ 5,051	$ 3,239

6. Stockholders' Equity

Immediately prior to the closing of the IPO, the Company had 2,585,976 common shares, including 540,977 restricted common shares, and 21,010,407 convertible preferred shares outstanding; all convertible preferred shares automatically converted into 21,010,407 shares of common stock upon closing of the IPO. As of September 30, 2019, the Company had 400,000,000 common shares authorized and 30,034,268 common shares issued and outstanding and 10,000,000 preferred shares authorized, none of which were outstanding.

Cashless Exercise of Warrants

In connection with a credit facility entered into in 2016, on March 31, 2016, the Company issued a warrant to SVB to purchase 3,409 Series Seed convertible preferred units at a purchase price of $4.39 per unit, and on December 31, 2016 the Company issued a warrant to purchase 3,416 Series Seed preferred units at a purchase price of $4.39, which became exercisable for 6,825 shares of common stock at a purchase price of $4.39 per share in connection with the IPO. The credit facility was paid off in full by the Company in 2018. In August 2019, SVB exercised warrants via a cashless exercise and the Company issued 5,766 common shares.

Shares Reserved for Future Issuance

As of September 30, 2019, the Company had reserved common shares for future issuance under the 2019 Stock Option and Incentive Plan and the 2019 Employee Stock Purchase Plan (described in note 7 below) as follows:

	As of September 30, 2019
Common shares reserved for issuance under the 2019 ESPP	300,000
Common shares reserved for exercise of outstanding stock options under the 2019 Plan	2,680,835
Common shares reserved for future issuance under the 2019 Plan	2,374,981
	5,355,816

7. Equity Based Compensation

2019 Stock Incentive Plan

The 2019 Stock Incentive Plan (the "2019 Plan") was approved by the Board of Directors on June 10, 2019 and replaced the 2018 Stock Incentive Plan (the "2018 Plan"), previously instituted as part of the Reorganization. The 2018 Plan provided for the grant of incentive stock options, non-qualified stock options, and restricted stock awards. As of December 31, 2018, there were 3,818,816 shares authorized under the 2018 Plan and 457,438 shares were reserved for future issuance. The 2019 Plan provides for the grant of stock options, restricted stock awards, stock bonus awards, cash awards, stock appreciation right, RSUs, and performance awards to purchase up to 2.8 million shares of common stock. The number of shares reserved for issuance under the Company's 2019 Plan will increase automatically on January 1 of each of 2020 through 2029 by the number of shares equal to the lesser of 4% of the aggregate number of outstanding shares of the Company's common stock as of the immediately preceding December 31, or a number as may be determined by the Company's board of directors. The 2019 Plan is administered by the Board of Directors, or at the discretion of the Board of Directors, by a committee of the board. The exercise prices, vesting, and other restrictions are determined at the discretion of the Board of Directors, or a committee if so delegated, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the share of common stock on the date of grant and the term of stock option may not be greater than ten years. The shares of common stock underlying any awards that are forfeited, cancelled, repurchased, or are otherwise terminated by the Company under the 2019 Plan will be added back to the shares of common stock available for issuance under the 2019 Plan. Options generally vest over a four-year period with the first 25% vesting following 12 months of employment or service and the remaining award vesting in equal monthly installments over the following 36 months. All options have a contractual term of 10 years.

Restricted Common Stock

The following table summarizes the stock and restricted common stock activity under the 2019 Plan during the nine months ended September 30, 2019:

	Number of Shares	Weighted Average Fair Value per Share at Issuance
Unvested restricted common stock as of December 31, 2018	753,053	$ 4.32
Granted	—	$ —
Vested	(285,172)	$ 4.32
Forfeited	(18,628)	$ 4.32
Unvested restricted common stock as of September 30, 2019	449,253	$ 4.32

As of September 30, 2019, the Company had unrecognized equity-based compensation expense of $1,119,000, which includes $392,000 related to the modification affected as part of the Reorganization for the restricted common shares issued to employees and non-employees, which is expected to be recognized over a weighted average period of 1 year. The Company recognized equity-based compensation expense for the restricted common stock of $162,000 and $577,000 during the three and nine months ended September 30, 2019, respectively. The Company recognized equity-based expense for the restricted incentive units of $136,000 and $394,000 during the three and nine months ended September 30, 2018, respectively.

Stock Options

The Company granted stock option awards under the 2019 Plan. The following table summarizes the Company's stock option activity under the 2019 Plan during the nine months ended September 30, 2019:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2018	1,786,551	$ 4.32	9.96	$ —
Granted	907,178	14.73	—	—
Exercised	—	—	—	—
Forfeited	(12,894)	4.32	—	—
Outstanding as of September 30, 2019	2,680,835	$ 7.84	9.39	$ 28,098
Options exercisable as of September 30, 2019	325,651	$ 4.44	9.21	$ 4,452

The weighted average grant-date fair value per share of stock options granted to employees and non-employees for stock option awards with service-based vesting conditions during the nine months ended September 30, 2019 was $9.75 per share.

The following table summarizes assumptions used in determining the fair value of the options granted in 2019:

Risk-free interest rate	1.91
Expected dividend yield	—
Expected term (in years)	6.01
Expected Volatility	74.96%

The Company determined the volatility for options granted in 2019 based on reported data for a guideline group of companies that issued options with substantially similar terms. The risk-free interest rate is based on a zero-coupon United States Treasury instrument with terms consistent with the expected life of the stock options. The expected term of options granted by us has been determined based upon the simplified method, because we do not have sufficient historical information regarding our options to derive the expected term. Under this approach, the expected term is the mid-point between the weighted average of vesting period and the contractual term. The Company has not paid and does not anticipate paying cash dividends on shares of common stock; therefore, the expected dividend yield is assumed to be zero.

Compensation Expense related to Stock Options

The Company recorded equity-based compensation expense for stock options granted to employees and non-employees of $707,000 and $1,457,000 for the three and nine months ended September 30, 2019, respectively. The Company did not recognize equity-based compensation expense related to stock options for the three and nine months ended September 30, 2018 as no such awards were granted and outstanding as of September 30, 2018.

As of September 30, 2019, the Company had unrecognized equity-based compensation expense of $12.4 million related to stock options issued to employees and non-employees, which is expected to be recognized over a weighted average period of 3.36 years.

2019 Employee Stock Purchase Plan

In June 2019, the Company adopted the 2019 Employee Stock Purchase Plan ("ESPP"), which became effective on June 26, 2019. The Company initially reserved 300,000 shares of common stock for sale under the ESPP. The number of shares reserved for issuance under the ESPP will increase automatically on January 1st of each of the first 10 calendar years following the first offering date by the number of shares equal to the lesser of 1% of the total outstanding shares of the Company's common stock as of the immediately preceding December 31 or an amount determined by the Company's board of directors. The aggregate number of shares issued over the term of the ESPP will not exceed 3,000,000 shares of the Company's common stock. The ESPP is a qualified, compensatory plan under Section 423 of the Internal Revenue Code and offers substantially all employees opportunity to purchase up to $25,000 of common stock per year at 15% discount to the lower of the beginning of the offering period price or the end of the offering period price.

Compensation expense for discounted purchases under the ESPP is measured using the Black-Scholes model to compute the fair value of the lookback provision plus the purchase discount and is recognized as compensation expense over the course of the offering period.

During the three and nine months ended September 30, 2019, the Company granted awards with the weighted average grant date fair value of $5.30 and recognized $120,000 in compensation expense related to the discount offered under the 2019 ESPP. The Company recognized no expense in the comparable periods of 2018.

Total Equity-based Compensation Expense

The Company recorded equity-based compensation expense related to all equity-based awards for employees and non-employees, which was allocated as follows in the condensed consolidated statements of operations (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development expense	$ 586	$ 81	$ 1,287	$ 230
General and administrative expense	403	55	867	164
	$ 989	$ 136	$ 2,154	$ 394

8. Income Taxes

The Company records income tax expense in any interim period based on the estimated effective tax rate for the fiscal year for those tax jurisdictions in which the Company can reliably estimate that rate. The calculation of the estimated effective tax rate requires an estimate of pre-tax income by tax jurisdiction as well as total tax expense for the fiscal year. Accordingly, the annual estimated effective tax rate is subject to adjustment if there are changes to the initial estimates of total tax expense or pre-tax income.

Provision for Income Taxes

The Company recorded an income tax expense of $304,000 and $0 for the three months ended September 30, 2019 and 2018, respectively. The Company recorded an income tax expense of $569,000 and $0 for the nine months ended September 30, 2019 and 2018, respectively. In the three and nine months ended September 30, 2019, the income tax expense recorded was driven largely by the projected current tax liability associated with the tax recognition of the upfront AbbVie collaboration payment received in 2018. A significant portion of the taxable income related to the collaboration payments is projected to be offset by current year expenses and prior year accumulated losses. A current tax liability has been projected for the remaining taxable income. The Company reported no income tax provision in the three and nine months ended September 30, 2018, as the Company generated a taxable loss, offset by an increase to the Company's valuation allowance.

Despite the collaboration revenue, the Company continues to maintain a valuation allowance against all deferred tax assets. The Company believes that it is more likely than not that the Company will not realize a future tax benefit of these attributes, as the research programs continue to require significant investment and future revenue is subject to uncertainties. Ultimate realization of any deferred tax asset is dependent on the Company's ability to generate sufficient future taxable income in the appropriate tax jurisdiction before the expiration of carryforward periods, if any.

The Company currently anticipates that there will be no change in its unrecognized tax benefits in the next twelve months. As of September 30, 2019, the Company had no unrecognized tax benefits. The Company has not yet conducted a study of its research and development credit carryforwards. Such a study may result in an adjustment to the Company's research and development credit carryforwards; however, until a study is completed and any adjustment is known, no amount is being presented as an uncertain tax position. A full valuation allowance has been provided against the Company's research and development credits, and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact to the balance sheet or statement of operations and comprehensive loss if an adjustment were required.

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 of key employees, in addition to the indemnification provided for in the restated certificate of incorporation and restated bylaws. These agreements, among other things, require the Company to indemnify directors, officers, and 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, 2019, the Company had not experienced any losses related to these indemnifications obligations, and no material claims were outstanding. The Company does not expect significant claims related to these

indemnifications' obligations and, consequently, concluded that the fair value of these obligations is negligible, and no related reserves were established.

Operating Leases

Facility Lease

The Company recognizes rent expense for the space it currently occupies and records a deferred rent obligation, representing the cumulative difference between actual rent payments and rent expense recognized ratably over the lease period, which is included in the Company's consolidated balance sheets as of December 31, 2018 and September 30, 2019.

Minimum annual rent payments under this lease for the remaining term of the amended lease, excluding operating expenses and taxes, which are not fixed for future periods as of September 30, 2019, are as follows (in thousands):

Year ending December 31,	Total Minimum Lease Payments	Sublease Income	Net Minimum Lease Payments
2019	$ 274	$ (20)	$ 254
2020	1,122	(83)	1,039
2021	1,175	—	1,175
2022	495	—	495
Total minimum lease payments	$ 3,066	$ (103)	$ 2,963

The Company recorded approximately $237,000 and $223,000 in rent expense for the three months ended September 30, 2019 and 2018, respectively, and $684,000 and $724,000 in rent expense for the nine months ended September 30, 2019 and 2018, respectively.

Legal Proceedings

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

10. Option and License Agreements

Detailed description of contractual terms and the Company's accounting for agreements described below were included in the Company's audited financial statements and notes in the prospectus filed with the Securities and Exchange Commission on June 27, 2019

AbbVie Agreement

During the three and nine months ended September 30, 2019, the Company continued to perform under its agreement with AbbVie, a research-based global biopharmaceutical company and an investor holding approximately 3.3% of the Company's common stock. During the three months ended September 30, 2019, the Company incurred $4.6 million in research and development costs and recognized revenue of $3.8 million related to research services performed during the period. During the nine months ended September 30, 2019, the Company incurred $15.3 million in research and development costs and recognized revenue of $13.7 million related to research services performed during the period. As of September 30, 2019, the Company has $82.9 million of deferred revenue, which is classified as either current or long-term deferred revenue in the accompanying 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, 2019. The Company expects to recognize revenue related to these performance obligations through 2024.

As the Company progresses towards satisfaction of performance obligations under the AbbVie agreement, the estimated costs associated with the remaining effort required to complete the performance obligations may change, which may impact revenue recognition. The Company regularly evaluates and, when necessary, updates the costs associated with the remaining effort associated with each performance obligation under the AbbVie agreement. Accordingly, revenue may fluctuate from period to period due to revisions to estimated costs as a percentage of the total budget, also impacting the allocation of deferred revenue between current and long term based on changes in expected timing of the satisfaction of performance obligations. During the quarter, the Company made such revisions to its estimated costs, and therefore reduced the amount of revenue recognized by $0.5 million for the performance obligations satisfied during the period.

On November 12, 2019, the Company announced that it's selective oral $\alpha_v\beta_6$ specific integrin inhibitor program for patients with fibrotic disease, MORF-720, conducted in collaboration with AbbVie, will require additional development activities, extending into the second half of 2020 based on feedback received during pre-IND interactions with the FDA, subsequent to September 30, 2019. As of the date of this filing, any such changes to the development plan have not been determined and the Company believes that it has no better estimate of the future costs to complete its performance obligation for MORF-720 than what was used as of September 30, 2019. Any change in estimated costs to complete the Company's performance obligations will be determined after upcoming discussions with AbbVie and could result in adjustments to revenue recognized in future periods pursuant to the collaboration and option agreement and such adjustments may be significant.

Janssen Agreement

During the three months ended September 30, 2019, the Company incurred $1.5 million in research and development costs and recognized revenue of $1.9 million related to research services. During the nine months ended September 30, 2019, the Company incurred $2.7 million in research and development costs and recognized revenue of $3.6 million related to research services. The Company had $2.4 million and $0 due from Janssen included in accounts receivable on the condensed consolidated balance sheets as of September 30, 2019 and December 31, 2018, respectively.

As of September 30, 2019, $9.2 million of deferred revenue is classified as either current or long-term deferred revenue in the accompanying consolidated balance sheets 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, 2019. The Company expects to recognize revenue related to these performance obligations through 2024.

11. Net Loss per Unit and Share

Basic and diluted net loss per share is calculated as follows (in thousands, except share and per share data) for the three and nine months ended September 30, 2019:

	Three Months Ended September 30, 2019	Nine Months Ended September 30, 2019
Net loss	$ (8,864)	(23,497)
Weighted average common shares outstanding, basic and diluted	29,999,170	11,393,192
Net loss per share, basic and diluted	$ (0.30)	$ (2.06)

Following the Reorganization, the Company calculates net loss per share based on its outstanding shares of common stock. For the three and nine months ended September 30, 2018, the weighted average number of common units outstanding includes the weighted average number of common units outstanding prior to the Reorganization.

Basic and diluted net loss per unit is calculated as follows (in thousands, except unit and per unit data) for the three and nine months ended September 30, 2018:

	Three Months Ended September 30, 2018	Nine Months Ended September 30, 2018
Net loss	$ (7,077)	$ (18,487)
Weighted average common units outstanding, basic and diluted	1,011,227	1,011,227
Net loss per unit, basic and diluted	$ (7.00)	$ (18.28)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Convertible preferred units	—	21,010,407	—	21,010,407
Incentive units	—	721,499	—	721,499
Restricted common stock	449,253	—	449,253	—
Warrant	—	6,825	—	6,825
Shares issuable under ESPP	300,000	—	300,000	—
Stock options	2,680,835	—	2,680,835	—
	3,430,088	21,738,731	3,430,088	21,738,731

12. Subsequent Events

On November 12, 2019, the Company announced that it's selective oral $\alpha_v\beta_6$ specific integrin inhibitor program for patients with fibrotic disease, MORF-720, conducted in collaboration with AbbVie, will require additional development activities, extending into the second half of 2020 based on feedback received during pre-IND interactions with the FDA. See Note 10 for further information.

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 condensed financial statements and the related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q. 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, business strategy, market size, potential growth opportunities, preclinical and clinical development activities, efficacy and safety profile of our product candidates, use of net proceeds from our public offering, 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 of potentially first-in-class oral small-molecule integrin therapeutics. Integrins are a target class with multiple approved injectable blockbuster drugs for the treatment of serious chronic diseases, including autoimmune, cardiovascular and metabolic diseases, fibrosis and cancer. To date, no oral small-molecule integrin therapies have been approved by the FDA. Despite significant unsuccessful efforts, we believe tremendous untapped potential remains for us to develop oral integrin therapies. We created the Morphic integrin technology platform, or MInT Platform, by leveraging our unique understanding of integrin structure and biology to develop novel product candidates designed to achieve the potency, high selectivity, and pharmaceutical properties required for oral administration. We are advancing our preclinical pipeline, including our lead wholly-owned program for $\alpha_4\beta_7$ specific integrin inhibitors affecting inflammation into clinical development for the treatment of inflammatory bowel disease, or IBD. We are also developing our product candidate, MORF-720, a selective oral $\alpha_v\beta_6$ specific integrin inhibitor into clinical development for the treatment of idiopathic pulmonary fibrosis, or IPF, in collaboration with AbbVie Inc., or AbbVie. We intend to advance our $\alpha_4\beta_7$ program and MORF-720 toward Investigational New Drug applications, or INDs, by the middle of 2020 and the second half of 2020, respectively. Beyond our current targets, we are using our MInT Platform to create a broad pipeline of programs across a variety of therapeutic areas, all of which aim to harness the potential of inhibition or activation.

We were formed as a limited liability company under the laws of the State of Delaware in August 2014 under the name Integrin Rock, LLC. We subsequently changed our name to Morphic Rock Holding, LLC in October 2014 and then to Morphic Holding, LLC in June 2016, and we subsequently converted to a corporation under the name Morphic Holding, Inc. in December 2018. In connection with the conversion to a Delaware corporation, or the Reorganization, each of the outstanding units of the members of the limited liability company were converted into shares of capital stock.

Upon consummation of the Reorganization, the historical consolidated financial statements of Morphic Holding, LLC became the historical consolidated financial statements of Morphic Holding, Inc. Except as otherwise indicated or as the context otherwise requires, all information included in this Quarterly Report is presented after giving effect to the Reorganization.

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 have been limited to the following. In October 2018, pursuant to our collaboration and option agreement with AbbVie, or the "AbbVie agreement", we received an upfront payment of $100.0 million for research and development activities, and provided to AbbVie exclusive license options on product candidates directed at multiple targets. In March 2019, pursuant to the Janssen Agreement, we received an upfront payment of $10.0 million and provided Janssen with exclusive license options on product candidates directed at multiple targets. We do not have any products approved for sale and have not generated any revenue from product sales. Through September 30, 2019, in addition to the foregoing sources of revenue, we have funded our operations primarily through the sale and issuance of our convertible preferred equity securities, borrowings under a loan and security agreement, or the credit facility, with Silicon Valley Bank, or SVB, and completing an initial public offering ("IPO"). From inception through September 30, 2019 we raised an aggregate of approximately $242.6 million of gross proceeds through the issuance of equity and debt, of which $138.1 million was from the issuance of convertible preferred equity securities and $1.0 million was from borrowings under the credit facility. On July 1, 2019, we completed an IPO of our common stock and issued and sold 6,900,000 shares of common stock at a public offering price of $15.00 per share, which included 900,000 shares sold upon full exercise of the underwriters' option to purchase additional shares of common stock resulting in net proceeds of $93.3 million after deducting underwriting discounts and commissions and offering expenses.

Since inception, we have incurred significant operating losses. Our net losses were $8.9 million and $7.1 million for the three months ended September 30, 2019 and 2018, respectively, and $23.5 million and $18.5 million for the nine months ended September 30, 2019 and 2018, respectively. As of September 30, 2019, we had an accumulated deficit of $77.7 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 potential collaboration agreements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on acceptable terms, or at all. Our failure to raise capital or enter into such agreements as, and when, needed, could have a material adverse effect on our business, results of operations, and financial condition.

As of September 30, 2019, we had cash, cash equivalents, and marketable securities of $251.7 million. We believe that our existing cash and cash equivalents, marketable securities, including the net proceeds of $93.3 million from our IPO completed on July 1, 2019 will enable us to fund our operating expenses and capital expenditure requirements through at least the end of 2022.

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 holding in aggregate approximately 3.3% of our common stock, designed to advance a number of our oral integrin therapeutics for fibrosis-related indications. Under the terms of the 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.

For each compound, we will 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. In addition, for certain compounds for which we have completed IND-enabling studies and which meet certain advancement criteria for a liver indication, we have the option to commit to share development costs in exchange for an increased fixed royalty rate. We may exercise this option following completion of the first phase IIb clinical trial for the relevant product.

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, Janssen paid us an upfront fee of $10.0 million for each of the first two research programs, will pay us an additional $5.0 million fee upon commencement of the third research program, and will fund research activities. Pursuant to the terms of the agreement, we are also eligible to receive additional milestone and royalty payments.

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;
- 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 deferred and capitalized. The capitalized amounts are 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 estimated 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 anticipate increased 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 Securities and Exchange Commission, or 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 expenses related to building a sales and marketing team to support product sales, marketing and distribution activities.

Interest Income, Net

Interest income, net consists primarily of interest income earned on our cash and cash equivalents and marketable securities, partially offset by interest expense incurred on our credit facility, including amortization of debt discount and debt issuance costs.

Provision for Income Tax Expense for Interim Periods

Provision for income tax expense recorded in any interim period is based on the estimated effective tax rate for the fiscal year for those tax jurisdictions that can be reliably estimated. Our calculation of the estimated effective tax rate requires us to estimate pre-tax income by tax jurisdiction as well as total tax expense for the fiscal year. Accordingly, the annual estimated effective tax rate is subject to adjustment if there are changes to the initial estimates of total tax expense or pre-tax income.

Results of Operations

Comparison of the Three Months Ended September 30, 2019 and 2018

The following table summarizes our results of operations for the three months ended September 30, 2019 and 2018:

	Three Months Ended September 30,		Change	
	2019	2018	$	%
	(in thousands, except percentages)			
Collaboration revenue — related party	$ 3,772	$ —	$ 3,772	*
Collaboration revenue — other	1,903	—	1,903	*
Total collaboration revenue	5,675	—	5,675	*
Operating expenses:				
Research and development	12,635	5,767	6,868	119%
General and administrative	2,898	1,405	1,493	106%
Total operating expenses	15,533	7,172	8,361	117%
Loss from operations	(9,858)	(7,172)	(2,686)	37%
Other income:				
Interest income, net	1,392	111	1,281	*
Other expense, net	(94)	(16)	(78)	*
Total other income, net	1,298	95	1,203	*
Loss before provision for income taxes	$ (8,560)	$ (7,077)	$ (1,483)	21%
Provision for income taxes	(304)	—	(304)	*
Net loss	$ (8,864)	$ (7,077)	$ (1,787)	25%

* Percentage not meaningful

Collaboration Revenue

Collaboration revenue increased to $5.7 million for the three months ended September 30, 2019 from $0 for the three months ended September 30, 2018. This increase was due to the revenue recognized under our collaboration with AbbVie that we executed in October 2018 to advance several oral integrin therapeutics for fibrosis-related indications, as well as revenue from our collaboration with Janssen that we executed in February 2019.

Research and Development Expenses

Research and development expense increased by $6.9 million, or 119%, from $5.8 million for the three months ended September 30, 2018 to $12.6 million for the three months ended September 30, 2019. A significant portion of our research and development costs have been external pre-clinical contract research organization (CRO) costs, which we track on a program-by-program basis related to a clinical product 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 the three months ended September 30, 2019 and 2018:

	Three Months Ended September 30,		Change	
	2019	2018	$	%
	(in thousands, except percentages)			
External costs by program:				
MORF-720	$ 3,160	$ 1,856	$ 1,304	70%
$\alpha_4\beta_7$	2,723	1,062	1,661	156%
Other early development candidates and unallocated costs	2,721	782	1,939	248%
Total external costs	8,604	3,700	4,904	133%
Internal costs:				
Employee compensation and benefits	3,617	1,829	1,788	98%
Facility and other	414	238	176	74%
Total internal costs	4,031	2,067	1,964	95%
Total research and development expense	$ 12,635	$ 5,767	$ 6,868	119%

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

- The $4.9 million increase in external costs primarily related to increased research and preclinical development and manufacturing costs associated with product candidate MORF-720 targeting αvβ6, α4β7, and other external research costs associated with our other early development candidates.

- The $2.0 million increase in internal costs was primarily driven by an increase in employee compensation and benefits costs related to increased headcount to support increased activities in our research and development function.

General and Administrative Expenses

General and administrative expense increased by $1.5 million, or 106%, from $1.4 million for the three months ended September 30, 2018 to $2.9 million for the three months ended September 30, 2019.

The increase in general and administrative expense was primarily attributable to an increase of $0.8 million in employee compensation and benefits due to increased headcount, an increase of $0.2 million in professional services and consulting fees primarily due to increases in legal fees related to business development, regulatory and patent costs, and expenses related to public company administrative costs, and a $0.5 million increase in other expenses.

Interest Income, Net

Interest income increased by $1.3 million from $111,000 for the three months ended September 30, 2018 to $1.4 million for the three months ended September 30, 2019.

The increase in interest income, net was attributable to increased income earned on our investment portfolio, which increased significantly year-over-year due to the Series B financing and up-front payments pursuant to the AbbVie and the Janssen agreements, and receipt of the IPO proceeds in July 2019.

Provision for Income Tax

We recorded an income tax expense of $304,000 and $0 for the three months ended September 30, 2019 and 2018, respectively. In the three months ended September 30, 2019, the income tax expense was driven largely by the projected current tax liability associated with the tax recognition of upfront collaboration payment received in 2018. We reported

no income tax provision in September 30, 2018, as we generated a taxable loss, offset by an increase to our valuation allowance.

Comparison of the Nine Months Ended September 30, 2019 and 2018

The following table summarizes our results of operations for the nine months ended September 30, 2019 and 2018:

	Nine Months Ended September 30,		Change	
	2019	2018	$	%
	(in thousands, except percentages)			
Collaboration revenue — related party	$ 13,736	$ —	$ 13,736	*
Collaboration revenue — other	3,575	—	3,575	*
Total collaboration revenue	17,311	—	17,311	*
Operating expenses:				
Research and development	36,912	15,344	21,568	141%
General and administrative	6,807	3,311	3,496	106%
Total operating expenses	43,719	18,655	25,064	134%
Loss from operations	(26,408)	(18,655)	(7,753)	42%
Other income:				
Interest income, net	3,574	214	3,360	*
Other expense, net	(94)	(46)	(48)	*
Total other income, net	3,480	168	3,312	*
Loss before provision for income taxes	$ (22,928)	$ (18,487)	$ (4,441)	24%
Provision for income taxes	(569)	—	(569)	*
Net loss	$ (23,497)	$ (18,487)	$ (5,010)	27%

* Percentage not meaningful

Collaboration Revenue

Collaboration revenue increased to $17.3 million for the nine months ended September 30, 2019 from $0 for the same period in the prior year. This increase was due to the revenue recognized under our collaboration with AbbVie that we executed in October 2018 to advance several oral integrin therapeutics for fibrosis-related indications, as well as revenue from our collaboration with Janssen that we executed in February 2019.

Research and Development Expenses

Research and development expense increased by $21.6 million, or 141%, from $15.3 million for the nine months ended September 30, 2018 to $36.9 million for the nine months ended September 30, 2019. A significant portion of our research and development costs consist of external costs, which we track on a program-by-program basis after a clinical product 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 the nine months ended September 30, 2019 and 2018:

	Nine Months Ended September 30,		Change	
	2019	2018	$	%
	(in thousands, except percentages)			
External costs by program:				
MORF-720	$ 11,360	$ 4,175	$ 7,185	172%
α4β7	8,272	2,732	5,540	203%
Other early development candidates and unallocated costs	6,321	2,299	4,022	175%
Total external costs	25,953	9,206	16,747	182%
Internal costs:				
Employee compensation and benefits	9,719	5,349	4,370	82%
Facility and other	1,240	789	451	57%
Total internal costs	10,959	6,138	4,821	79%
Total research and development expense	$ 36,912	$ 15,344	$ 21,568	141%

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

- The $16.7 million increase in external costs primarily related to increased research and preclinical development and manufacturing costs associated with product candidate MORF-720 targeting αvβ6, α4β7, and other external research costs associated with our other early development candidates.

- The $4.8 million increase in internal costs was primarily driven by an increase in employee compensation and benefits costs related to increased headcount to support increased activities in our research and development function.

General and Administrative Expenses

General and administrative expense increased by $3.5 million, or 106%, from $3.3 million for the nine months ended September 30, 2018 to $6.8 million for the nine months ended September 30, 2019.

The increase in general and administrative expense was primarily attributable to an increase of $1.8 million in employee compensation and benefits due to increased headcount, an increase of $0.9 million in professional services and consulting fees primarily due to increases in legal fees related to business development, regulatory and patent costs, accounting and audit fees, and public and investor relations fees due to ongoing business activities, and a $0.8 million increase in expenses related to public company administrative costs.

Interest Income, Net

Interest income increased by $3.4 million from $0.2 million for the nine months ended September 30, 2018 to $3.6 million for the nine months ended September 30, 2019.

The increase in interest income, net was attributable to increased income earned on our investment portfolio, which increased significantly year-over-year due to the Series B financing and up-front payments pursuant to the AbbVie and Janssen agreements, and receipt of the IPO proceeds in July 2019.

Provision for Income Tax

We recorded an income tax expense of $569,000 and $0 for the nine months ended September 30, 2019 and 2018, respectively. In the nine months ended September 30, 2019, the income tax expense was driven largely by the projected

current tax liability associated with the tax recognition of upfront collaboration payments received in 2018. The Company reported no income tax provision in the nine months ended September 30, 2018, as the Company generated a taxable loss, offset by an increase to the company's valuation allowance.

Liquidity and Capital Resources

Sources of Liquidity

From inception through September 30, 2019, we have funded our operations with net proceeds of $93.3 million from sale of common stock in our IPO, the gross proceeds of $138.1 million from sales of our convertible preferred equity securities and borrowings of $1.0 million under our credit facility with SVB, $100.0 million we received as an up-front, non-refundable payment from our collaboration with AbbVie, $10.0 million we received as an up-front, non-refundable payment from the Janssen Agreement, as well as on-going research funding from the Janssen Agreement.

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, 2019 and December 31, 2018:

	September 30, 2019	December 31, 2018
	(in thousands)	
Cash	$ 224	$ 225
Money market funds	159,583	185,676
Marketable securities	91,939	—
Total cash, cash equivalents, and marketable securities	$ 251,746	$ 185,901

In March 2016, we entered into a credit facility with SVB for an equipment line of credit of up to $1.5 million to finance the purchase of eligible equipment. Principal and interest payments commenced on January 1, 2017 for a period of 36 months. The loan and security agreement also included a final payment fee equal to 5.0% of the aggregate advances and a pre-payment fee of 0.5% to 1.0%, depending on when the prepayment occurs. In December 2018, we paid the entire balance back to SVB, including a prepayment penalty of 0.5% and terminated the credit facility. We had no balances outstanding due to SVB or any other lender as of September 30, 2019 or December 31, 2018.

In connection with the credit facility, we issued warrants to SVB to purchase 6,825 Series Seed convertible preferred units at a purchase price of $4.39 per unit, which became exercisable for 6,825 shares of common stock at a purchase price of $4.39 per share in connection with the IPO. In August 2019, SVB exercised warrants via a cashless exercise which resulted in the issuance of 5,766 common shares.

Cash Flows

The following table provides information regarding our cash flows for the nine months ended September 30, 2019 and 2018:

	Nine Months Ended September 30,	
	2019	2018
	(in thousands)	
Net cash used in operating activities	$ (27,576)	$ (16,222)
Net cash used in investing activities	(91,785)	(492)
Net cash provided by financing activities	93,267	89,875
Net decrease in cash and cash equivalents and restricted cash	$ (26,094)	$ 73,161

Net Cash Used in Operating Activities

The use of cash in all periods 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 $27.6 million for the nine months ended September 30, 2019 compared to $16.2 million for the nine months ended September 30, 2018. The increase in cash used in operating activities was primarily due to an increase in net loss of $5.0 million, adjusted for non-cash items, including depreciation, premium amortization and discount accretions on marketable securities, and stock-based compensation, and changes in operating assets and liabilities for the nine months ended September 30, 2019 as compared to the nine months ended September 30, 2018.

Net Cash Used in Investing Activities

Net cash used in investing activities was $91.8 million for the nine months ended September 30, 2019 compared to net cash used in investing activities of $0.5 million for the nine months ended September 30, 2018, an increase of $91.3 million. This increase was primarily due to the purchase of $225.8 million in marketable securities, and a net increase of $1.0 million in capital expenditures, offset by $135.5 million in proceeds from maturities of marketable securities.

Net Cash Used in Financing Activities

Net cash used in financing activities was $93.3 million for the nine months ended September 30, 2019 compared to $89.9 million in the comparable prior year period. The increase of $3.4 million was due to increase in funds raised from the Company's IPO.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue research and development, initiate 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. Furthermore, as a result of the IPO, we expect to incur additional costs associated with operating as a newly public company. 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, we would be forced to delay, reduce, or eliminate our research and development programs or future commercialization efforts.

We expect our existing cash and cash equivalents and marketable securities will enable us to fund our operating expenses and capital expenditure requirements through at least the end of 2022.

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 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 headcount growth and associated costs as we expand our business operations and research and development activities; 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.

Accounting Policies and Significant Estimates

This management's discussion and analysis is based on our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these consolidated financial statements requires us to make judgments and estimates that affect the reported amounts of assets, liabilities, revenues and expenses, and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events, and various other factors that we believe to be reasonable under the circumstances. Actual results may differ from these estimates under different assumptions or conditions. On an ongoing basis, we evaluate our judgments and estimates in light of changes in circumstances, facts, and experience. The effects of material revisions in estimates, if any, will be reflected in the consolidated financial statements prospectively from the date of change in estimates.

While our significant accounting policies are described in more detail in the notes to our condensed consolidated financial statements included in the registration statement on Form S-1 (File No. 333-231837), filed with the SEC on May 30, 2019, as amended, and declared effective by the SEC on June 26, 2019, we believe the following accounting policies used in the preparation of our consolidated financial statements require the most significant judgments and estimates.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf, and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date based on

facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments, if necessary. The significant estimates in our accrued research and development expenses include the costs incurred for services performed by our vendors in connection with research and development activities for which we have not yet been invoiced. In certain instances, we prepay for services to be provided in the future. These amounts are expensed as the services are performed.

We base our expenses related to research and development activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the research and development expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid balance accordingly. Non-refundable advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Although we do not expect our estimates to be materially different from amounts incurred, if our estimates of the status and timing of services performed differ from the actual status and timing of services performed, it could result in us reporting amounts that are too high or too low in any particular period. To date, there have been no material differences between our estimates of such expenses and the amounts incurred.

Equity-Based Compensation

Prior to the Reorganization, we granted incentive units, which we accounted for as equity-classified awards. As part of the Reorganization, the incentive units were exchanged for shares of our common stock and restricted common stock, which we account for as equity-classified awards. In December 2018 and during the nine months ended September 30, 2019, we granted stock options, which we account for as equity-classified awards.

We measure employee equity-based compensation based on the grant date fair value of the equity-based awards and recognize equity-based compensation expense on a straight-line basis over the requisite service period of the awards, which is generally the vesting period of the respective award. As of January 1, 2018, we made an accounting policy election to recognize forfeitures as they occur upon full retrospective adoption of guidance per Accounting Standard Update, or ASU, No. 2016-09, *Compensation — Stock Compensation*, or ASU 2016-09. The adoption of ASU 2016-09 did not have a material impact on our consolidated financial statements. The term "forfeitures" is distinct from "cancellations" or "expirations" and represents only the unvested portion of the surrendered equity-based award. In addition, on January 1, 2018, we adopted, using modified retroactive approach, the guidance of Accounting Standard Update 2018-07, Compensation — Stock Compensation (Topic 718) — Improvements to Nonemployee Share-Based Payment Accounting and account for awards to non-employees using the grant date fair value without subsequent periodic remeasurement. The adoption of ASU 2018-07 did not have a material effect on our consolidated financial statements.

We classify equity-based compensation expense in our consolidated statements of operations in the same manner in which the award recipient's salary and related costs are classified or in which the award recipient's service payments are classified. In future periods, we expect equity-based compensation expense to increase, due in part to our existing unrecognized stock-based compensation expense and as we grant additional stock-based awards to continue to attract and retain our employees.

We determine the fair value of restricted common stock awards granted based on the fair value of our common stock. We estimate the fair value of stock option awards and restricted stock granted using the Black-Scholes option-pricing model, which uses as inputs, the fair value of our common stock or unit and subjective assumptions we make, including the expected stock price volatility, the expected term of the award, the risk-free interest rate, and expected dividends. Due to insufficient company-specific historical data, we base the estimate of expected volatility on the historical volatility of a representative group of publicly traded companies for which historical information is available. The

historical volatility is generally calculated based on a period of time commensurate with the expected term assumption. We use the simplified method to calculate the expected term for options granted to employees and directors. We utilize this method as we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate the expected term. For options granted to non-employees, we utilize the expected term. The risk-free interest rate is based on a U.S. treasury instrument whose term is consistent with the expected term of the stock options. The expected dividend yield is assumed to be zero, as we have never paid dividends and do not have current plans to pay any dividends on our common stock.

Revenue from Contracts with Customers

As of September 30, 2019, all of our revenue to date has been generated from the AbbVie Agreement and Janssen Agreement. Effective January 1, 2018, we adopted the provisions of ASC Topic 606, *Revenue from Contracts with Customers*, or ASC 606, using the full retrospective transition method.

Under ASC 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. To determine the appropriate amount of revenue to be recognized for arrangements determined to be within the scope of ASC 606, we perform the following five steps: (i) identification of the contract(s) with the customer, (ii) identification of the promised goods or services in the contract and determination of whether the promised goods or services are performance obligations, (iii) measurement of the transaction price, (iv) allocation of the transaction price to the performance obligations, and (v) recognition of revenue when (or as) we satisfy each performance obligation. We only apply the five-step model to contracts when it is probable that we will collect the consideration we are entitled to in exchange for the goods or services we transfer to our customer.

Identification of the Contracts with the Customers

We evaluate every contract to determine whether it in its entirety or in part represent a contract with a customer, or a collaboration agreement and, based on this determination, apply appropriate accounting guidance.

We account for a contract with a customer that is within the scope of ASC 606 when all of the following criteria are met: (i) the arrangement has been approved by the parties and the parties are committed to perform their respective obligations, (ii) each party's rights regarding the goods or services to be transferred can be identified, (iii) the payment terms for the goods or services to be transferred can be identified, (iv) the arrangement has commercial substance and (v) collection of substantially all of the consideration to which we will be entitled in exchange for the goods or services that will be transferred to the customer is probable.

Identification of the Performance Obligations

The promised goods or services in our collaboration and option arrangements consist of research and development services. The arrangements also have options for additional items (i.e., license rights). Options are considered to be marketing offers and are to be accounted for as separate contracts when the customer elects such options, unless we determine the option provides a material right which would not be provided without entering into the contract. The determination as to whether such options are material rights requires significant management judgment, and management considers factors such as other similar arrangements, market data and the terms of the contractual arrangement to make such conclusion. Performance obligations are promised goods or services in a contract to transfer a distinct good or service to the customer. Promised goods or services are considered distinct when: (i) the customer can benefit from the good or service on its own or together with other readily available resources and (ii) the promised good or service is separately identifiable from other promises in the contract. In assessing whether promised goods or services are distinct, we consider factors such as the stage of development of the underlying intellectual property, the capabilities of our customer to develop the intellectual property on their own and whether the required expertise is readily available.

Determination of the Transaction Price

We estimate the transaction price based on the amount of consideration we expect to receive for transferring the promised goods or services in the contract. The consideration may include both fixed consideration and variable consideration. At the inception of each arrangement that includes variable consideration, we evaluate the amount of the potential payments and the likelihood that the payments will be received. We utilize either the most likely amount method or expected value method to estimate the transaction price based on which method better predicts the amount of consideration expected to be received. If it is probable that a significant revenue reversal would not occur, the variable consideration is included in the transaction price.

All contingent future payments, which include research, development, regulatory, and sales-based royalty payments, have not been considered in the initial analysis, as they are contingent upon option(s) being exercised or are subject to significant risk of achievement.

Allocation of Transaction Price

We allocate the transaction price based on the estimated standalone selling price. We must develop assumptions that require judgment to determine the standalone selling price for each performance obligation identified in the contract. We utilize key assumptions to determine the standalone selling price, which may include other comparable transactions, pricing considered in negotiating the transaction, and the estimated costs. Certain variable consideration is allocated specifically to one or more performance obligations in a contract when the terms of the variable consideration relate to the satisfaction of the performance obligation and the resulting amounts allocated to each performance obligation are consistent with the amounts we would expect to receive for satisfying each performance obligation.

Recognition of Revenue

We recognize revenue as we perform the research and development services based on the costs incurred to date, as such costs have a direct relationship between our effort and the progress made towards satisfying its performance obligations to AbbVie and Janssen. Consideration allocated to material rights is recognized upon exercise or expiration of the related option.

As the Company progresses towards satisfaction of performance obligations under the AbbVie and Janssen agreements, the estimated costs associated with the remaining effort required to complete the performance obligations may change, which may impact revenue recognition. The Company regularly evaluates and, when necessary, updates the costs associated with the remaining effort associated with each performance obligation under the AbbVie and Janssen agreements.

Off-Balance Sheet Arrangements

We did not have, during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under applicable SEC rules.

Contractual Obligations

The following table summarizes our significant contractual obligations by period presented according to the payment due date at September 30, 2019 (in thousands):

As of September 30, 2019	Total	Less than 1 Year	1 to 3 Years	3 to 5 Years	More than 5 Years
Operating lease obligations[1]	$ 3,066	$ 274 [2]	$ 2,792	$ —	$ —
Total	$ 3,066	$ 274	$ 2,792	$ —	$ —

(1) Represents future minimum repayments under our non-cancellable operating leases as of September 30, 2019.

(2) The amounts are for the three months ending December 31, 2019.

We entered into contracts with a number of third parties, including external CROs, that require us to make upfront payments, some of which may be non-refundable. Under various licensing and related agreements with third parties, we have agreed to make milestone payments and pay royalties to third parties. Pursuant to an exclusive license agreement with Children's Medical Center Corporation, or CMCC, a holder of our common stock, we paid CMCC an annual license maintenance fee of $10,000 in each of 2015-2018. In 2018, we amended the agreement and this obligation increased to $80,000 per year, and continues until the agreement is terminated. We will also be responsible for up to $1.3 million of development milestone payments through the first regulatory approval of a licensed product, tiered royalty payments of low single-digit percentages on net sales of licensed products in the event that we realize sales from products covered by the license agreement, and between 10% and 20% of non-royalty income attributable to a sublicense of the CMCC rights. Amounts paid to CMCC are recorded as research and development expense in the statements of operations.

Pursuant to a collaboration agreement with Schrödinger, a holder of approximately 2.74% of our outstanding common stock, Schrödinger may be eligible to receive certain payments from us related to development milestones, not to exceed in the aggregate, on a target-by-target basis, a low six-figure payment upon initiation of lead optimization and $3,100,000 on a compound-by-compound basis, as well as royalties in the low single digits on sales of products containing such compounds. In addition, we have agreed to pay Schrödinger a percentage, in the mid-single digits, of certain payments we receive from third parties in connection with the licensing or transfer of the rights to exploit such compounds to such third parties, including a one-time fee of $1,000,000 payable in 2019 in the event no payments are otherwise received from a third party.

We enter into agreements in the normal course of business with vendors for preclinical studies, preclinical and clinical supply and manufacturing services, professional consultants for expert advice, and other vendors for other services for operating purposes. We have not included these payments in the table of contractual obligations above since the contracts do not contain any minimum purchase commitments and are cancelable at any time by us, generally upon 30 days prior written notice, and therefore we believe that our non-cancelable obligations under these agreements are not material.

Emerging Growth Company and Smaller Reporting Status

We are an "emerging growth company," or EGC, under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Section 107 of the JOBS Act provides that an EGC can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act, for complying with new or revised accounting standards. Thus, an EGC can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of delayed adoption of new or revised accounting standards and, therefore, we will be subject to the same requirements to adopt new or revised accounting standards as private entities.

As an EGC, we may take advantage of certain exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an EGC:

- we will avail ourselves of the exemption from providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act;
- we will avail ourselves of the exemption from complying with any requirement that may be adopted by the Public Company Accounting Oversight Board, or PCAOB, regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis;
- we will provide reduced disclosure about our executive compensation arrangements; and
- we will not require nonbinding advisory votes on executive compensation or stockholder approval of any golden parachute payments.

We will remain an EGC until the earliest of (i) December 31, 2025 (the last day of the fiscal year following the fifth anniversary of the completion of our initial public offering), (ii) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more, (iii) the date on which we have issued more than $1.0 billion in non-convertible debt during the previous rolling three-year period, or (iv) the date on which we are deemed to be a large accelerated filer under the Securities Exchange Act of 1934, as amended, or the Exchange Act.

We are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates is less than $700.0 million and our annual revenue is less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250.0 million or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million.

If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

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

We are exposed to market risk related to changes in interest rates. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because of our cash equivalents, in the form of a money market fund, and marketable securities which is primarily invested in short-term U.S. Treasury obligations. However, because of the short-term nature of the investments in our portfolio, an immediate one percentage point change in market interest rates would not have a material impact on the fair market value of our investment portfolio or on our financial position or results of operations.

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates; however, we have contracted with and may continue to contract with foreign vendors that are located in Europe. Our operations may be subject to fluctuations in foreign currency exchange rates in the future.

Inflation generally affects us by increasing our cost of labor. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the years ended 2018 or the three and nine months ended September 30, 2019.

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 Vice President of Finance and Operations and our Chief Executive Officer, 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 the Securities Exchange Act of 1934 (Exchange Act)) as of September 30, 2019. 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 Vice President of Finance and Operations), as of the end of the period covered by this report, our Chief Executive Officer and our Vice President of Finance and Operations 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, 2019 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, 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.

Risks Related to Our Financial Position and Need for Capital

We are a preclinical stage biopharmaceutical company with a limited operating history and no products in clinical development or 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 preclinical stage biopharmaceutical company with a limited operating history on which to base your investment decision. 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.

We have identified lead product candidates for our $\alpha_4\beta_7$ and $\alpha_v\beta_6$ programs, which are still in the preclinical testing stage. We have no products in clinical development or 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, 2019, we reported a net loss of $23.5 million. As of September 30, 2019, we had an accumulated deficit of approximately $77.7 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 lead wholly-owned $\alpha_4\beta_7$ program and for our product candidate $\alpha_v\beta_6$ program, MORF-720, 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, pre-clinical, 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;
- § identify additional compounds or product candidates and acquire rights from third parties to those compounds or product candidates through licenses; and
- § incur additional costs associated with operating as a public company.

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, if any, unless and until we, either alone or with a collaborator, are able to obtain regulatory approval for, and successfully commercialize, our lead product candidates, 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. Additionally, our expenses could increase if we are required by the U.S. Food and Drug Administration, or the FDA, or any comparable foreign regulatory authority to perform clinical trials in addition to those currently expected, or if there are any delays in completing our clinical trials or the development of any of our product candidates.

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 for our product candidates from our lead programs, $\alpha_4\beta_7$ and $\alpha_v\beta_6$. Preclinical studies and clinical trials for our product candidates will require substantial funds to complete. As of September 30, 2019, we had $251.7 million in cash, cash equivalents and marketable securities. We expect to incur substantial expenditures in the foreseeable future as we seek to advance our current product candidates from our lead programs, $\alpha_4\beta_7$ and $\alpha_v\beta_6$, and any future product candidates through preclinical and clinical development, the regulatory approval process and, if approved, commercial launch activities. Based on our current operating plan, we believe that our available cash and cash equivalents, including the net proceeds from our IPO, will be sufficient to fund our operating expenses and capital expenditure requirements through at least the end of 2022. 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. Our monthly spending levels vary based on new and ongoing research and development and other corporate activities. 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.

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. We do not expect to realize revenue from sales of commercial products or royalties from licensed products in the foreseeable future, if at all, and, in no event, before our product candidates are clinically tested, approved for commercialization and successfully marketed. 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 additional collaborations and/or licensing agreements, public or private equity offerings or debt financings, credit or loan facilities, or a combination of one or more of these funding sources. If we raise additional funds by issuing equity securities, 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 available, 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 candidate 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 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. We expect the Investigational New Drug applications, or INDs, with respect to our $\alpha_4\beta_7$ program and MORF-720 to be submitted by the middle of 2020 and the second half of 2020, respectively. 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;
- greater than anticipated costs of our clinical trials;
- manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that no longer make a product candidate economically feasible;
- 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
- 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.

Our business is heavily dependent on the success of our $\alpha_4\beta_7$ program and of our product candidate, MORF-720. 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 $\alpha_4\beta_7$ program and MORF-720. However, our lead product candidates are still in the preclinical stage. 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 candidates. 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 $\alpha_4\beta_7$ program, MORF-720, and our other product candidates will depend on many factors, including the following:

- 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;
- 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.

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 Morphic integrin technology platform, or 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. We are aware of certain companies currently exploring oral approaches to integrins. For example, Pliant Therapeutics, Inc. is currently in clinic for an $\alpha_v\beta_6$ /$\alpha_v\beta_1$ oral small-molecule integrin inhibitor. Development efforts and clinical results of these other companies may be unsuccessful, which could result in a negative perception of oral integrins and negatively impact the regulatory approval process of our product candidates, which would have a material and adverse effect on our business. For example, Biogen recently terminated a Phase 2 study of its monoclonal antibody targeting $\alpha_v\beta_6$, citing safety concerns. 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.

To date, we have not tested any of our product candidates in any clinical studies. 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. We currently have only pre-clinical data regarding oral bioavailability of our product candidates. We may spend substantial funds attempting to introduce these properties and may never succeed in doing so. 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.

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 development and their risk of failure is high. It is impossible to predict 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.

Our two lead programs are $\alpha_4\beta_7$ and $\alpha_v\beta_6$. We intend to advance our $\alpha_4\beta_7$ program and MORF-720, our development candidate for our $\alpha_v\beta_6$ program, toward IND submissions by the middle of 2020 and the second half of 2020, respectively. Commencing our future 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, any future clinical trials that we could conduct that could delay or prevent our ability to receive marketing approval or commercialize our $\alpha_4\beta_7$ program or MORF-720 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 contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trial sites deviating from trial protocol or dropping 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;
- our inability 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;
- our failure 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 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 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 future 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 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 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. $\alpha_4\beta_7$ and $\alpha_v\beta_6$ are our lead preclinical programs and our research programs 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 wholly-owned $\alpha_4\beta_7$ program and for our product candidate, MORF-720. 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 $\alpha_4\beta_7$ program, initially under development for treatment of IBD, if approved would face competition from approved IBD treatments marketed by UCB, Johnson & Johnson, Biogen Inc., and Pfizer Inc., in addition to other major pharmaceutical companies. In addition, we are aware of IBD treatments in development by Roche Holding AG, AbbVie Inc., Gilead Sciences, RedHill Biopharma Ltd, Celgene Corporation, Eli Lilly and Company, and Boehringer Ingelheim GmbH. Further, Takeda Pharmaceutical Company Ltd. currently markets Entyvio, which is an $\alpha_4\beta_7$ monoclonal antibody to treat ulcerative colitis and Crohn's disease. Protagonist Therapeutics, Inc. also has a Phase 1 clinical gut-restricted $\alpha_4\beta_7$ program under development.

MORF-720, under development for the treatment of IPF, if approved, would face competition from approved IPF treatments marketed by Roche Holding AG and Boehringer Ingelheim GmbH. In addition, we are aware of IPF treatments in development by Galapagos NV. Further, we are aware of programs targeting $\alpha_v\beta_6$ that are currently being investigated in preclinical studies or clinical trials by companies including Pliant Therapeutics, Inc., and Indalo Therapeutics, Inc. Biogen recently terminated a Phase 2 study of its monoclonal antibody targeting $\alpha_v\beta_6$, citing safety concerns.

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 future 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. For example, we may explore the use of our oral small-molecule integrin therapeutics targeting $\alpha_4\beta_7$ as a combination therapy with other drugs for the treatment of inflammatory bowel disease. 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, 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.

Our collaborations with AbbVie and Janssen are important to our business. We have entered into collaborations with AbbVie and Janssen to discover or develop certain integrin-based therapeutics, and such collaborations currently represent a significant portion of our product pipeline. In particular, MORF-720 is developed in collaboration with AbbVie. In both collaborations, we will 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 expect a significant portion of our future revenue and cash resources to be derived 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.

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, 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 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 our product candidates in the most efficient manner or at all. If a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated. Any failure to successfully develop or commercialize our product candidates pursuant to our current or any future collaboration agreements could have a material and adverse effect on our business, financial condition, results of operations and prospects.

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

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

In June 2015, we entered into a Collaboration Agreement with Schrödinger, which was subsequently amended in March 2018 and in May 2019, 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. See “Management’s Discussion and Analysis of Financial Condition and Results of Operation.” 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 not successfully engage in strategic transactions, including any additional collaborations we seek, which 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 expect 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 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 intend to 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 our collaboration agreements with AbbVie and Janssen, our collaborators will assume responsibility for the manufacturing according to the terms of those agreements 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.

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 verification 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 or unstable political environments. 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.

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 Our Business and Operations

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

As of September 30, 2019, we had approximately 76 full-time employees. As a newly public company, and 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 key management, advisors and other specialized personnel, including Praveen P. Tipirneni, M.D., our chief executive officer, Robert E. Farrell, Jr., CPA, our vice president of finance and operations and treasurer, Bruce N. Rogers, Ph.D., our chief scientific officer, Alexey A. Lugovskoy, Ph.D., our chief development officer, and Timothy A. Springer, Ph.D., our founder and advisor. 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 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 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 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.

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. 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 maybe imposed; and could materially adversely affect our business, results of operations, financial condition and prospects. For example, the loss of clinical trial data from completed or ongoing clinical trials for any of our product candidates could result in delays in our development and regulatory approval efforts and significantly increase our costs to recover or reproduce the data. 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 involves 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 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, 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. 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, 2018, we had net operating loss carryforwards for federal and state income tax purposes of $34.7 million and $21.4 million, respectively, which begin to expire in 2036. As of December 31, 2018, we also had available tax credit carryforwards for federal and state income tax purposes of $0.6 million and $0.4 million, respectively, which begin to expire in 2031. To the extent that our taxable income exceeds any current year operating losses, we plan to use our carryforwards to offset income that would otherwise be taxable. However, utilization of carryforwards generated in tax years beginning after December 31, 2017 are 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 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. 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. 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. Under the Tax Cuts and Jobs Act of 2017, net operating losses generated after December 31, 2017 will not be subject to expiration.

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, 2019, we solely owned published and unpublished pending global patent applications including U.S. and ex-U.S. international counterpart patent filings protecting our integrin therapeutic compounds across multiple programs (including our product candidates). In addition, we hold an exclusive, worldwide license agreement with the Children's Medical Center Corporation the "CMCC Agreement" to one U.S. patent and a related pending U.S. patent application relating to the 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 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 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 were the first to make the inventions claimed in our patents or pending patent applications, or that we 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. 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.

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 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, various 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 these 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, time consuming, delay or prevent the development and commercialization of our product candidates, or put our patents, if and when granted, and other proprietary rights at risk.

Competitors may infringe our patents, if and when granted, or other intellectual property. If we were to initiate legal proceedings against a third party to enforce a patent covering one of our products 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, for example, 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 products 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 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 products 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 products or the use of our products. 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. 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 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 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 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 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 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 products.

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 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. It is impossible to predict whether 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. For example, certain policies of the current U.S. presidential administration may impact our business and industry. Namely, the current U.S. presidential administration has taken several executive actions, including the issuance of a number of executive orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities such as implementing statutes through rulemaking, issuance of guidance, and review and approval of marketing applications. 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

these executive actions 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.

The current U.S. presidential administration and U.S. Congress have sought, and we expect they will continue to, seek to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA. Since January 2017, the current U.S. presidential administration has issued two executive orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. For example, on October 12, 2017, the current U.S. presidential administration issued an executive order that expands the use of association health plans and allows anyone to purchase short-term health plans that provide temporary, limited insurance. This executive order also calls for the halt of federal payments to health insurers for cost-sharing reductions previously available to lower-income Americans to afford coverage. There is still uncertainty with respect to the impact this executive order could have on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. The Tax Cuts and Jobs Act of 2017, or the Tax Reform 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." Additionally, on January 22, 2018, the current U.S. presidential administration signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain ACA-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain

health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. 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". More recently, in July 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Reform Act. While the Texas U.S. District Court Judge, as well as the current U.S. presidential administration and CMS, have stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA. There is still uncertainty with respect to the impact the current U.S. presidential administration and Congress may have, if any, and any changes will likely take time to unfold, and could have an impact on coverage and reimbursement for healthcare items and services covered by plans that were authorized by the ACA. However, we cannot predict the ultimate content, timing or effect of any healthcare reform legislation or the impact of potential legislation on us.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted to reduce healthcare expenditures. U.S. federal government agencies also currently face potentially significant spending reductions, which may further impact 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. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will remain in effect through 2027 unless additional Congressional action is taken. Moreover, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, 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, and reform government program reimbursement methodologies for drug products. At the federal level, the current U.S. presidential administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Additionally, on May 11, 2018, the current U.S. presidential administration laid out the

administration's "Blueprint" to reduce the cost of prescription medications while preserving innovation and cures. While the Department of Health and Human Services, or HHS, is soliciting feedback on some of these measures, other actions may be immediately implemented by HHS under existing authority. Further, on January 31, 2019, the HHS Office of Inspector General, proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. Although a number of these, and other potential, proposals will require additional authorization to become effective, Congress and the current U.S. presidential administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. 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.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA authorization under an FDA expanded access program; however, manufacturers are not obligated to provide investigational new drug products under the current federal right to try law.

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, or CCPA. (which will go into effect on January 1, 2020) 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.

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.

The recent 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 European Union, or 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, the recent United Kingdom referendum on its membership in the EU resulted in a majority of United Kingdom voters voting to exit the European Union, often referred to as Brexit. Brexit could lead to legal uncertainty and potentially divergent national laws and regulations, including those related to the pricing of prescription pharmaceuticals, as the United Kingdom determines which EU laws to replicate or replace. If the United Kingdom were to significantly alter its regulations affecting the pricing of prescription pharmaceuticals, we could face significant new costs. As a result, Brexit could impair our ability to transact business in the EU and the United Kingdom.

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 European Union to the United States. 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 United Kingdom. In particular, it is unclear whether the United Kingdom will enact data protection legislation equivalent to the GDPR and how data transfers to and from the United Kingdom will be regulated.

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 future clinical trials, or the addition or termination of 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 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.

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 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 future 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;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters and other calamities; and
- general economic, industry and market conditions.

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

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for biopharmaceutical companies, which have experienced significant stock price volatility in recent years.

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 before or after the lock-up and other legal restrictions on resale lapse in connection with our IPO, the market price of our common stock could decline significantly. Each of our officers, directors, and our stockholders have entered into lock-up agreements with the underwriters that restrict their ability to sell or transfer their shares. These

lock-up agreements pertaining to our IPO will expire December 23, 2019. However, our underwriters may, in their sole discretion, permit our officers, directors, and other current stockholders who are subject to the contractual lock-up to sell shares prior to the expiration of the lock-up agreements. After the lock-up agreements expire, a substantial number of shares of common stock will be eligible for sale in the public market.

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 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.

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.

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, 2019, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 69% 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.

We are an "emerging growth company" and a "smaller reporting company" and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies or smaller reporting companies will make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or the Sarbanes-Oxley Act, (ii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (iii) exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not approved

previously. In addition, as an emerging growth company, we are only required to provide two years of audited financial statements and two years of selected financial data in this report.

We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the closing of our initial public offering – December 31, 2025, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700.0 million as of the prior June 30th, and (ii) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards. Until the date that we are no longer an "emerging growth company" or affirmatively and irrevocably opt out of the exemption provided by Section 7(a)(2)(B) of the Securities Act, upon issuance of a new or revised accounting standard that applies to our financial statements and that has a different effective date for public and private companies, we will disclose the date on which adoption is required for non-emerging growth companies and the date on which we will adopt the recently issued accounting standard.

We are also a "smaller reporting company," meaning that as of the date of our initial public offering, the market value of our stock held by non-affiliates was less than $700.0 million and our annual revenue was less than $100.0 million during the most recently completed fiscal year. We may continue to be a smaller reporting company until (i) the market value of our stock held by non-affiliates is less than $250.0 million as of the prior June 30th, or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700.0 million as of the prior June 30th. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our share price may be more volatile.

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 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 and asserts claims under the Securities Act, inasmuch as Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rule and regulations thereunder. There is uncertainty as to whether a court would enforce such provision with respect to claims under the Securities Act, and our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

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.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. The increased costs may require us to reduce costs in other areas of our business or increase the prices of our services. Moreover, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by

regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

We are not currently required to comply with the SEC's rules that implement Section 404 of the Sarbanes-Oxley Act, and are therefore not required to make a formal assessment of the effectiveness of our internal control over financial reporting for that purpose. Pursuant to Section 404, we will be required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. This process will be time-consuming, costly and complicated. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. In addition, if we are not able to continue to meet these requirements, we may not be able to remain listed on the Nasdaq Global Market.

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.

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

Use of the IPO Proceeds

On July 1, 2019, we closed our IPO, in which we sold 6,900,000 shares of our common stock at a price of $15.00 per share. The offer and sale of the shares in the IPO were registered under the Securities Act pursuant to a registration statement on Form S-1 (File No. 333-231837), which was filed with the SEC on May 30, 2019, as amended, and declared effective by the SEC on June 26, 2019, as supplemented by a registration statement on Form S-1 filed pursuant to Rule 462 (File No. 333-232373). We raised approximately $93.3 million in net proceeds after deducting underwriting discounts and commissions of $7.3 million and offering expenses. We intend to use the net proceeds we received from our IPO for the development of our $\alpha_4\beta_7$ program and our MInT Platform, and to broaden our pipeline of product candidates, and to fund working capital and general corporate purposes. The representatives of the underwriters of our IPO were Jefferies LLC, Cowen and Company, LLC, BMO Capital Markets Corp. and Wells Fargo Securities, LLC. No payments were made by us to directors, officers or persons owning ten percent or more of our common stock or to their associates, or to our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors pursuant to our director compensation policy.

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
3.1	Restated Certificate of Incorporation of Morphic Holding, Inc.	10-Q	001-38940	08/13/2019	
3.2	Restated Bylaws of Morphic Holding, Inc.	10-Q	001-38940	08/13/2019	
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	XBRL Instance Document				X
101.SCH	XBRL Taxonomy Extension Schema Document.				X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.				X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.				X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.				X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document.				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 12, 2019	By:	/s/ Praveen P. Tipirneni Praveen P. Tipirneni, M.D. President, Chief Executive Officer and Director (Principal Executive Officer)
November 12, 2019	By:	/s/ Robert E. Farrell Jr. Robert E. Farrell Jr. CPA Vice President Finance and Operations and Treasurer (Principal Financial & 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)) 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. 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

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

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

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

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

Date: November 12, 2019

/s/ Praveen P. Tipirneni
Praveen P. Tipirneni, M.D.
President, 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, Robert E. Farrell, Jr., 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)) 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. 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

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

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

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

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

Date: November 12, 2019

/s/ Robert E. Farrell, Jr.
Robert E. Farrell, Jr., CPA
Vice President of Finance and Operations and Treasurer
(Principal Accounting and 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, 2019 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended;

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

Dated: November 12, 2019

/s/ Praveen P. Tipirneni
Praveen P. Tipirneni, M.D.
President, 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, Robert E. Farrell, Jr., Vice President of Finance and Operations 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, 2019 (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.

Dated: November 12, 2019

/s/ Robert E. Farrell Jr.
Robert E. Farrell, Jr., CPA
Vice President of Finance and Operations and Treasurer
(Principal Accounting and Financial Officer)