UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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: 001-39067

VIELA BIO, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**82-4187338**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
One MedImmune Way	
First Floor, Area Two	
Gaithersburg, MD	**20878**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (240) 558-0038

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value per share	VIE	The Nasdaq Global Select Market

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

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

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

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

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

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

As of November 14, 2019, the registrant had 50,962,060 shares of common stock, $0.001 par value per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve risks and uncertainties. All statements other than statements of historical facts contained in in this Form 10-Q are forward-looking statements. In some cases, you can identify forward-looking statements by words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “seek,” “should,” “target,” “will,” “would,” or the negative of these words or other comparable terminology. These forward-looking statements include, but are not limited to, statements about:

- our ability to successfully commercialize and market inebilizumab and/or our other product candidates, if approved;
- our ability to contract with third-party suppliers, manufacturers and other service providers and their ability to perform adequately;
- the potential market size, opportunity and growth potential for inebilizumab and/or our other product candidates, if approved;
- our ability to build our own sales and marketing capabilities, or seek collaborative partners, to commercialize inebilizumab and/or our other product candidates, if approved;
- our ability to obtain funding for our operations;
- the initiation, timing, progress and results of our pre-clinical studies and clinical trials, and our research and development programs;
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals;
- our ability to advance product candidates into, and successfully complete, clinical trials;
- our ability to recruit and enroll suitable patients in our clinical trials;
- the timing or likelihood of the accomplishment of various scientific, clinical, regulatory filings and approvals and other product development objectives;
- the pricing and reimbursement of our product candidates, if approved;
- the degree of market acceptance of inebilizumab and/or our other product candidates by physicians, patients, third-party payors and others in the medical community;
- the rate and degree of market acceptance of our product candidates, if approved;
- the implementation of our business model, strategic plans for our business, product candidates and technology;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- developments relating to our competitors and our industry;
- the accuracy of our estimates regarding expenses, capital requirements and needs for additional financing; and
- our financial performance.

These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including those described in the “Risk Factors” section and elsewhere in this Form 10-Q. Moreover, we operate in a very competitive and rapidly changing environment, and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this Form 10-Q may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable as of the date of this Form 10-Q, we cannot guarantee that the future results, levels of activity, performance or events and circumstances reflected in the forward-

looking statements will be achieved or occur. We undertake no obligation to update publicly any forward-looking statements for any reason after the date of this Form 10-Q to conform these statements to new information, actual results or to changes in our expectations, except as required by law.

You should read this Form 10-Q and the documents that we reference in this Form 10-Q and have filed with the Securities and Exchange Commission, or SEC, as exhibits to this Form 10-Q with the understanding that our actual future results, levels of activity, performance, and events and circumstances may be materially different from what we expect.

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

VIELA BIO, INC.

BALANCE SHEETS
(In thousands, except share and per share amounts)
(Unaudited)

	September 30, 2019	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	$ 155,747	$ 126,898
Marketable securities	42,495	—
Receivable from stockholders	—	12,000
Accounts receivable	5,128	—
Prepaid and other current assets	4,577	456
Total current assets	207,947	139,354
Marketable securities, non-current	24,915	—
Property and equipment, net	905	473
Other assets	73	—
Total assets	$ 233,840	$ 139,827
Liabilities, redeemable convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 5,660	$ 1,142
Accrued expenses	7,487	2,769
Related party liability	13,100	12,054
Total current liabilities	$ 26,247	15,965
Commitments and contingencies (Note 11)		
Series A-1 preferred stock, $.001 par value; 14,225,324 shares authorized, issued and outstanding as of September 30, 2019 and December 31, 2018	142,253	142,253
Series A-2 preferred stock, $.001 par value; 17,000,000 shares authorized, issued and outstanding as of September 30, 2019 and December 31, 2018	170,000	170,000
Series A-3 preferred stock, $.001 par value; 4,705,882 shares authorized, issued and outstanding as of September 30, 2019; 6,470,588 shares authorized and no shares issued or outstanding as of December 31, 2018	80,000	—
Series B preferred stock, $.001 par value; 4,687,500 shares authorized, issued and outstanding as of September 30, 2019; no shares authorized, issued or outstanding as of December 31, 2018	75,000	—
Total redeemable convertible preferred stock	467,253	312,253
Stockholders' deficit:		
Common stock, $.001 par value; 46,159,941 and 41,254,509 shares authorized as of September 30, 2019 and December 31, 2018; 872,324 and 10 shares issued and outstanding as of September 30, 2019 and December 31, 2018	1	—
Additional paid-in capital	5,498	1,879
Accumulated other comprehensive loss	(30)	—
Accumulated deficit	(265,129)	(190,270)
Total stockholders' deficit	(259,660)	(188,391)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 233,840	$ 139,827

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

VIELA BIO, INC.

STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Revenue:				
License revenue	$ —	$ —	$ 20,000	$ —
Total revenue	—	—	20,000	—
Operating expenses:				
Research and development	38,700	13,928	72,113	28,892
General and administrative	10,230	2,401	24,575	4,399
Acquisition of in-process research and development	—	—	—	143,333
Total operating expenses	48,930	16,329	96,688	176,624
Loss from operations	(48,930)	(16,329)	(76,688)	(176,624)
Other income:				
Interest income	520	647	1,829	1,408
Total other income	520	647	1,829	1,408
Net loss	$ (48,410)	$ (15,682)	$ (74,859)	$ (175,216)
Net loss per share attributable to common stockholders—basic and diluted	$ (65)	$ (1,568,200)	$ (150)	$ (17,521,600)
Weighted average common shares outstanding—basic and diluted	749,539	10	497,924	10
Other comprehensive loss				
Change in unrealized gains losses on marketable securities, net	$ (30)	$ —	$ (30)	$ —
Total other comprehensive loss	(30)	—	(30)	—
Total comprehensive loss	$ (48,440)	$ (15,682)	$ (74,889)	$ (175,216)

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

VIELA BIO, INC. STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT
(In thousands, except share and per share amounts)
(Unaudited)

	For the Three Months Ended September 30,													
	Redeemable convertible preferred stock													
	Series A-1		Series A-2		Series A-3		Series B		Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at June 30, 2019	**14,225,324**	**$ 142,253**	**17,000,000**	**$ 170,000**	**—**	**$ —**	4,687,500	**$ 75,000**	**724,795**	**$ 1**	**$ 4,190**	**$ —**	**$ (216,719)**	**$ (212,528)**
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	931	—	—	931
Issuance of common stock for stock options exercised	—	—	—	—	—	—	—	—	132,529	—	377	—	—	377
Issuance of common stock upon vesting of RSAs	—	—	—	—	—	—	—	—	15,000	—	—	—	—	—
Issuance of preferred stock	—	—	—	—	4,705,882	80,000	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(48,410)	(48,410)
Other comprehensive loss	—	—	—	—	—	—	—	—	—	—	—	(30)	—	(30)
Balances at September 30, 2019	**14,225,324**	**$ 142,253**	**17,000,000**	**$ 170,000**	**4,705,882**	**$ 80,000**	**4,687,500**	**$ 75,000**	**872,324**	**$ 1**	**$ 5,498**	**$ (30)**	**$ (265,129)**	**$ (259,660)**
Balances at June 30, 2018	**14,225,324**	**$ 142,253**	**14,000,000**	**$ 140,000**	**—**	**$ —**	**—**	**$ —**	**10**	**$ —**	**$ 688**	**$ —**	**$ (159,534)**	**$ (158,846)**
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	580	—	—	580
Issuance of common stock for stock options exercised	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Issuance of common stock upon vesting of RSAs	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Issuance of preferred stock	—	—	—	—	—	—	—	—				—	—	—
Net loss	—	—	—	—	—	—			—	—	—	—	(15,682)	(15,682)
Balances at September 30, 2018	**14,225,324**	**$ 142,253**	**14,000,000**	**$ 140,000**	**—**	**$ —**	**—**	**$ —**	**10**	**$ —**	**$ 1,268**	**$ —**	**$ (175,216)**	**$ (173,948)**

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

	For the Nine Months Ended September 30,													
	Redeemable convertible preferred stock													
	Series A-1		Series A-2		Series A-3		Series B		Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Accumulated deficit	Total stockholders' deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at December 31, 2018	**14,225,324**	**$ 142,253**	**17,000,000**	**$ 170,000**	**—**	**$ —**	**—**	**$ —**	**10**	**$ —**	**$ 1,879**	**$ —**	**$ (190,270)**	**$ (188,391)**
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	2,218	—	—	2,218
Issuance of common stock for stock options exercised	—	—	—	—	—	—	—	—	493,525	1	1,401	—	—	1,402
Issuance of common stock upon vesting of RSAs	—	—	—	—	—	—	—	—	378,789	—	—	—	—	—
Issuance of preferred stock	—	—	—	—	4,705,882	80,000	4,687,500	75,000	—	—	—		—	—
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(74,859)	(74,859)
Other comprehensive loss												(30)	.	(30)
Balances at September 30, 2019	**14,225,324**	**$ 142,253**	**17,000,000**	**$ 170,000**	**4,705,882**	**$ 80,000**	**4,687,500**	**$ 75,000**	**872,324**	**$ 1**	**$ 5,498**	**$ (30)**	**$ (265,129)**	**$ (259,660)**
Balances at December 31, 2017	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**10**	**$ —**	**$ —**	**$ —**	**$ —**	**$ —**
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	1,268	—	—	1,268
Issuance of common stock for stock options exercised	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Issuance of common stock upon vesting of RSAs	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Issuance of preferred stock	14,225,324	142,253	14,000,000	140,000	—	—	—	—					—	—
Net loss	—	—	—	—	—	—			—	—	—	—	(175,216)	(175,216)
Balances at September 30, 2018	**14,225,324**	**$ 142,253**	**14,000,000**	**$ 140,000**	**—**	**$ —**	**—**	**$ —**	**10**	**$ —**	**$ 1,268**	**$ —**	**$ (175,216)**	**$ (173,948)**

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

VIELA BIO, INC.

STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (74,859)	$ (175,216)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	44	36
Stock-based compensation expense	2,218	1,268
Acquisition of in-process research and development	—	143,333
Amortization of premium and discount on marketable securities, net	(3)	—
Changes in operating assets and liabilities:		
Accounts receivable	(5,000)	—
Prepaid and other current assets	(867)	(280)
Accounts payable, accrued expenses and related party liability	9,265	15,261
Net cash used in operating activities	(69,202)	(15,598)
Cash flows from investing activities:		
Purchase of marketable securities	(67,436)	—
Purchase of property and equipment	(476)	(467)
Acquisition of in-process research and development	—	(143,333)
Net cash used in investing activities	(67,912)	(143,800)
Cash flows from financing activities:		
Proceeds from exercise of common stock options	1,273	—
Proceeds from issuance of redeemable convertible preferred stock	167,000	282,253
Payment of deferred offering costs	(2,310)	—
Net cash provided by financing activities	165,963	282,253
Net increase in cash and cash equivalents	28,849	122,855
Cash and cash equivalents at beginning of period	126,898	—
Cash and cash equivalents at end of year	$ 155,747	$ 122,855
Supplemental disclosure of non-cash financing and investing activities:		
Cash due from stock option exercises	$ 128	$ —
Deferred offering costs	1,017	—

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

1. Nature of the business and basis of presentation

Viela Bio, Inc. ("Viela" or the "Company") is a clinical-stage biotechnology research and development company pioneering and advancing treatments for severe inflammation and autoimmune diseases by selectively targeting shared critical pathways that are the root cause of disease. The Company was incorporated on December 11, 2017 under the laws of the State of Delaware. From December 11, 2017 to December 31, 2017 the Company had no substantive operations.

In February 2018, pursuant to an Asset Purchase Agreement (the "Asset Purchase Agreement") with MedImmune, LLC, MedImmune Limited (collectively, "MedImmune"), and AstraZeneca Collaboration Ventures, LLC ("AZ", and, together with MedImmune, the "AZ Parties"), the Company acquired intellectual property and the biological, regulatory and other materials associated with a portfolio of clinical and pre-clinical molecules, for a purchase price of approximately $142,253 financed by AZ's purchase of the Company's Series A preferred stock. Following the asset purchase, the Company entered into several agreements with AZ and MedImmune, including a license agreement, sublicense agreements, a transition services agreement, a clinical supply agreement and a commercial supply agreement.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, ability to secure additional capital to fund operations, completion and success of clinical testing, compliance with applicable governmental regulations, development by competitors of new technological innovations, dependence on key personnel and protection of proprietary technology. Drug candidates currently under development will require extensive clinical testing prior to regulatory approval and 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.

In October, 2019, the Company completed an initial public offering (the "IPO") of its common stock and issued and sold 7,900,000 shares of common stock at a public offering price of $19.00 per share, resulting in gross proceeds of $150,100 and net proceeds of $136,266 after deducting underwriting discounts and commissions and offering expenses of approximately $13,834. In addition, and contemporaneously with the closing of the issuance and sale of the aforementioned shares, the Company issued and sold an additional 1,185,000 shares of common stock, pursuant to the full exercise of the underwriter's option to purchase additional shares, for gross proceeds of $22,515 and net proceeds of $20,939 after deducting underwriting discounts and commissions of $1,576. Thus, the aggregate gross proceeds to the Company from the IPO were $172,615 and net proceeds after deducting underwriting discounts and commissions and other offering costs, were $157,205. Upon the closing of the IPO, the outstanding shares of series A redeemable convertible preferred stock (the "Series A Preferred Stock"), and series B redeemable convertible preferred stock (the "Series B Preferred Stock" and together with the Series A Preferred Stock, the "Preferred Stock") converted into an aggregate of 40,618,706 shares of common stock.

Basis of Presentation

The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). All adjustments necessary for the fair presentation of the Company's financial statements have been presented.

The accompanying balance sheet as of September 30, 2019, the related statements of operations and comprehensive loss and redeemable convertible preferred stock and stockholders' deficit for the three and nine months ended September 30, 2019 and 2018, and the statements of cash flows for the nine months ended September 30, 2019 and 2018 and related footnote disclosures are unaudited. All adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of the accompanying interim balance sheet, statements of operations and comprehensive loss, redeemable convertible preferred stock and stockholders' deficit and cash flows have been made. The results for the nine months ended September 30, 2019 and 2018, are not necessarily indicative of results to be expected for the year ending December 31, 2019, any other interim periods or any future year or period.

2. Summary of significant accounting policies

Use of estimates

The preparation of the Company's financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of expenses during the reporting period. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, the recognition of research and development expenses based on when services are performed, the valuations of share based compensation arrangements, and the valuation allowance for deferred tax assets. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates when there are changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results could differ from those estimates.

Cash and cash equivalents

The Company considers all highly liquid instruments with an original maturity of 90 days or less at acquisition to be cash equivalents.

Marketable Securities

The Company's marketable securities are classified as available-for-sale and are carried at fair value, with the unrealized gains and losses reported as a component of accumulated other comprehensive loss in stockholder's deficit. Realized gains and losses and declines in value determined to be other than temporary are based on the specific identification method and are included as a component of other income (expense), net in the statements of operations and comprehensive loss. Marketable securities that mature within one year from the balance sheet date are classified as short-term.

The Company evaluates its marketable securities with unrealized losses for other-than-temporary impairment. When assessing marketable securities for other-than-temporary declines in value, the Company considers such factors as, among other things, how significant the decline in value is as a percentage of the original cost, how long the market value of the investment has been less than its original cost, the Company's ability and intent to retain the investment for a period of time sufficient to allow for any anticipated recovery in fair value and market conditions in general. If any adjustments to fair value reflects a decline in the value of the investment that the Company considers to be "other-than-temporary", the Company reduces the investment to fair value through a charge to the statements of operations and comprehensive loss. No such adjustments were necessary during the periods presented.

Concentrations of credit risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and the Company's money market fund investment. Periodically, the Company maintains deposits in accredited financial institutions in excess of federally insured limits. The Company deposits its cash in financial institutions that it believes have high credit quality and has not experienced any losses on such accounts and does not believe it is exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Fair value measurements

Certain assets and liabilities of the Company are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1—Quoted prices in active markets for identical assets or liabilities.

- Level 2—Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3—Unobservable inputs that are supported by little or no market activity that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The carrying amount of the Company's financial instruments, including cash and cash equivalents and accounts payable approximate their fair values. No transfer of assets between Level 1 and Level 2 of the fair value hierarchy occurred during the three and nine months ended September 30, 2019 and 2018.

Deferred Offering Costs

The Company has deferred offering costs, consisting of legal, accounting, printer and filing fees related to the IPO, that were deferred and were offset against the offering proceeds upon the completion of the IPO in October, 2019. As of September 30, 2019, $3,327 of deferred offering costs were recorded within prepaids and other current assets on the balance sheet. As of December 31, 2018, no amounts were deferred.

Segment information

The Company manages its operations as a single operating segment for the purposes of assessing performance and making operating decisions. The Company's singular focus is developing and commercializing transformative treatments for severe inflammation and autoimmune diseases.

Research and development expenses

Research and development expenses are expensed as incurred. Research and development expenses consist of costs incurred to discover, research and develop drug candidates, including personnel expenses, stock-based compensation expense, allocated facility-related and depreciation expenses, third-party license fees and external costs including fees paid to consultants and clinical research organizations ("CROs"), in connection with nonclinical studies and clinical trials, and other related clinical trial fees, such as for investigator grants, patient screening, laboratory work, clinical trial database management, clinical trial material management and statistical compilation and analysis.

Costs incurred in purchasing technology or technology licenses are charged immediately to research and development expense if the technology has not reached technological feasibility and has no alternative future uses.

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. A majority of these payments are pass-through payments that are made to AZ Parties due to the existing contracts in place associated with the in-process research and development ("IPR&D") assets acquired (see Note 7, "Asset acquisition"). The Company, through the AZ Parties outsources a substantial portion of its clinical trial activities, utilizing external entities such as CROs, independent clinical investigators, and other third-party service providers to assist it with the execution of its clinical studies. For each clinical trial that the Company conducts, certain clinical trial costs are expensed immediately, while others are expensed over time based on the expected total number of patients in the trial, the rate at which patients enter the trial, and/or the period over which clinical investigators or CROs are expected to provide services.

Clinical activities which relate principally to clinical sites and other administrative functions to manage the Company's clinical trials are performed primarily by CROs. CROs typically perform most of the start-up activities for the Company's trials, including document preparation, site identification, screening and preparation, pre-study visits, training, and program management. These start-up costs usually occur within a few months after the contract has been executed and are event-driven in nature. The remaining activities and related costs, such as patient monitoring and administration, generally occur ratably throughout the life of the individual contract or study. In the event of early termination of a clinical trial, the Company accrues and recognizes expenses in an amount based on its estimate of the remaining non-cancelable obligations associated with the winding down of the clinical trial and/or penalties.

For clinical study sites, where payments are made periodically on a per-patient basis to the institutions performing the clinical study, the Company accrues expenses on an estimated cost-per-patient basis, based on subject enrollment and activity in each period. The amount of clinical study expense recognized in a period may vary from period to period based on the duration and progress of the study, the activities to be performed by the sites each quarter, the required level of patient enrollment, the rate at which patients actually enroll in and drop out of the clinical study, and the number of

sites involved in the study. Clinical trials that bear the greatest risk of change in estimates are typically those that have a significant number of sites, require a large number of patients, have complex patient screening requirements, and span multiple years. During the course of a trial, the Company adjusts its rate of clinical expense recognition if actual results differ from the Company's estimates. The Company's estimates and assumptions for clinical expense recognition could differ significantly from the Company's actual results, which could cause material increases or decreases in research and development expenses in future periods when the actual results become known.

Patent costs

All patent-related costs incurred in connection with filing and prosecuting patent applications are expensed as incurred due to the uncertainty about the recovery of the expenditure. Amounts incurred are classified as general and administrative expenses.

Property and equipment

Property and equipment, which consists mainly of laboratory equipment, are carried at cost less accumulated depreciation. Depreciation is computed over the estimated useful lives of the respective assets, generally ten years, using the straight-line method. Leasehold improvements are amortized over the shorter of the estimated useful lives of the assets or the lease term. Expenditures for maintenance and repairs which do not materially extend the useful lives of the assets are charged to expense as incurred. The cost and accumulated depreciation or amortization of assets that meet the guidance within Accounting Standards Codification ("ASC") Topic 360 as either retired or sold are removed from the respective accounts, and any gain or loss is recognized in operations upon closing of the transaction. The Company periodically assesses the recoverability of long-lived assets, such as property and equipment, and evaluates such assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable.

Revenue Recognition for Contracts with Customers

To date, the Company has recognized revenues through commercialization and collaboration agreements.

Effective January 1, 2019, the Company adopted Accounting Standards Update ("ASU") No. 2014-09, Revenue (ASC 606): Revenue from Contracts with Customers ("ASC 606"), using the modified retrospective transition method. Under this method, results for reporting periods beginning on January 1, 2019 are presented under ASC 606, while prior periods were prepared and reported in accordance with ASC Topic 605, Revenue Recognition ("ASC 605"). The adoption of ASC 606 resulted in no cumulative adjustment as the Company had substantially no assets until executing the Asset Acquisition in February 2018 (as described in Note 7, "Asset acquisition") and did not enter into a revenue contract with a customer until May 2019 (as described in Note 13, "Collaboration agreements").

ASC 606 applies to all contracts with customers, except for contracts that are within the scope of other standards. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, the Company performs the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

At contract inception, once the contract is determined to be within the scope of ASC 606, the Company assesses the goods or services promised within each contract and determines those that are performance obligations and assesses whether each promised good or service is distinct. The Company then recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered options. We assess if these options provide a material right to the customer and if so, they are considered performance obligations. The exercise of a material right is accounted for as a contract modification for accounting purposes.

The Company recognizes as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) each performance obligation is satisfied at a point in time or over time, and if over time this is based on the use of an output or input method.

Amounts recognized as revenue for which the Company has the contractual right to bill, but has not yet received, are classified as accounts receivable in the accompanying balance sheets. Amounts recognized as revenue for which the

Company does not have the contractual right to bill are generally recognized as contract assets in the accompanying balance sheets.

Amounts received prior to revenue recognition are recorded as deferred revenue. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current liabilities in the accompanying balance sheets. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as long-term liabilities.

Licenses of Intellectual Property – The terms of the Company's contracts with customers may include the license of functional intellectual property, given the functionality of the intellectual property is not expected to change substantially as a result of the Company's ongoing activities. If the license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from the portion of the transaction price allocated to the license when the license is transferred to the licensee and the licensee is able to use and benefit from the license. For licenses that are bundled with other promises (that is, for licenses that are not distinct from other promised goods and services in an arrangement), the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Milestone Payments – If an arrangement includes development and regulatory milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control or the licensee's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received.

Royalties – For arrangements that include sales-based royalties, including milestone payments based on a level of sales, which are the result of a customer-vendor relationship and for which the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, the Company has not recognized any royalty revenue or milestone payments resulting from any of its licensing arrangements.

Significant Financing Component – In determining the transaction price, the Company adjusts consideration for the effects of the time value of money if the timing of payments provides the Company with a significant benefit of financing. The Company does not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the licensees and the transfer of the promised goods or services to the licensees will be one year or less. The Company assessed each of its revenue arrangements in order to determine whether a significant financing component exists and concluded that a significant financing component does not exist in any of its arrangements.

Collaborative Arrangements – The Company enters into collaboration agreements, which are within the scope of ASC 606, to discover, develop, manufacture or commercialize product candidates. The terms of these agreements typically contain multiple promises or obligations, which may include: (1) licenses, or options to obtain licenses, to use the Company's technology, (2) research and development activities to be performed on behalf of the collaboration partner, and (3) in certain cases, services in connection with the manufacturing of preclinical and clinical material. Payments the Company receives under these arrangements typically include one or more of the following: non-refundable, upfront license fees; clinical and development, regulatory, and sales milestone payments; and royalties on future product sales.

The Company also analyzes its collaboration arrangements to assess whether they are within the scope of ASC 808, Collaborative Arrangements ("ASC 808") to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, the Company first determines which elements of the collaboration are deemed to be within the scope of ASC 606. For those elements of the arrangement that are accounted for pursuant to ASC 606, the Company applies the five-step model described above.

Stock-based compensation

The Company measures all stock-based awards granted to employees based on the fair value on the date of the grant and recognizes compensation expense into either general and administrative expense or research and development expense for those awards over the requisite service period, which is generally the vesting period of the respective award. The Company accounts for forfeitures as they occur. For stock-based awards with service-based vesting conditions, the Company recognizes compensation expense using the straight-line method.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option pricing model, which requires inputs based on certain subjective assumptions, including the fair value of the Company's common stock, expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option, and the Company's expected dividend yield. In order to determine the fair value, the Company considered, among other things, contemporaneous valuations of the Company's common stock, the Company's business, financial condition and results of operations, including related industry trends affecting its operations; the likelihood of achieving a liquidity event, such as an IPO or sale, given prevailing market conditions; the lack of marketability of the Company's common stock; the market performance of comparable publicly traded companies; and U.S. and global economic and capital market conditions. As there was no public market for its common stock prior to October 3, 2019, which was the first day of trading, the Company estimates its expected share price volatility based on the historical volatility of publicly traded peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded share price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future. The fair value of each restricted common stock award is estimated on the date of grant based on the fair value of the Company's common stock on that same date.

The Company classifies stock-based compensation expense in its statement of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Income taxes

The Company accounts for income taxes in accordance with ASC Topic 740, *Income Taxes*. Under the asset and liability method, deferred income taxes are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis and operating loss carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the year in which those temporary differences are expected to be recovered or settled. The effect of changes in tax rates on deferred tax assets and liabilities is recognized in income in the period such changes are enacted. A valuation allowance is provided against net deferred tax assets if recoverability is uncertain on a more likely than not basis. As of September 30, 2019, the Company has established a full valuation allowance with respect to its deferred tax assets.

The Company recognizes the impact of an uncertain tax position if the position will more likely than not be sustained upon examination by a taxing authority, based on the technical merits of the position. The Company's policy is to recognize interest related to unrecognized tax benefits as interest expense and penalties as operating expenses. As of September 30, 2019, the Company had no unrecognized tax benefits and as such, no liability, interest or penalties were required to be recorded. The Company does not expect this to change significantly in the next twelve months.

Net loss per share

Basic net loss per share is computed by dividing the net loss by the weighted average number of common shares outstanding during the period.

Diluted net loss per share is computed by dividing net loss by the weighted average number of common shares adjusted for the dilutive effect of common equivalent shares outstanding during the period. As of September 30, 2019, and December 31, 2018, common stock equivalents consisted of the Preferred Stock and stock options that were vested and exercisable as of September 30, 2019 and December 31, 2018. Net loss per share attributable to common stockholders is calculated using the two-class method, which is an earnings allocation formula that determines net loss per share for the

holders of the Company's common shares and participating securities. The C ompany's Preferred Stock contains participating rights in any dividend paid by the Company and are deemed to be participating securities. Net loss attributable to common stockholders and participating preferred shares is allocated to each share on an as-converted basis as if all of the earnings for the period had been distributed. The participating securities do not include a contractual obligation to share in the losses of the Company and are not included in the calculation of net loss per share in the periods that have a net loss. Common equivalent shares are excluded from the computation in periods in which they have an anti-dilutive effect on net loss per share.

Diluted net loss per share is computed using the more dilutive of (a) the two-class method or (b) the if-converted method. In periods in which the Company reports a net loss attributable to common stockholders, diluted net loss per share attributable to common stockholders is the same as basic net loss per share attributable to common stockholders since dilutive common shares are not assumed to have been issued if their effect is anti-dilutive. Diluted net loss per share is equivalent to basic net loss per share for the periods presented herein because common stock equivalent shares from the Series A and Series B Preferred Stock were anti-dilutive. Due to their dilutive effect, the calculation of diluted net loss per share for the nine months ended September 30, 2019, and 2018 does not include the following common stock equivalent shares:

	September 30,	
	2019	2018
Series A Preferred Stock	35,931,206	28,225,324
Series B Preferred Stock	4,687,500	—
Stock Options	391,720	—
Total	41,010,426	28,225,324

For the three and nine months ended September 30, 2019 and 2018, there were no reconciling items between basic and diluted net loss per share.

Emerging growth company

The Company is an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act"). Under the JOBS Act, companies have extended transition periods available for complying with new or revised accounting standards. The Company has elected this exemption to delay adopting new or revised accounting standards until such time as those standards apply to private companies. Where allowable, the Company has early adopted certain standards as described below.

Recently adopted accounting pronouncements

In January 2017, the Financial Accounting Standards Board ("FASB") issued ASU No. 2017-01, *Business Combinations (Topic 805): Clarifying the Definition of a Business* ("ASU 2017-01"), which clarifies the definition of a business and provides a screen to determine when an integrated set of assets and activities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired (or disposed of) is concentrated in a single identifiable asset or a group of similar identifiable assets, the asset is not a business. For non-public entities, ASU 2017-01 is effective for annual reporting periods beginning after December 15, 2018, including interim periods within those fiscal years. Early adoption is permitted. The Company early adopted ASU 2017-01 as of January 1, 2018. The Company applied this standard when evaluating the asset acquisition discussed in Note 7, "Asset acquisition".

In May 2017, the FASB issued ASU No. 2017-09, *Compensation—Stock Compensation (Topic 718): Scope of Modification Accounting* ("ASU 2017-09"). The amendments in ASU 2017-09 clarify that modification accounting is required only if the fair value, the vesting conditions or the classification of the awards (as equity or liability) change as a result of the change in terms or conditions. For non-public entities, ASU 2017-09 is effective for annual reporting periods beginning after December 15, 2017, including interim periods within those fiscal years. The Company adopted ASU 2017-09 as of January 1, 2018. The adoption of ASU 2017-09 did not have a material impact on the Company's financial position, results of operations or cash flows, but will impact the accounting for modifications of stock-based awards, if any, after the date of adoption.

In November 2018, the FASB issued ASU No. 2018-18, Collaborative Arrangements (Topic 808)—Clarifying the Interaction between Topic 808 and ASC 606 ("ASU 2018-18"). The amendments in ASU 2018-18 make targeted improvements to GAAP for collaborative arrangements by clarifying that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606 when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in ASC 606 should be applied, including recognition, measurement, presentation, and disclosure requirements. In addition, unit-of-account guidance in ASU 2018-18 was aligned with the guidance in ASC 606 (that is, a distinct good or service) when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of ASC 606. ASU 2018-18 is effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted, including adoption in any interim period. The amendments should be applied retrospectively to the date of initial application of ASC 606. The Company adopted this guidance effective January 1, 2019 with its initial application of ASC 606. The adoption of the standard did not have an impact on the Company's financial statements.

Recently issued accounting pronouncements

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), which sets out the principles for the recognition, measurement, presentation and disclosure of leases for both parties to a contract (i.e., lessees and lessors). The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less at lease inception may be accounted for similar to existing guidance for operating leases today. For non-public entities, ASU 2016-02 is effective for annual reporting periods beginning after December 15, 2019, including interim periods within those fiscal years, and early adoption is permitted. In July 2019, the FASB voted to approve the delay of the effective date of the standard for private companies and non-profit organizations to annual reporting periods beginning December 15, 2020, included interim periods within those fiscal years. The Company is in the process of completing its review of its existing lease agreements under ASC 842 and does not expect the adoption of ASU 2016-02 to have a material impact on its financial position, results of operations or cash flows.

In July 2017, the FASB issued ASU No. 2017-11, *Earnings Per Share (Topic 260), Distinguishing Liabilities from Equity (Topic 480), Derivatives and Hedging (Topic 815) (Part I) Accounting for Certain Financial Instruments with Down Round Features (Part II) Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain Nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception* ("ASU 2017-11"). Part I applies to entities that issue financial instruments such as warrants, convertible debt or convertible preferred stock that contain down-round features. Part II replaces the indefinite deferral for certain mandatorily redeemable noncontrolling interests and mandatorily redeemable financial instruments of non-public entities contained within ASC Topic 480 with a scope exception and does not impact the accounting for these mandatorily redeemable instruments. For non-public entities, ASU 2017-11 is effective for annual reporting periods beginning after December 15, 2019, including interim periods within those fiscal years. The Company is currently evaluating the impact that the adoption of ASU 2017-11 will have on its financial statements.

In August 2018, the FASB issued No. ASU 2018-13, *Fair Value Measurement (Topic 820)—Disclosure Framework* ("ASU 2018-13"), which improves the disclosure requirements for fair value measurements. For non-public entities, ASU 2018-13 is effective for annual reporting periods beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted for any removed or modified disclosures. The Company is currently evaluating the impact that the adoption of ASU 2018-13 will have on its financial statements.

3. Marketable securities

The following is a summary of the Company's available-for-sale marketable securities and cash equivalents as of September 30, 2019:

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Market Value
Cash equivalents				
Certificates of deposit and time deposits	$ 400	$ —	$ —	$ 400
Commercial paper	11,532	—	(1)	11,531
Total cash equivalents	$ 11,932	$ —	$ (1)	$ 11,931
Current marketable securities:				
Certificates of deposit and time deposits	$ 3,802	$ —	$ (1)	$ 3,801
Commercial paper	17,922	—	(2)	17,920
Corporate debt securities	20,783	3	(12)	20,774
Total marketable securities, current	$ 42,507	$ 3	$ (15)	$ 42,495
Non-current marketable securities:				
U.S. Treasury securities	$ 8,037	$ —	$ (8)	$ 8,029
Corporate debt securities	16,895	3	(12)	16,886
Total marketable securities, non-current	$ 24,932	$ 3	$ (20)	$ 24,915
Total marketable securities	$ 67,439	$ 6	$ (35)	$ 67,410

The maturities of the Company's long-term marketable securities ranges from one to two years. The Company did not hold any available-for-sale marketable securities as of December 31, 2018.

4. Fair value measurement

As of September 30, 2019, the Company held certain assets that required to be measured at fair value on a recurring basis, as follows:

	September 30, 2019		
	Cash and Cash equivalents	Short-Term Marketable Securities	Long-Term Marketable Securities
Cash	$ 123,863	$ —	$ —
Level 1			
Money market funds	19,953	—	—
Level 2			
U.S. Treasury securities	—	—	8,029
Certificates of deposits and time deposits	400	3,801	—
Corporate debt securities	—	20,774	16,886
Commercial paper	11,531	17,920	—
Subtotal	11,931	42,495	24,915
Total	$ 155,747	$ 42,495	$ 24,915

As of December 31, 2018, the Company held certain assets that required to be measured at fair value on a recurring basis, as follows:

	December 31, 2018		
	Cash and Cash equivalents	Short-Term Marketable Securities	Long-Term Marketable Securities
Cash	$ 21,681	$ —	$ —
Level 1			
Money market funds	105,217	—	—
Total	$ 126,898	$ —	$ —

5. Common stock

As of September 30, 2019 and December 31, 2018, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 46,159,941 and 41,254,509 shares, respectively, of $0.001 par value common stock. As of September 30, 2019 and December 31, 2018, there were 872,324 shares and 10 shares of common stock issued and outstanding, respectively.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders, provided, however, that except as otherwise required by law, holders of common stock shall not be entitled to vote on any amendment to the Company's certificate of incorporation that relates solely to the terms of one or more outstanding series of preferred stock, if the holders of the affected series are entitled to vote thereon. Common stockholders are entitled to receive dividends, as may be declared by the board of directors, if any, subject to the preferential dividend rights of preferred stock.

Through September 30, 2019, no cash dividends had been declared or paid. During the year ended December 31, 2018, the Company granted 757,577 shares of restricted common stock to employees under the 2018 Equity Incentive Plan. The Company did not grant any shares of restricted common stock to employees under the 2018 Equity Incentive Plan during the nine months ended September 30, 2019. As of September 30, 2019, 378,789 shares granted under the 2018 Equity Incentive Plan have vested. No shares had vested as of December 31, 2018.

6. Convertible redeemable preferred stock

At September 30, 2019 and December 31, 2018, the Company had 40,618,706 and 37,695,912 shares of preferred stock, par value $0.001 per share, in authorized capital, respectively.

At September 30, 2019, the Company's redeemable convertible preferred stock consisted of the following:

	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value
Series A-1 Preferred Stock	14,225,324	14,225,324	$ 142,253
Series A-2 Preferred Stock	17,000,000	17,000,000	170,000
Series A-3 Preferred Stock	4,705,882	4,705,882	80,000
Series B Preferred Stock	4,687,500	4,687,500	75,000
Total	40,618,706	40,618,706	$ 467,253

At December 31, 2018, the Company's redeemable convertible preferred stock also consisted of the following:

	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value
Series A-1 Preferred Stock	14,225,324	14,225,324	$ 142,253
Series A-2 Preferred Stock	17,000,000	17,000,000	170,000
Series A-3 Preferred Stock	6,470,588	—	—
Series B Preferred Stock	—	—	—
Total	37,695,912	31,225,324	$ 312,253

Series A Preferred Stock

On February 23, 2018 (the "Transaction Date"), pursuant to the Series A Preferred Stock Purchase Agreement, by and among the Company and certain purchasers, and as part of an initial tranche closing, the Company issued 14,225,324 shares of Series A-1 preferred stock and 14,000,000 shares of Series A-2 preferred stock, par value $0.001 per share, at a purchase price of $10.00 per share, resulting in gross proceeds of approximately $282,253 to the Company (the "Initial Tranche Closing").

In addition to the Initial Tranche Closing, the Series A Preferred Stock Purchase Agreement provided for the issuance of up to 6,470,588 shares of Series A-3 at a purchase price of $17.00 per share upon acceptance for review by the U.S. FDA of the Company's first biologics license application for lead product candidate, inebilizumab, for the

indication neuromyelitis optica spectrum disorder (the “Milestone Closing”). However, at any time prior to the Milestone Closing, the b oard of directors could determine that the Company required additional capital to fund its operations, upon which the board of directors may cause the Company to sell and the holders of the Series A-2 to purchase up to 3,000,000 additional shares of Series A-2 preferred stock at a purchase price of $10.00 per share (the “Additional Closing”). In December 2018, the Additional Closing occurred, and the Company received $30,000 in exchange for 3,000,000 shares of Series A-2. As of December 31, 2018, $12,000 of the $30,000 was recorded as a receivable as funds were not received until January 2019 and the Company provided supplemental non-cash financing disclosure on its statement of cash flows for the year ended December 31, 2018. The proceeds received upon the Additional Closing would reduce the proceeds from the Milestone Closing. Both the Additional Closing and Milestone Closing were evaluated and determined to be embedded features within the Series A Preferred Stock that did not require bifurcation. In addition, if any holder of Series A-2 preferred stock failed to purchase the committed amount under either the Additional Closing or Milestone Closing (“Purchaser Default”), then all shares of Series A-2 preferred stock held by such holder would automatically be converted into shares of Common Stock as is determined by dividing (i) the aggregate number of shares of Series A-2 preferred stock held by such individual by (ii) 10 and (b) if such individual had previously converted their Series A-2 shares to Common Stock, 90% of such shares would automatically be redeemed by the Company for no consideration (the “Special Mandatory Redemption”). The Special Mandatory Redemption was evaluated and determined to be accounted for as an embedded derivative. However, the Company determined an insignificant value should be ascribed to the Special Mandatory Redemption as the likelihood of a Purchaser Default occurring was deemed to be remote both at the Transaction Date and December 31, 2018.

In September 2019, the Company issued an aggregate of 4,705,882 shares of Series A-3 preferred stock at a purchase price of $17.00 per share for an aggregate gross consideration of $80,000.

Series B Preferred Stock

During June 2019, pursuant to the Series B Preferred Stock Purchase Agreement, by and among the Company and certain purchasers, the Company issued 4,687,500 shares of Series B preferred stock, par value $0.001 per share, at a purchase price of $16.00 per share, resulting in gross proceeds of approximately $75,000 to the Company.

Prior to the closing of the IPO, the holders of the Preferred Stock had the following rights and preferences:

Voting

Each holder of the Preferred Stock was entitled to the number of votes equal to the number of shares of Common Stock into which the number of shares of Preferred Stock held by such holder were convertible and should vote together with the holders of Common Stock as a single class. The holders of the preferred stock were entitled to elect seven of the eight directors on the Board of Directors. Two of the seven directors were elected by the Series A-1 preferred stockholders, four of the directors were elected by the Series A-2 preferred stockholders, one of the directors was elected by the Series B preferred stockholders, and the remaining director is the Company’s chief executive officer.

Dividends

The Series B preferred stock accrued cumulative dividends o n a daily basis at a fixed dividend rate of $1.28 per share per annum payable only when, as and if declared by the Board of Directors of the Company, prior and in preference to any declaration or payment of any dividend on shares of any other class or series of capital stock of the Company (“Accruing Dividends”) unless the holders of the Series B preferred stock first (and Series A preferred stock thereafter) received, or simultaneously received, a dividend in an amount at least equal to the formula included in the Company’s charter which varied based on whether the dividend was on the Common Stock or on any other class or series not convertible into Common Stock. Through September 30, 2019, no dividends had been declared or paid by the Company.

Liquidation

In the event of any liquidation, dissolution or winding-up of the Company or a Deemed Liquidation Event (as defined below), the holders of the Series B preferred stock then outstanding would be entitled to be paid out of the assets of the Company available for distribution to stockholders, and before any payment would be made to holders of Series A preferred stock and Common Stock, in an amount per share equal to the original issue price per share, plus all Accruing Dividends accrued but unpaid thereon, whether or not declared, together with all other declared but unpaid dividends thereon. If upon such event, the assets of the Company available for distribution were insufficient to permit payment in full to the holders of Series B preferred stock, the proceeds would be ratably distributed among the holders of Series B preferred stock. After satisfaction of the Series B preferred stock liquidation preference, the holders of the Series A preferred stock were entitled to be paid before any payment shall be made to the holders of Common Stock in an amount equal to the original issue price per share, plus any declared but unpaid dividends thereon. Due to this redemption option, the Preferred Stock was recorded in mezzanine equity and subject to subsequent measurement under the guidance provided under ASC 480-10-S99. In accordance with that guidance, the Company has elected to not recognize any subsequent changes in the redemption value as the Company has determined it is not probable that the Preferred Stock will become redeemable.

After payments have been made in full to the holders of the Preferred Stock, the remaining assets of the Company available for distribution would be distributed among the holders of Preferred Stock and the holders of Common Stock on a pro-rata basis as if the shares of Preferred Stock were converted into Common Stock immediately prior to the liquidation event.

A merger or consolidation involving the Company in which the stockholders of the Company do not own a majority of the outstanding shares of the surviving company shall be considered a Deemed Liquidation Event. A sale, lease, transfer, exclusive license or other disposition of all or substantially all of the assets of the Company shall also be considered a Deemed Liquidation Event. As of September 30, 2019 and December 31, 2018, the liquidation preference of the outstanding shares of the Preferred Stock was approximately $468,995 and $312,253, respectively.

Conversion

Each share of Preferred Stock was convertible into Common Stock at the option of the holder at any time after the date of issuance. In addition, each share of Preferred Stock would be automatically converted into shares of Common Stock, at the applicable conversion ratio then in effect, upon the earlier of (i) a qualified public offering with net proceeds of at least $75,000 and a price of not less than $17.60 per share, subject to appropriate adjustment for any stock dividend, stock split, combination or other similar recapitalization, (ii) by the affirmative vote of the holders of at least 75% of the then-outstanding Series A preferred stock and a majority of the holders of the outstanding shares of the Series B preferred stock, if such vote was obtained prior to the Milestone Closing or (iii) by the affirmative vote of the holders of at least 75% of the then-outstanding shares of Series A-2 preferred stock and Series A-3 preferred stock (voting together as a single class on an as-converted to Common Stock basis) and a majority of the outstanding shares of Series B preferred stock (voting together as a single class on an as-converted to Common Stock basis) if such vote was obtained after the Milestone Closing. Upon conversion, the shares of Preferred Stock would be converted into Common Stock, at par value, with the remainder recorded to additional paid-in capital.

The conversion ratio of the Preferred Stock was determined by dividing the original issue price per share by the conversion price in effect at the time of conversion. The initial conversion price was equal to the original issuance price of the Preferred Stock and was subject to appropriate adjustment in the event of any stock dividend, stock split, combination or recapitalization affecting the Preferred Stock.

Upon the closing of the IPO, the Company's outstanding Preferred Stock converted into an aggregate of 40,618,706 shares of common stock. Upon conversion of the Preferred Stock, the Company reclassified the carrying value of the Preferred Stock to common stock and additional paid-in capital.

7. Asset acquisition

Contemporaneously on the Transaction Date, the Company entered into the Asset Purchase Agreement with the AZ Parties to acquire the intellectual property and the biological, regulatory and other materials associated with a portfolio of clinical molecules ("Clinical Molecules") and pre-clinical molecules for potential therapies for autoimmune diseases and inflammation (collectively, the "Acquired Molecules"), for a purchase price of approximately $142,253 ("Asset Acquisition"), which includes direct and incremental transaction expenses of approximately $1,000. The Acquired Molecules consist of multiple in-process research and development projects related to biological therapies which are intended to treat an interrelated subset of auto-immune disorders, represented in part by common biological

characteristics. As of the acquisition date, the Acquired Molecules were either in the pre-clinical stage, Phase 1a trial, Phase 1b trial or Phase 2 trial. Further, the Acquired Molecules are related to various potential indications, all of which were identified by the Company as preliminary on the Transaction Date. Until a lead indication is identified, it is not uncommon for the preliminary indications of a drug compound to change during the early clinical development stages.

In addition to the Acquired Molecules, in connection with the Asset Acquisition certain former employees of the AZ Parties were either hired by the Company simultaneously or shortly following the Transaction Date. Further, the Company assumed certain ongoing CRO contracts from the AZ Parties related to the research and development of the Acquired Molecules. The services provided by the CRO contracts are readily available in the marketplace and are not considered to be unique or scarce. The estimated fair value associated with the employees and CRO contracts was deemed to be insignificant.

The Asset Acquisition was accounted for as acquisition of assets that did not meet the definition of a business. The Asset Acquisition did not constitute a business as substantially all of the fair value of the gross assets acquired was concentrated in the Clinical Molecules, which represent a group of similar identifiable assets as of the acquisition date. As of the acquisition date, the Clinical Molecules were deemed to share similar risk characteristics as (1) each of the Clinical Molecules were in the early development stages of a drug compound and shared a similar financial, technical and regulatory risk profile, (2) only preliminary indications had been identified for any of the Clinical Molecules and (3) the underlying biologic therapies of the Clinical Molecules were similar in that each was intended to treat an interrelated subset of autoimmune disorders by interrupting biologic mechanisms that otherwise result in inflammation and tissue damage.

Because the Acquired Molecules were accounted for as an asset acquisition that did not meet the definition of a business, the Acquired Molecules were recorded at their fair values, which equaled the fair value of the consideration paid of approximately $142,253. However, because the Acquired Molecules represent in-process research and development with no alternative future use, the Company immediately expensed the fair value of the Acquired Molecules in the Statement of Operations and Comprehensive Loss.

8. Stock-based compensation

The Company's Amended and Restated 2018 Equity Incentive Plan (the "Equity Incentive Plan") provides for the grant of stock options (both incentive and non-statutory), restricted stock awards, restricted stock unit awards, stock appreciation rights, and other forms of stock-based awards to employees, consultants and directors.

During the nine months ended September 30, 2019 and 2018, the Company granted stock options that vest over four years and have a maximum contractual term of ten years. The Company also granted restricted stock awards that vest over two years during the nine months ended September 30, 2018. Vesting is subject to the holder's continuous service with the Company. The Company reserved 5,541,224 shares of common stock for issuance under the Equity Incentive Plan.

Stock options

The following table summarizes the Company's stock option activity for the nine months ended September 30, 2019:

	Number of options	Weighted-average exercise price	Weighted-average remaining contractual term (years)
Outstanding at December 31, 2018	2,485,650	$ 2.84	9.25
Granted	1,242,700	$ 11.92	
Exercised	(493,525)	$ 2.84	
Cancelled	(92,000)	$ 2.84	
Outstanding at September 30, 2019	3,142,825	$ 6.43	9.0
Exercisable at September 30, 2019	391,720	$ 2.84	8.4
Vested and expected to vest at September 30, 2019	3,142,825	$ 6.43	9.0

No options were vested or exercisable as of December 31, 2018. The weighted average grant date fair value per share of options granted during the nine months ended September 30, 2019 and 2018 was $8.51 and $1.99, respectively.

The aggregate intrinsic value of options vested and expected to vest as of September 30, 2019 was approximately $39,505. The aggregate intrinsic value of options vested and exercisable as of September 30, 2019 was approximately $6,330.

As of September 30, 2019, there was approximately $13,071 total unrecognized compensation expense, related to the unvested stock options, which is expected to be recognized over a weighted average period of 2.99 years.

Restricted common stock

The following table summarizes the information about restricted stock awards ("RSA") outstanding at September 30, 2019:

	Number of shares	Grant-date fair value
Unvested as of December 31, 2018	757,577	$ 2.84
Granted	—	$ —
Vested/Released	(378,789)	$ 2.84
Cancelled	(6,258)	$ 2.84
Unvested as of September 30, 2019	372,530	$ 2.84

There were no shares of restricted common stock granted to employees during the nine months ended September 30, 2019. The restricted stock vests 50% on each anniversary date of the grant, over a two-year period. Vesting is subject to the holder's continuous service with the Company.

As of September 30, 2019, there was approximately $463 of total unrecognized compensation expense, related to the restricted stock grants, which is expected to be recognized over a weighted average period of 0.44 years.

Stock-based compensation

Stock-based compensation expense for the three and nine months ended September 30, 2019 and 2018 was comprised of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Research and development	$ 460	$ 297	$ 1,100	$ 621
Selling, general and administrative	471	283	1,118	647
Total stock-based compensation expense	$ 931	$ 580	$ 2,218	$ 1,268

9. Income taxes

During the nine months ended September 30, 2019 and 2018, the Company recorded no income tax benefits for the net operating losses incurred or for the research and development tax credits generated in each period due to its uncertainty of realizing a benefit from those items. All of the Company's operating losses since inception have been generated in the United States.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. Management has considered the Company's history of cumulative net losses incurred since inception and its lack of commercialization of any products or generation of any revenue from product sales since inception and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the net deferred tax assets as of September 30, 2019 and December 31, 2018. Management reevaluates the positive and negative evidence at each reporting period. As of September 30, 2019 and December 31, 2018, no facts or circumstances arose that affected the Company's determination as to the full valuation established against the net deferred tax assets.

As of September 30, 2019 and December 31, 2018, the Company had not recorded any amounts for unrecognized tax benefits. The Company's policy is to record interest and penalties related to income taxes as part of its income tax provision. As of September 30, 2019 and December 31, 2018, the Company had no accrued interest or penalties related to uncertain tax positions and no amounts had been recognized in the Company's statements of operations and

comprehensive loss. The Company files income tax returns in the U.S. and Maryland, as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending tax examinations. The Company is open to future tax examination under statute from 2018 to the present.

10. Benefit plan

The Company maintains a defined contribution 401(k) plan, under which employee contributions are voluntary and are determined on an individual basis, limited by the maximum amounts allowable under federal tax regulations. The Company provides an automatic matching contribution of $1.00 per $1.00 of employee contribution into the plan up to a maximum of 4% of employee deferral. The Company's matching contributions to employees totaled approximately $110 and $59, during the three months ended September 30, 2019 and 2018, respectively, and $353 and $111, during the nine months ended September 30, 2019 and 2018, respectively.

11. Commitments and contingencies

Contingencies

In the ordinary course of business, the Company may become a party to lawsuits involving various matters. The Company is not currently a party, and its properties are not currently subject, to any legal proceedings that, in the opinion of management, are expected to have a material adverse effect on the Company's business, financial condition or results of operations.

Milestone and Royalty Payments

At the inception of each license and collaboration agreement with third parties, which may require the Company to make milestone payments, the Company evaluates whether each milestone and royalty payments are substantive and at risk to both parties on the basis of the contingent nature of the milestone and royalty. The Company aggregates milestones into three categories (i) research milestones, (ii) development milestones and (iii) commercial milestones and royalties. Research milestones are typically achieved upon reaching certain criteria as defined in each agreement related to developing a molecule against the specified target. Development milestones are typically reached when a molecule reaches a defined phase of clinical research or passes such phase, or upon gaining regulatory approvals. Commercial milestones and royalties are typically achieved when an approved pharmaceutical product reaches the status for commercial sale or certain defined levels of net sales by the licensee, such as when a product first achieves global sales or annual sales of a specified amount. The Company made a regulatory milestone payment of approximately $19,800 in September 2019, in connection with acceptance for review by the FDA of the Company's Biologics License Application ("BLA") for inebilizumab in patients with neuromyelitis optica spectrum disorder ("NMOSD") in August 2019. For the three and nine months ended September 30, 2019, the $19,800 of regulatory milestone payments were recorded within research and development expenses on the statement of operations. In addition, the Company expects to pay approximately $20,000 if the BLA is approved by the FDA for NMOSD.

Employment Agreements

The Company has entered into employment agreements with certain of its executive officers. Generally, the terms of these agreements provide that, if the Company terminates the officer other than for cause, death or disability, or if the officer terminates his or her employment with the Company for good cause, the officer shall be entitled to receive certain severance compensation and benefits as described in each such agreement.

Office Lease

The Company entered into an operating lease agreement with a related party for its headquarters in Gaithersburg, Maryland. The lease is effective July 1, 2018 and expires in June 2021 with the option to extend it by one year. Total lease payments under the lease are: $300 for 2018; $365 for the year ended December 31, 2019; $376 for the year ended December 31, 2020; and $191 for the remainder of the lease.

Rent expense was $64 and $51 for the three months ended September 30, 2019 and 2018, respectively, and $167 and $119 for the nine months ended September 30, 2019 and 2018, respectively.

12. Related party transactions

In connection with the Asset Acquisition, the Company also entered into certain other agreements with the AZ Parties, including transition services agreement, a clinical supply agreement, a commercial supply agreement, a master supply and development services agreement, and a long-term lease agreement. During the nine months ended September 30, 2019, the Company incurred $28,805 of costs under these agreements, of which $13,100 is recorded as a related party liability on the Company's balance sheet as of September 30, 2019. During the nine months ended September 30, 2018, the Company incurred $23,254 of costs under these agreements.

13. Collaboration agreements

Commercial license and collaboration agreement with Hansoh

On May 24, 2019 (the "Effective Date"), the Company entered into an exclusive commercial license and collaboration agreement with Hansoh Pharmaceutical Group Company Limited ("Hansoh"). By entering into this agreement, the Company promised to Hansoh the following goods or services:

(i) deliver an exclusive, sub-licensable, license to commercialize any pharmaceutical product that includes inebilizumab, the Company's lead product candidate, in the mainland of the People's Republic of China, Hong Kong and Macau (the "Territory") (the "Commercial License");

(ii) to use commercially reasonable efforts to obtain regulatory approval from the FDA for a monotherapy use of inebilizumab in connection with the NMOSD indication ("FDA Approval");

(iii) to use commercially reasonable efforts to obtain regulatory approval from the National Medical Products Administration ("NMPA") for monotherapy use of inebilizumab in connection with the NMOSD indication, as well as any other licensed product containing inebilizumab (including both monotherapy use and in combination with other agents), as approved by the joint coordination committee ("JCC") in the Territory ("NMPA Approval");

(iv) provide Hansoh the ability to select two or more of the following indications: Non-Hodgkin lymphoma ("NHL"), Chronic lymphocytic leukemia ("CLL"), Multiple Sclerosis ("MS"), Rheumatoid Arthritis ("RA"), Multiple Myeloma ("MM"), and for any other indication that is presented by Hansoh to the Company and approved by the Company to replace one of the predetermined indications for further development in the territory, each of which Hansoh will be responsible for the development and commercialization while the Company will be responsible for performing the regulatory approval activities in the Territory (collectively, the "Selected Indications");

(v) at the Company's discretion, provide Hansoh with certain participation rights related to the Company's development and commercialization of other uses of inebilizumab in the Territory, including both monotherapy and in combination with other agents, but excluding the following indications: NMOSD, NHL, CLL, MS, RA and MM (the "Opt-In"). In the event that Hansoh does not elect to participate in these development activities or meet its payment terms with respect to costs incurred in the Territory that are reimbursable to the Company, all commercial rights with respect to the developed indication revert to the Company; and

(vi) deliver a co-exclusive license, which provides Hansoh with the exclusive rights to (i) develop inebilizumab, including any clinical trials and other activities directed toward obtaining regulatory approval in the Territory, for all indications within the Selected Indications and (ii) co-develop inebilizumab with the Company for those indications within the Opt-In (the "Co-Development License").

In addition, the Company and Hansoh formed a JCC to provide oversight to the activities performed under the agreement; however, the substance of the Company's participation in the JCC does not represent an additional promised service, but rather, a right of the Company to protect its own interests in the arrangement. Further, the Company and Hansoh entered into a supply agreement through which the Company shall supply to Hansoh, and Hansoh agrees to purchase from the Company, any and all requirements of any licensed product including inebilizumab for development and commercialization in the Territory during the term. The terms of the supply agreement do not provide for either (i) an option to Hansoh to purchase product from the Company at a discount from the standalone selling price or (ii) minimum purchase quantities. Finally, Hansoh will bear (i) all costs and expenses for any development of inebilizumab for all indications in the Territory subject to the exclusive license and (ii) all costs and fees associated with applying for regulatory approval of any product candidates in the Territory.

The Company received a non-refundable upfront payment of $15,000 in June 2019 and an additional $5,000 is payable within six months after the Effective Date. In addition, the Company has the ability to receive additional payments under the agreement of up to approximately $203,000, including up to $180,000 in commercial milestone payments and

development milestone payments ranging from $2,000 to $5,000 on an indication-by-indication basis. The Company is also entitled to receive tiered royalties ranging from the low double-digit percentages to the upper-teen percentages on aggregate net sales of any products developed and commercialized in the Territory, subject to customary potential reductions.

The Company assessed this arrangement in accordance with ASC 606 and concluded that the promises summarized above represent transactions with a customer within the scope of ASC 606. The Company determined that the following promises represent distinct promised services, and therefore, separate performance obligations: (i) the Commercialization License, (ii) FDA Approval, (iii) NMPA Approval, (iv) the Selected Indications (inclusive of the Co-Development License) and (y) the Opt-In (inclusive of the Co-Development License).

Specifically, in making these determinations, the Company considered the following factors:

- Shortly after the Effective Date, the Company received Breakthrough Therapy Designation for the treatment of NMOSD with Inebilizumab from the FDA and the Company submitted a BLA in June 2019. Accordingly, the Company is not promising, nor expecting, to perform additional research and development activities pursuant to the agreement that would either significantly modify or customize or be considered highly interdependent or interrelated with Inebilizumab.
- The Commercialization License represents functional intellectual property given the functionality of the Commercialization License is not expected to change substantially as a result of the Company's ongoing activities.
- The Company previously incurred a significant portion of the total estimated costs necessary for FDA Approval prior to the Effective Date. That is, as of the Effective Date, the remaining costs to achieve FDA Approval are expected to be immaterial.
- The services necessary to seek NMPA Approval are a readily available resource that are sold separately by third-party vendors.
- Hansoh can benefit from both the Selected Indications and the Opt-In together with readily available resources. Further, the Company is not providing a significant service of integration, nor are they significantly modifying or customizing Inebilizumab through these promises.
- The Co-Development License does not grant any development rights to Hansoh outside of those indications included within the Selected Indications and the Opt-In.
- The Co-Development License is highly interdependent or interrelated with the Selected Indications and the Opt-In. Specifically, (1) the Co-Development License significantly affects the Selected Indications and the Opt-In because in the absence of the Co-Development License, Hansoh would be limited to just selecting certain indications that it would like to develop, but would have no legal right to develop such indication; and (2) the Selected Indications and the Opt-In significantly affect the Co-Development License because the scope of the Co-Development License is limited to the development of Inebilizumab for those indications included within the Selected Indications and the Opt-In.

Under the agreement with Hansoh, in order to evaluate the appropriate transaction price, the Company determined that the upfront payment amount of approximately $20,000, $5,000 of which has yet to be received, constituted the entire consideration to be included in the transaction price as of the outset of the arrangement. While the Company identified multiple performance obligations, this amount was allocated entirely to the Commercialization License performance obligation as the standalone selling price of the remaining performance obligations was deemed to be immaterial at contract inception. In making this determination, the Company observed that the estimated costs associated with both the FDA Approval and NMPA Approval performance obligations are immaterial in the context of the arrangement with Hansoh. In addition, the Company also observed that significant uncertainty existed at the contract inception date related to whether (i) the Company would pursue any indications that would, in-turn, provide Hansoh with an opportunity to utilize the Opt-In (inclusive of the Co-Development License), (ii) Hansoh would pursue the development of any of the Selected Indications (inclusive of the Co-Development License), and (iii) the likelihood that any development activities would ultimately be successful.

The potential commercial and development milestone payments that the Company is eligible to receive were excluded from the transaction price, as all milestone amounts were fully constrained based on the probability of achievement, since the milestones relate to successful achievement of certain commercialization, developmental and regulatory approval goals, which might not be achieved. None of the future royalty payments were included in the

transaction price, as the potential payments we re determined to be subject to the sales-based royalty exception. The Company will reevaluate the transaction price, including all constrained amounts, at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur, and, if necessary, adjust its estimate of the transaction price.

Because the entire transaction price was allocated to the Commercialization License performance obligation, which represents functional intellectual property, the Company recognized the associated revenue of $20,000 at the Effective Date. As noted previously, approximately $15,000 of the total upfront payment was received within 30 days after the Effective Date. The remaining $5,000 is payable to the Company within six months after the Effective Date, and therefore, was recorded within accounts receivable as of September 30, 2019 as the Company currently has the contractual right to bill for this amount.

14. Subsequent events

On October 8, 2019, the Company, entered into a license agreement (the "License Agreement"), with Mitsubishi Tanabe Pharma Corporation ("MTPC"), for co-development and commercialization of inebilizumab in Japan, Thailand, South Korea, Indonesia, Vietnam, Malaysia, Philippines, Singapore, and Taiwan (the "MTPC Territory") for NMOSD as well as other indications that the Company and MTPC mutually agree to add to the License Agreement. Under the terms of the License Agreement, the Company is eligible to receive up-front licensing fees of an aggregate of $30,000 as well as development and commercialization milestones and payments based, in part, on sales revenue.

Pursuant to the License Agreement, the Company granted MTPC an (i) exclusive license under its intellectual property to develop, commercialize, and conduct final manufacturing of inebilizumab in the MTPC Territory, and (ii) a non-exclusive license under any patent it controls solely to the extent useful or necessary to enable MTPC to develop, commercialize and finally manufacture products in the MTPC Territory, but excluding rights to any active pharmaceutical ingredient or compound other than inebilizumab. MTPC will be responsible for leading development, commercialization, and final manufacturing of inebilizumab in the MTPC Territory. The Company will be responsible for supplying inebilizumab to MTPC pursuant to a supply agreement that it expects to enter into. On a country-by-country and product-by-product basis, the licenses will become perpetual, non-exclusive and fully paid-up upon the later of (a) the expiration of the last valid claim of a Company patent covering the product; (b) the expiration of any regulatory exclusivity with respect to the product; or (c) 10 years after the first commercial sale of the product in such country.

The License Agreement continues for so long as MTPC is developing or commercializing inebilizumab in the MTPC Territory, unless terminated by MTPC or by the Company. MTPC may terminate the License Agreement at any time upon 180 days' notice to the Company. The Company may terminate the License Agreement upon the occurrence of certain adverse events that are not cured by MTPC within the specified cure periods. Either party may terminate the License Agreement under specified circumstances relating to the other party's insolvency.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our final prospectus for our initial public offering filed pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, or the Securities Act, on October 4, 2019 (the "Prospectus"). Some of the information contained in this discussion and analysis or set forth elsewhere in this Form 10-Q, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Form 10-Q, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biotechnology company pioneering treatments for autoimmune disease. Our approach seeks to redefine the treatment of autoimmune diseases by focusing on critical biological pathways shared across multiple indications. We believe this approach, which targets the underlying molecular pathogenesis of the disease allows us to develop more precise therapies, identify patients more likely to respond to treatment and pursue multiple diseases for each of our product candidates. Our lead product candidate, inebilizumab, is a humanized mAb designed to target CD19, a molecule expressed on the surface of a broad range of immune system B cells. In January 2019, we reported positive pivotal clinical trial data for inebilizumab in patients with NMOSD. NMOSD is a rare, devastating condition that attacks the optic nerve, spinal cord and brain stem, and often leads to irreversible blindness and paralysis. We received Breakthrough Therapy Designation for the treatment of this disease from the FDA in April 2019 and in August 2019, the FDA accepted for review our BLA for inebilizumab. The FDA set a PDUFA date of June 11, 2020. In addition, we have a broad pipeline of two additional clinical-stage and two pre-clinical product candidates focused on a number of other autoimmune diseases with high unmet medical needs, including myasthenia gravis, IgG4-related disease, Sjögren's syndrome and lupus, as well as other conditions such as kidney transplant rejection. For one of these product candidates, VIB4920, we expect to initiate two Phase 2 trials in the fourth quarter of 2019.

We incorporated on December 11, 2017 under the laws of the State of Delaware. From December 11, 2017 to December 31, 2017 we had no substantive operations. In February 2018, we acquired six molecules from MedImmune, of which five constitute our current product candidates, for a purchase price of approximately $142.3 million financed by AstraZeneca's purchase of our Series A preferred stock. Following the asset purchase, we entered into several agreements with AstraZeneca and MedImmune, including a license agreement, a master supply and development services agreement, sublicense agreements, a transition services agreement, a clinical supply agreement and a commercial supply agreement.

To date, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, identifying and developing product candidates, enhancing our intellectual property portfolio, undertaking research, conducting pre-clinical studies and clinical trials, conducting pre-commercial and commercial launch activities, and securing manufacturing for our development programs. We do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations primarily through the private placement of convertible preferred stock. As of September 30, 2019, we have raised gross proceeds of approximately $467.3 million from the issuance of convertible preferred stock.

We have incurred significant operating losses since our inception, which are mainly attributed to research and development costs and employee payroll expense included in general and administrative expenses. Our net loss was $48.4 million and $74.9 million for the three and nine months ended September 30, 2019, respectively. As of September 30, 2019, we had an accumulated deficit of $265.1 million. Included within the accumulated deficit as of September 30, 2019 are expenses of $143.3 million associated with the acquisition of in-process research and development, or IPR&D, acquired from MedImmune and AstraZeneca. Our operating losses may fluctuate significantly from quarter-to-quarter and year-to-year as a result of several factors, including the timing of our pre-clinical studies and clinical trials and our expenditures related to other research and development activities. We expect to continue to incur operating losses for the foreseeable future. We anticipate these losses will increase substantially as we advance our product candidates through pre-clinical and clinical development, develop additional product candidates and seek regulatory approvals for our product candidates. We do not expect to generate any revenues from product sales unless and until we successfully complete development and obtain regulatory approval for one or more product candidates. In addition, if we obtain marketing approval for any product candidate, we expect to incur pre-commercialization expenses and significant commercialization expenses related to marketing, sales, manufacturing and distribution. We may also incur expenses in connection with the in-licensing of additional product candidates. Furthermore, we expect to incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations, compliance and other expenses that we did not incur as a private company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from sales of our product candidates, if ever, we expect to finance our cash needs through public or private equity offerings, debt financings, collaborations and licensing arrangements or other capital sources. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates that we would otherwise prefer to develop and market ourselves.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of September 30, 2019, we had cash and cash equivalents of $155.7 million. In addition, in October 2019, we completed an initial public offering (the “IPO”) of our common stock and issued and sold in aggregate 9,085,000 shares of common stock, which included 1,185,000 shares of our common stock issued pursuant to the underwriters’ option to purchase additional shares, at a public offering price of $19.00 per share, for net proceeds of $157.2 million after deducting underwriting discounts and commissions and offering expenses.

In October 2019, we entered into a license agreement (the “License Agreement”), with Mitsubishi Tanabe Pharma Corporation (“MTPC”), for co-development and commercialization of inebilizumab in Japan, Thailand, South Korea, Indonesia, Vietnam, Malaysia, Philippines, Singapore, and Taiwan (the “MTPC Territory”) for NMOSD as well as other indications that we and MTPC mutually agree to add to the License Agreement. Under the terms of the License Agreement, we are eligible to receive up-front licensing fees of an aggregate of $30,000 as well as development and commercialization milestones and payments based, in part, on sales revenue.

Pursuant to the License Agreement, we granted MTPC an (i) exclusive license under our intellectual property to develop, commercialize, and conduct final manufacturing of inebilizumab in the MTPC Territory, and (ii) a non-exclusive license under any patent we control solely to the extent useful or necessary to enable MTPC to develop, commercialize and finally manufacture products in the MTPC Territory, but excluding rights to any active pharmaceutical ingredient or compound other than inebilizumab. MTPC will be responsible for leading development, commercialization, and final manufacturing of inebilizumab in the MTPC Territory. We will be responsible for supplying inebilizumab to MTPC pursuant to a supply agreement that we expects to enter into. On a country-by-country and product-by-product basis, the licenses will become perpetual, non-exclusive and fully paid-up upon the later of (a) the expiration of the last valid claim of a Company patent covering the product; (b) the expiration of any regulatory exclusivity with respect to the product; or (c) 10 years after the first commercial sale of the product in such country.

Components of our Results of Operations

Revenue

We have not generated any revenue from the sale of products since our inception and do not expect to generate substantial revenue from the sale of products in the near future, if at all. We have generated revenue from a commercial license and collaboration agreement related to the treatment of NMOSD with inebilizumab. In addition, if our development efforts for our product portfolio, including inebilizumab, or for other, non-NMOSD target indications are successful and result in marketing approval or if we enter into collaboration or license agreements with third parties, we may generate revenue in the future from product sales or payments from such collaboration or license agreements, or a combination of product sales and payments from such agreements.

Research and Development Expenses

To date, our research and development expenses, net of the acquisition of IPR&D that is disclosed separately, have related primarily to development of inebilizumab, VIB4920 and VIB7734, pre-clinical studies and other pre-clinical activities related to our portfolio. Research and development expenses are recognized as incurred, and payments made prior to the receipt of goods or services to be used in research and development are capitalized until the goods or services are received.

Research and development expenses include:

- salaries, payroll taxes, employee benefits, and stock-based compensation charges for those individuals involved in research and development efforts;
- external research and development expenses incurred under agreements with contract research organizations and consultants to conduct our pre-clinical, toxicology and other pre-clinical studies, as well as clinical trials of our product candidates;
- laboratory supplies;
- costs related to manufacturing product candidates, including fees paid to third-party manufacturers and raw material suppliers;
- license fees and research funding; and
- facilities, depreciation and other allocated expenses, which include direct and allocated expenses for rent, maintenance of facilities, insurance, equipment and other supplies.

Clinical trial costs are a significant component of research and development expenses and include costs associated with third-party contractors. A majority of these payments are pass-through payments that are made to MedImmune and AstraZeneca pursuant to the existing contracts in place associated with the IPR&D assets acquired (see Note 7, “Asset acquisition” for additional information). Through our agreements with MedImmune and AstraZeneca, we outsource a substantial portion of our clinical trial activities, utilizing external entities such as CROs, independent clinical investigators and other third-party service providers to assist us with the execution of our clinical trials. We also expect to incur additional expenses related to milestone and royalty payments payable to third parties with whom we have entered into license agreements relating to our product candidates.

We plan to substantially increase our research and development expenses for the foreseeable future, as we continue the development of our product candidates and seek to discover and develop new product candidates. Due to the inherently unpredictable nature of pre-clinical and clinical development, we cannot determine with certainty the timing of the initiation, duration or costs of future clinical trials and pre-clinical studies of product candidates. Clinical and pre-clinical development timelines, the probability of success and the amount of associated development costs can differ materially from expectations. We anticipate that we will make determinations as to which product candidates and development programs to pursue and how much funding to direct to each product candidate or program on an ongoing basis in response to the results of ongoing and future pre-clinical studies and clinical trials, regulatory developments and our ongoing assessments as to each product candidate’s commercial potential. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements.

Our future clinical development costs may vary significantly based on factors such as:

- per patient trial costs;
- the number of patients needed to determine a recommended dose;
- the number of trials required for regulatory approval;
- the number of sites included in the trials;
- the countries in which the trials are conducted;
- the length of time required to enroll eligible patients;
- the number of patients who participate in the trials;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- potential additional safety monitoring requested by regulatory agencies;
- the duration of patient participation in the trials and follow-up;
- the phase of development of the product candidate; and
- the efficacy and safety profile of the product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and employee-related costs, including stock-based compensation for personnel in our executive, finance and other administrative functions. Other significant costs include facility and/or rent-related costs, legal fees relating to intellectual property and corporate matters, professional fees for accounting and consulting services and insurance costs. We anticipate that our general and administrative expenses will increase in the future to support our continued research and development activities, pre-commercialization and, if any product candidates receive marketing approval, commercialization activities. We also anticipate increased expenses related to audit, legal, regulatory and tax-related services associated with maintaining compliance with stock exchange listing and SEC requirements, director and officer insurance premiums and investor relations costs associated with operating as a public company.

Acquisition of In-Process Research and Development

Acquisition of IPR&D represents the expense recognized related to the Asset Purchase Agreement with AstraZeneca and MedImmune (the "APA"). The six molecules we acquired from MedImmune pursuant to the APA consist of multiple IPR&D projects related to biological therapies which are intended to treat an interrelated subset of autoimmune disorders, represented in part by common biological characteristics. See Note 7, "Asset acquisition" for further information.

Interest Income

Interest income consists of interest earned on our cash and cash equivalents during the period.

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,		
	2019	2018	Change
	(in thousands)		
Revenue:			
License Revenue	$ —	$ —	$ —
Total Revenue	—	—	—
Operating expenses:			
Research and development	38,700	13,928	24,772
General and administrative	10,230	2,401	7,829
Total operating expenses	48,930	16,329	32,601
Loss from operations	(48,930)	(16,329)	(32,601)
Other income			
Interest income	520	647	(127)
Total other income	520	647	(127)
Net loss	$ (48,410)	$ (15,682)	$ (32,728)

Research and Development Expenses. Research and development expenses were $38.7 million and $13.9 million for the three months ended September 30, 2019 and 2018, respectively. The increase of $24.8 million primarily driven by regulatory milestone payments of approximately $19.8 million in September 2019, in connection with acceptance for review by the FDA of the Company's BLA for inebilizumab in patients with NMOSD in August 2019, an increases of $2.4 million in personnel related costs due to an increase in headcount, and $2.6 million of direct program and external costs for payments to our research and development contractors driven primarily by manufacturing activities to support the BLA filing and pending approval process, potential U.S. commercial launch and clinical trials for other potential indications for inebilizumab, as well as increased clinical material supplies for VIB4920.

General and Administrative Expenses. General and administrative expenses were $10.2 million and $2.4 million for the three months ended September 30, 2019 and 2018, respectively. The increase of $7.8 million was due primarily to increases of $4.9 million in professional services related to accounting services, corporate legal fees and patent legal fees and $2.2 million in personnel related expenses, including stock-based compensation, due to an increase in headcount.

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,		
	2019	2018	Change
	(in thousands)		
Revenue:			
License Revenue	$ 20,000	$ —	$ 20,000
Total Revenue	20,000	—	20,000
Operating expenses:			
Research and development	72,113	28,892	43,221
General and administrative	24,575	4,399	20,176
Acquisition of in-process research and development	—	143,333	(143,333)
Total operating expenses	96,688	176,624	(79,936)
Loss from operations	(76,688)	(176,624)	99,936
Other income			
Interest income	1,829	1,408	421
Total other income	1,829	1,408	421
Net loss	$ (74,859)	$ (175,216)	$ 100,357

License Revenue. License revenue was $20.0 million for the nine months ended September 30, 2019. The increase of $20.0 million was due to the revenue recognized pursuant to the Co-Development and Commercial License Agreement with Hansoh Pharma in May 2019. There was no revenue generated during the nine months ended September 30, 2018.

Research and Development Expenses. Research and development expenses were $72.1 million and $28.9 million for the nine months ended September 30, 2019 and 2018, respectively. The increase of $43.2 million was primarily driven by regulatory milestone payments of approximately $19.8 million in September 2019, in connection with acceptance for review by the FDA of the Company's BLA for inebilizumab in patients with NMOSD in August 2019, an increases of $6.2 million in personnel related costs due to an increase in headcount, and $17.1 million of direct program and external costs for payments to our research and development contractors driven primarily by manufacturing activities to support the BLA filing and pending approval process, potential U.S. commercial launch and clinical trials for other potential indications for inebilizumab, as well as increased clinical material supplies for VIB4920.

General and Administrative Expenses. General and administrative expenses were $24.6 million and $4.4 million for the nine months ended September 30, 2019 and 2018, respectively. The increase of $20.2 million was due primarily to increases of $13.5 million in professional services related to accounting services, corporate legal fees and patent legal fees, $4.8 million in personnel related expenses, including stock-based compensation, due to an increase in headcount, and $1.9 million of facility related and other administrative expenses.

Acquisition of In-process Research and Development. Acquisition of IPR&D was $143.3 million for the nine months ended September 30, 2018 and consisted of IPR&D assets with no alternative future use acquired from MedImmune and AstraZeneca. We did not acquire any IPR&D assets in 2019.

Interest Income. Interest income was $1.8 million and $1.4 million for the nine months ended September 30, 2019 and 2018, respectively. The increase of $0.4 million was due primarily to higher cash and cash equivalents as of September 30, 2019.

Liquidity and Capital Resources

Cash Flows

We have incurred net losses and negative cash flows from operations since our inception and anticipate we will continue to incur net losses for the foreseeable future. As of September 30, 2019, we had cash and cash equivalents of $155.7 million.

The following table sets forth a summary of the net cash flow activity for each period presented:

	Nine Months Ended September 30,	
	2019	2018
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (69,202)	$ (15,598)
Investing activities	(67,912)	(143,800)
Financing activities	165,963	282,253
Net increase (decrease) in cash	$ 28,849	$ 122,855

Operating Activities

Net cash used in operating activities was $69.2 million and $15.6 million for the nine months ended September 30, 2019 and 2018, respectively. The net cash used in operating activities for the nine months ended September 30, 2019 was primarily due to our net loss of $74.9 million, partially offset by non-cash charges of $2.2 million related to stock-based compensation expense and depreciation and cash provided by changes in our operating assets and liabilities of $3.4 million. The net cash used in operating activities for the nine months ended September 30, 2018 was primarily due to our net loss of $175.2 million, partially offset by non-cash charges of $143.3 million primarily related to our acquisition of IPR&D assets from MedImmune and AstraZeneca and cash provided by changes in our operating assets and liabilities of $15.0 million.

Investing Activities

Net cash used in investing activities was $67.9 million and $143.8 million for the nine months ended September 30, 2019 and 2018, respectively. The net cash used in investing activities for the nine months ended September 30, 2019 was primarily due to purchase of marketable securities and property and equipment. The net cash used in investing activities for the nine months ended September 30, 2018 was primarily due to our acquisition of IPR&D from MedImmune and AstraZeneca and purchases of property and equipment.

Financing Activities

Net cash provided by financing activities was $166.0 million for the nine months ended September 30, 2019, primarily due to the net proceeds of $167.0 million from the issuance of Series B convertible preferred stock and $1.3 million of proceeds from exercise of stock options, partially offset by cash paid for deferred offering costs of $2.3 million in connection with the IPO. Net cash provided by financing activities was $282.3 million for the nine months ended September 30, 2018, primarily due to proceeds from the issuance of Series A-1 and A-2 convertible preferred stock of $282.3 million.

Funding Requirements

We believe that our existing cash, together with the net proceeds from the IPO, will be sufficient to meet our anticipated cash requirements through 2022. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect.

Our future capital requirements will depend on many factors, including:

- the receipt of marketing approval, if any, and revenue received from any potential commercial sales of inebilizumab or other product candidates, and product pricing, as well as product coverage and the adequacy of reimbursement of third-party payors, relating to any such product;
- the cost of commercialization activities for and manufacturing of inebilizumab and other product candidates if we receive marketing approval for any such product candidate, including marketing, sales and distribution costs;
- the initiation, progress, timing, costs and results of drug discovery, pre-clinical studies and clinical trials of inebilizumab, VIB4920 and VIB7734 and any other future product candidates;
- the number and characteristics of product candidates that we pursue;
- the outcome, timing and costs of seeking regulatory approvals;

- the cost of manufacturing VIB4920 and VIB7734 and future product candidates for clinical trials in preparation for marketing approval and in preparation for commercialization;
- the costs of any third-party products used in our combination clinical trials that are not covered by such third party or other sources;
- the costs associated with hiring additional personnel and consultants as our pre-clinical and clinical activities increase;
- the emergence of competing therapies and other adverse market developments;
- the ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the extent to which we in-license or acquire other products and technologies; and
- the costs of operating as a public company.

Until such time, if ever, as we can generate substantial product revenues to support our capital requirements, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, collaborations and licensing arrangements or other capital sources. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, or other similar arrangements with third parties, we may need to relinquish valuable rights to our product candidates, future revenue streams, research programs or may have to grant licenses on terms that may not be favorable to us and/or may reduce the value of our common stock. If we are unable to raise additional funds through equity or debt financings as and when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves.

Contractual Obligations and Commitments

The following table summarizes our contractual obligations at September 30, 2019:

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
	(in thousands)				
Operating lease obligations	$ 658	$ 373	$ 285	$ —	$ —
Total	$ 658	$ 373	$ 285	$ —	$ —

We enter into contracts in the normal course of business with CROs, clinical supply manufacturers and vendors for pre-clinical studies, research supplies and other services and products for operating purposes. These contracts generally provide for termination after a notice period, and, therefore, are cancelable contracts and not included in the table above.

We have also entered into license and collaboration agreements with third parties, which are in the normal course of business. We have not included future payments under these agreements in the table of contractual obligations above since obligations under these agreements are contingent upon future events such as our achievement of specified development, regulatory, and commercial milestones, or royalties on net product sales. We made regulatory milestone payments of approximately $19.8 million in September 2019, in connection with acceptance for review by the FDA of our BLA for inebilizumab in patients with NMOSD in August 2019, and additionally we expect to pay approximately $20.0 million if the BLA for inebilizumab is approved by the FDA for NMOSD. However, we are currently unable to estimate the timing or likelihood of achieving other milestones or generating future product sales.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events, and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2, "Summary of significant accounting policies", we believe the following accounting policies and estimates to be most critical to the preparation of our financial statements.

Accrued Research and Development

As part of the process of preparing our 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. 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.

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 expense accordingly. 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 actually 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 actually incurred.

Revenue Recognition for Contracts with Customers

To date, we have generated no revenues from sales of products.

Effective January 1, 2019, we adopted Accounting Standards Update, or ASU, No. 2014-09, Revenue (ASC 606): Revenue from Contracts with Customers, or ASC 606, using the modified retrospective transition method. Under this method, results for reporting periods beginning on January 1, 2019 are presented under ASC 606, while prior periods were prepared and reported in accordance with ASC Topic 605, Revenue Recognition, or ASC 605. The adoption of ASC 606 resulted in no cumulative adjustment as we had substantially no assets until executing the Asset Acquisition in February 2018 (as described in Note 7, "Asset Acquisition") and did not enter into a revenue contract with a customer until May 2019 (as described in Note 13, "Collaboration Agreements").

ASC 606 applies to all contracts with customers, except for contracts that are within the scope of other standards. Under ASC 606, an entity recognizes revenue when its customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that an entity determines are within the scope of ASC 606, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the entity satisfies a performance obligation.

At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determine those that are performance obligations and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. Arrangements that include rights to additional goods or services that are exercisable at a customer's discretion are generally considered options. We assess if these options provide a material right to the customer and if so, they are considered performance obligations. The exercise of a material right is accounted for as a contract modification for accounting purposes.

We recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) each performance obligation is satisfied at a point in time or over time, and if over time this is based on the use of an output or input method.

Amounts received prior to revenue recognition are recorded as deferred revenue. Amounts expected to be recognized as revenue within the 12 months following the balance sheet date are classified as current portion of deferred revenue in the accompanying balance sheet. Amounts not expected to be recognized as revenue within the 12 months following the balance sheet date are classified as deferred revenue, net of current portion.

Milestone Payments—If an arrangement includes development and regulatory milestone payments, we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the transaction price. Milestone payments that are not within our control or the licensee's control, such as regulatory approvals, are generally not considered probable of being achieved until those approvals are received.

Royalties—For arrangements that include sales-based royalties, including milestone payments based on a level of sales, which are the result of a customer-vendor relationship and for which the license is deemed to be the predominant item to which the royalties relate, we recognize revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied or partially satisfied. To date, we have not recognized any royalty revenue resulting from any of our licensing arrangements.

Significant Financing Component—In determining the transaction price, we adjust consideration for the effects of the time value of money if the timing of payments provides us with a significant benefit of financing. We do not assess whether a contract has a significant financing component if the expectation at contract inception is such that the period between payment by the licensees and the transfer of the promised goods or services to the licensees will be one year or less. We assessed each of our revenue arrangements in order to determine whether a significant financing component exists and concluded that a significant financing component does not exist in any of our arrangements.

Collaborative Arrangements—We enter into collaboration agreements, which are within the scope of ASC 606, to discover, develop, manufacture and commercialize product candidates. The terms of these agreements typically contain multiple promises or obligations, which may include: (1) licenses, or options to obtain licenses, to use our technology, (2) research and development activities to be performed on behalf of the collaboration partner, and (3) in certain cases, services in connection with the manufacturing of preclinical and clinical material. Payments we receive under these arrangements typically include one or more of the following: non-refundable, upfront license fees; clinical and development, regulatory, and sales milestone payments; and royalties on future product sales.

We also analyze our collaboration arrangements to assess whether they are within the scope of ASC 808, Collaborative Arrangements, or ASC 808, to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards dependent on the commercial success of such activities. This assessment is performed throughout the life of the arrangement based on changes in the responsibilities of all parties in the arrangement. For collaboration arrangements within the scope of ASC 808 that contain multiple elements, we first determine which elements of the collaboration are deemed to be within the scope of ASC 606. For those elements of the arrangement that are accounted for pursuant to ASC 606, we apply the five-step model described above.

For a complete discussion of accounting for collaboration revenues, see Note 13, "Collaboration agreements".

Stock-Based Compensation Expense

Stock-based compensation expense represents the cost of the grant date fair value of equity awards recognized over the requisite service period of the awards (usually the vesting period) on a straight-line basis. We estimate the fair value of equity awards using the Black-Scholes option pricing model and recognize forfeitures as they occur. Estimating the fair value of equity awards as of the grant date using valuation models, such as the Black-Scholes option pricing model, is affected by assumptions regarding a number of variables, including the risk-free interest rate, the expected stock price volatility, the expected term of stock options, the expected dividend yield and the fair value of the underlying common stock on the date of grant. Changes in the assumptions can materially affect the fair value and ultimately how much stock-based compensation expense is recognized. These inputs are subjective and generally require significant analysis and judgment to develop. See Note 2, “Summary of significant accounting policies” for information concerning certain of the specific assumptions we used in applying the Black-Scholes option pricing model to determine the estimated fair value of our stock options granted for nine months ended September 30, 2019 and 2018.

As of September 30, 2019, there was approximately $13.1 million and $0.5 million of total unrecognized compensation expense related to the unvested stock options and restricted stock grants, respectively, which are expected to be recognized as expense over a weighted average period of approximately 2.99 years and 0.44 years, respectively. The aggregate intrinsic value of options vested and expected to vest as of September 30, 2019 was approximately $39.5 million. The aggregate intrinsic value of options vested and exercisable as of September 30, 2019 was approximately $6.3 million.

Common stock valuations

Prior to the IPO, our common stock was not publicly traded, therefore we estimated the fair value of our common stock as discussed in the Prospectus. Following our IPO, the closing sale price per share of our common stock as reported on the Nasdaq Global Select Market on the date of grant will be used to determine the exercise price per share of our share-based awards to purchase common stock.

Other Company Information

Net Operating Loss and Research and Development Carryforwards and Other Income Tax Information

At December 31, 2018, we had federal and state net operating loss carryforwards of $57.5 million. Federal and state net operating losses generated in 2018 and future years can be carried forward indefinitely. As of December 31, 2018, we also had federal research credit carryforwards of $4.7 million. The federal research and development tax credit carryforwards expire beginning in 2038 unless previously utilized, and the state research and development tax credit carryforwards do not expire.

We believe that it is more likely than not that we will not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance has been established against the net deferred tax assets as of December 31, 2018. Management reevaluates the positive and negative evidence at each reporting period.

We have not completed a Section 382 study to assess whether an ownership change has occurred or whether there have been multiple ownership changes since our formation due to the complexity and cost associated with such a study and the fact that there may be additional such ownership changes in the future. Pursuant to Sections 382 and 383 of the Internal Revenue Code, annual use of our net operating loss and research and development tax credit carryforwards may be limited in the event a cumulative change in ownership of more than 50% occurs within a three-year period.

Emerging Growth Company Status

We are an emerging growth company as defined in the JOBS Act. Under the JOBS Act, companies have extended transition periods available for complying with new or revised accounting standards. We have elected this exemption to delay adopting new or revised accounting standards until such time as those standards apply to private companies. Where allowable, we have early adopted certain standards as described in Note 2, “Summary of significant accounting policies”.

In addition, we intend to rely on the other exemptions and reduced reporting requirements provided by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, we are entitled to rely on certain exemptions as an emerging growth company, we are not required to, among other things, (i) provide an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b), (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board

regarding mandatory audit firm rotation or a supplement to th e auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis), and (iv) disclose certain executive compensation-related items. These exemptions will apply for a period of five years following the completion of our IPO or until we no longer meet the requirements of being an emerging growth company, whichever is earlier.

Recently Issued and Adopted Accounting Pronouncements

A description of recently issued and adopted accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2, "Summary of significant accounting policies".

Off-Balance Sheet Arrangements

During the periods presented we did not have, nor do we currently have, any off-balance sheet arrangements as defined under SEC rules.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate risks, foreign currency exchange rate risks and inflation risks. Periodically, we maintain deposits in accredited financial institutions in excess of federally insured limits. We deposit our cash in financial institutions that we believe have high credit quality and have not experienced any losses on such accounts and do not believe we are exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Interest Rate Risk

Our cash consists of cash in readily-available checking accounts and short-term money market fund investments. Such interest-earning instruments carry a degree of interest rate risk; however, historical fluctuations in interest income have not been significant.

Foreign Currency Exchange Risk

All of our employees and our operations are currently located in the United States. We have, from time-to-time, engaged in contracts with contractors or other vendors in a currency other than the U.S. dollar. To date, we have had minimal exposure to fluctuations in foreign currency exchange rates as the time period between the date that transactions are initiated and the date of payment or receipt of payment is generally of short duration. Accordingly, we believe we do not have a material exposure to foreign currency risk.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and research and development contract costs. We do not believe inflation has had a material effect on our results of operations during the periods presented.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, have evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of the end of the period covered by this Quarterly Report on Form 10-Q.

Disclosure controls and procedures are controls and other procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted 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 controls and procedures designed to ensure that information required to be disclosed in our reports filed under the Exchange Act is accumulated and communicated to management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure. Based on that evaluation of our disclosure controls and procedures, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures were not effective as of September 30, 2019 due to the material weaknesses in our internal control over financial reporting described below. In light of this fact, our management has taken additional steps to assure there is appropriate disclosure in this report and has concluded that, notwithstanding the material weaknesses in our internal control over financial reporting, the financial statements for the periods covered by and included in this Quarterly Report on Form 10-Q fairly present, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with GAAP.

Material Weakness and Remediation of Material Weakness

The management of the company is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. As previously disclosed in the Prospectus, we identified material weaknesses in our internal control over financial reporting related to our control environment. More specifically, we have determined that we have not maintained adequate formal accounting policies, processes and controls related to complex transactions as a result of a lack of finance and accounting staff with the appropriate GAAP technical expertise needed to identify, evaluate and account for complex and non-routine transactions. We also determined that we have not maintained sufficient staffing or written policies and procedures for accounting and financial reporting, which contributed to the lack of a formalized process or controls for management's timely review and approval of financial information. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis.

We are currently in the process of implementing our remediation plans. We have implemented and expect to continue to implement over the next several months, a number of measures to address the material weaknesses we have identified. We have hired additional accounting personnel with appropriate GAAP technical accounting expertise and expect to continue to hire further additional accounting personnel as is necessary. We are also designing additional controls around identification, documentation and application of technical accounting guidance with particular emphasis on complex and non-routine transactions. These controls are expected to include the implementation of additional supervision and review activities by qualified personnel, and the adoption of additional policies and procedures related to accounting and financial reporting. We intend to complete the implementation of our remediation plan during 2019. In addition, we have engaged a third-party provider to help us assess and improve our internal controls in preparation for compliance with the Sarbanes-Oxley Act.

The process of designing and implementing an effective accounting and financial reporting system is a continuous effort that requires us to anticipate and react to changes in our business and the economic and regulatory environments and to expend significant resources to maintain an accounting and financial reporting system that is adequate to satisfy our reporting obligations. As we continue to evaluate and take actions to improve our internal control over financial reporting, we may determine to take additional actions to address control deficiencies or determine to modify certain of the remediation measures described above. We cannot assure you that the measures we have taken to date, or any measures we may take in the future, will be sufficient to remediate the material weaknesses we have identified or avoid potential future material weaknesses.

Changes in Internal Controls over Financial Reporting

Other than as described above, there were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the fiscal quarter ended September 30, 2019 that have materially affected, or are 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 become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below, the section of this Quarterly Report Form 10-Q entitled "Management's Discussion and Analysis of Financial Condition and Results of Operation" and our financial statements and related notes, before investing in our common stock. 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. If any of the following risks occur, our business, operating results and prospects could be materially harmed. In that event, the price of our common stock could decline, and you could lose part or all of your investment. We have marked with an asterisk (*) those risk factors that reflect changes from the similarly titled risk factors included in the Prospectus.

Risks Related to Our Financial Position and Need For Additional Capital

We have incurred significant operating losses since our inception. We expect to incur losses for the foreseeable future and may never achieve or maintain profitability.*

We have incurred significant operating losses since our inception, including an operating loss of $48.4 million and $74.9 million for the three and nine months ended September 30, 2019, respectively. To date, we have financed our operations through private placements of our preferred stock. We have not commercialized any products and have never generated any revenue from product sales. We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The operating losses we incur may fluctuate significantly from quarter-to-quarter and year-to-year. We anticipate that our expenses will increase substantially if and as we:

- seek approval and pursue commercial activities for inebilizumab for treatment in patients with NMOSD;
- continue development of our product candidates, including initiating additional clinical trials of inebilizumab, VIB4920 and VIB7734;
- identify, acquire and develop new product candidates;
- initiate nonclinical studies and clinical trials for any additional product candidates that we may pursue in the future;
- seek marketing approvals for our product candidates that successfully complete clinical trials;
- continue to establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- achieve market acceptance of our product candidates in the medical community and with third-party payors;
- maintain, expand and protect our intellectual property portfolio;
- attract, hire and retain additional personnel;
- enter into additional collaboration arrangements, if any, for the development of our product candidates or in-license other products and technologies;
- make royalty, milestone or other payments under current and any future in-license or collaboration agreements;
- add operational, financial and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts; and
- incur increased costs as a result of operating as a public company.

Because of the numerous risks and uncertainties associated with developing pharmaceutical drugs, we are unable to predict the extent of any future losses or when we will become profitable, if at all. In addition, our expenses could increase beyond expectations if we are required by the FDA or foreign regulatory agencies, to perform nonclinical studies and clinical trials in addition to those that we currently anticipate, or if there are any delays in our or our partners completing clinical trials or the development of any of our product candidates.

To become and remain profitable, we must develop and eventually commercialize a product or products with significant product revenue. This will require us to be successful in a range of challenging activities, including the following:

- completing clinical trials of our product candidates that meet their clinical endpoints;
- submitting applications for and obtaining marketing approval for our product candidates;
- establishing a new sales and marketing presence for, or entering into a collaboration with respect to the sales and marketing of, our product candidates;
- manufacturing, marketing and selling those products for which we may obtain marketing approval and satisfying any post-marketing regulatory requirements;
- achieving market acceptance of our product candidates in the medical community and with third-party payors;
- maintaining, protecting and expanding our portfolio of intellectual property rights, including patents, trade secrets and know-how; and
- attracting, hiring and retaining additional personnel.

In cases where we are successful in obtaining marketing approval for one or more of our product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain marketing approval, the accepted price for the product, the ability to obtain coverage and adequate reimbursement, and ownership of commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue of such products, even if approved.

Even if we do generate revenues, they may not be significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates. Our failure to become and remain profitable would decrease our value and could impair our ability to raise capital, maintain our discovery and nonclinical development efforts, expand our business or continue our operations and may require us to raise additional capital that may dilute your ownership interest. A decline in our value could also cause you to lose all or part of your investment.

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We are a clinical-stage biopharmaceutical company. Biopharmaceutical drug development is a highly speculative undertaking and involves a substantial degree of risk. We were incorporated in December 2017, and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, developing our technology, identifying potential product candidates, undertaking nonclinical studies and conducting clinical trials. Each of our five current product candidates was acquired from MedImmune in February 2018. Accordingly, prior to the February 2018 asset purchase, all nonclinical studies and clinical trials related to our current product candidates were conducted by MedImmune. We have not yet demonstrated our ability to successfully obtain marketing approvals, manufacture a commercial scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Typically, it takes several years to develop one new drug from the time it is discovered to when it is available for treating patients. In addition, as a new business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition from a company with a research focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We will need substantial additional funding. If we are unable to raise capital when needed, we would be compelled to delay, reduce or eliminate our product development programs or commercialization efforts.*

The development of biological products is capital-intensive. We expect our expenses to increase in parallel with our ongoing activities, particularly as we seek marketing approval of inebilizumab for treatment in patients with NMOSD and conduct larger-scale clinical trials of, and seek marketing approval for, our other product candidates. If we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. In addition, our expenses could increase beyond expectations if the FDA or comparable foreign regulatory authorities require us to perform nonclinical studies and clinical trials in addition to those that we currently anticipate. We may also need to raise additional funds sooner if we choose to pursue additional indications and/or geographies for our product candidates or otherwise expand more rapidly than we presently anticipate. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, reduce or eliminate our clinical programs, development efforts or any future commercialization efforts.

As of September 30, 2019, we had $155.7 million in cash and cash equivalents. Subsequent to September 30, 2019, we completed an initial public offering (the "IPO") of our common stock and issued and sold in aggregate 9,085,000 shares of common stock at a public offering price of $19.00 per share, for net proceeds of $157.2 million after deducting underwriting discounts and commissions and offering expenses. We believe that, based upon our current operating plan, our existing capital resources, together with the net proceeds from the IPO, will be sufficient to fund our anticipated operations through 2022. Our future capital requirements and the period for which we expect our existing resources to support our operations may vary significantly from what we expect. 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 approved marketing and commercialization activities. In addition, our future capital requirements will depend on many factors, and could increase significantly as a result of many factors, including:

- the FDA's approval of our BLA for inebilizumab for treatment in patients with NMOSD;
- the costs of future commercialization activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the scope, progress, results and costs of nonclinical development, laboratory testing and clinical trials for our product candidates;
- the scope, prioritization and number of our research and development programs;
- the costs, timing and outcome of regulatory review of our product candidates;
- the extent to which we enter into non-exclusive, jointly funded clinical research collaboration arrangements, if any, for the development of our product candidates in combination with other companies' products;
- our ability to establish collaboration arrangements for the development of our product candidates on favorable terms, if at all;
- the achievement of milestones or occurrence of other developments that trigger payments under any collaboration agreements into which we enter, if any;
- the extent to which we are obligated to reimburse, or entitled to reimbursement of, clinical trial costs under future collaboration agreements, if any;
- the extent to which we acquire or in-license other product candidates and technologies;
- 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, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;

- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel; and
- the costs associated with being a public company.

Conducting nonclinical studies and clinical trials is a time-consuming, expensive and uncertain process that can take years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, may be derived from sales of products that may not be commercially available for several years, if ever. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates. Volatility in the financial markets have generally made equity and debt financing more difficult to obtain and may have a material adverse effect on our ability to meet our fundraising needs. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue one or more of our research or development programs or the commercialization of any product candidate or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.*

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of private and public equity financings, debt financings, collaborations, strategic alliances and licensing arrangements. The sale of additional equity or convertible debt securities would dilute all of our stockholders and the terms of these securities may include liquidation or other preferences that adversely affect the rights of other stockholders. The incurrence of indebtedness would result in increased fixed payment obligations, and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights, limitations on declaring dividends, limitations on our ability to redeem our shares and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through collaborations, strategic alliances or licensing arrangements with third parties, and we could be required to do so at an earlier stage than otherwise would be desirable. In connection with any such collaborations, strategic alliances or licensing arrangements, we may be required to relinquish valuable rights to our intellectual property, future revenue streams, research programs or product candidates, grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves, or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects.

Risks Related to Development of Our Product Candidates

We depend heavily on the success of inebilizumab, VIB4920 and VIB7734, which are in various stages of clinical development. If we are unable to advance our product candidates in clinical development, obtain regulatory approval and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

We do not currently generate any revenue from sales of any products, and we may never be able to develop or commercialize marketable products. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval. We may not receive regulatory approval for inebilizumab for the treatment of patients with NMOSD, we may receive approval in a limited patient population or we may experience delays in receiving such regulatory approval. Even if we successfully commercialize inebilizumab for the treatment of patients with NMOSD, we may not be successful in developing and commercializing our other product candidates, and our commercial opportunities may be limited.

Commencing clinical trials in the United States is subject to acceptance by the FDA of an Investi gational New Drug Application ("IND"), with respect to each product candidate in each indication, and finalizing the trial design based on discussions with the FDA. For example, we will need to obtain an IND prior to commencing our planned clinical trials of inebilizumab in myasthenia gravis and IgG4-related diseases. In the event that the FDA requires us to complete additional pre-clinical studies or we are required to satisfy other FDA requests, the start of our planned future clinical trials in the United States may be delayed. In particular, the FDA has not yet acknowledged IgG4-related diseases as an indication. Our ability to commence our planned clinical trial in this target indication is subject to the FDA acknowledging it as a recognized indication.

We have three product candidates in various stages of clinical development and two product candidates in the pre-clinical development stage. We may not be able to demonstrate that they are safe or effective in the indications for which we are studying them, and they may not be approved. We submitted a BLA to the FDA for inebilizumab in June 2019, which the FDA accepted for review in August 2019. The FDA set a PDUFA date of June 11, 2020. In the second half of 2019, we expect to initiate a Phase 2 trial for VIB4920 in Sjögren's syndrome, which will be designed as Phase 3-enabling, and initiate a separate Phase 2 trial for VIB4920 in kidney transplant rejection. Our Phase 1b multiple ascending dose trial for VIB7734 is ongoing and an interim analysis of data in CLE is planned for the first half of 2020. We also have pre-clinical product candidates that will need to progress through IND-enabling studies prior to clinical development. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates.

Other than the BLA for inebilizumab in patients with NMOSD that we submitted to the FDA in June 2019, which the FDA accepted for review in August 2019, we have not submitted, and we may never submit, marketing applications to the FDA or comparable foreign regulatory authorities for our product candidates. We cannot be certain that any of 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 and we do submit marketing applications seeking regulatory authorization for their use. If we do not receive regulatory approvals for one or more of our product candidates, we may not be able to continue our operations.

For each product candidate, we must demonstrate its safety and efficacy in humans, obtain regulatory approval in one or more jurisdictions, obtain manufacturing supply, capacity and expertise, and substantially invest in marketing efforts before we are able to generate any revenue from such product candidate. The success of our product candidates will depend on several factors, including the following:

- approval by the FDA of a BLA for inebilizumab;
- submission to, and acceptance by, the FDA of an IND and of clinical trial applications to foreign governmental authorities, for our product candidates to commence planned clinical trials and future clinical trials;
- successful enrollment in, and completion of, clinical trials, the design and implementation of which are agreed to by the applicable regulatory authorities, and the conduct of clinical trials by contract research organizations, or CROs, to successfully conduct such trials within our planned budget and timing parameters and without materially adversely impacting our trials;
- successful data from our clinical programs that support an acceptable risk-benefit profile of our product candidates for the targeted indications in the intended populations to the satisfaction of the applicable regulatory authorities;
- timely receipt, if at all, of regulatory approvals from applicable regulatory authorities;
- establishment of arrangements with third-party manufacturers, as applicable, for continued clinical supply and commercial manufacturing;
- successful development of our manufacturing processes and transfer to new third-party facilities to support future development activities and commercialization that are operated by contract manufacturing organizations, or CMOs, in a manner compliant with all regulatory requirements;
- establishment and maintenance of patent and trade secret protection or regulatory exclusivity for our product candidates;
- successful commercial launch of our product candidates, if and when approved;

- acceptance of our products, if and when approved, b y patients, the relevant medical communities and third-party payors;
- effective competition with other therapies;
- establishment and maintenance of adequate healthcare coverage and reimbursement;
- our ability to avoid infringing upon the patent and other intellectual property rights of third parties;
- enforcement and defense of intellectual property rights and claims;
- continued compliance with any post-marketing requirements imposed by regulatory authorities, including any required post-marketing clinical trials or the elements of any post-marketing Risk Evaluation and Mitigation Strategy, or REMS, that may be required by the FDA or comparable requirements in other jurisdictions to ensure the benefits of the product outweigh its risks; and
- maintenance of a continued acceptable safety profile of the product candidates following approval.

If we are unable to address one or more of these factors in a timely manner or at all, we could experience significant delays in the successful commercialization of, or an inability to successfully commercialize, our product candidates, which would materially harm our business. If we do not receive regulatory approvals for one or more of our product candidates, we may not be able to continue our operations. Even if we successfully obtain regulatory approvals to manufacture and 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 in the United States and potentially in foreign countries. While the scope of regulatory approval is similar in many countries, to obtain separate regulatory approval in multiple countries we will be required to comply with numerous and varying regulatory requirements of each such country or jurisdiction regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution, and we cannot predict success in any such jurisdictions. The time required to obtain approval in foreign countries may differ substantially from that required to obtain FDA approval.

Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

The risk of failure in drug development is high. All of our product candidates are in clinical and pre-clinical development, and we have never received marketing approval in any jurisdiction or country. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete nonclinical development and conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical trials are expensive, difficult to design and implement and can take several years to complete, and their outcomes are inherently uncertain. Failure can occur at any time during the clinical trial process. Nonclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in nonclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. While we believe the results of our pivotal trial of inebilizumab for the treatment of patients with NMOSD are positive, the FDA or a comparable foreign regulatory authority may disagree and may conclude that the results of our pivotal trial are not sufficient to approve inebilizumab. It is impossible to predict when or if any of our product candidates will prove to be effective or safe in humans or will receive marketing approval.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates. Clinical trials may be delayed, suspended or prematurely terminated because costs are greater than we anticipate or for a variety of other reasons, such as:

- delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a trial design that we are able to execute;
- delay or failure in obtaining authorization to commence a trial, including approval from the appropriate Institutional Review Board (“IRB”), to conduct testing of a candidate on human subjects, or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial;

- delays in reaching, or failure to reach, agreement on acceptable terms with prospective trial sites and prospective CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- inability, delay or failure in identifying and maintaining a sufficient number of trial sites, many of which may already be engaged in other clinical programs;
- delay or failure in recruiting and enrolling suitable subjects to participate in a trial;
- delay or failure in having subjects complete a trial or return for post-treatment follow-up;
- clinical sites and investigators deviating from the clinical protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial;
- failure to initiate or delay of or inability to complete a clinical trial as a result of the authorizing IND or clinical trial agreement being placed on clinical hold by the FDA or comparable foreign regulatory authority;
- lack of adequate funding to continue a clinical trial, including unforeseen costs due to enrollment delays, requirements to conduct additional clinical trials and increased expenses associated with the services of our CROs and other third parties;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional nonclinical studies, clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials 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;
- regulators, the IRB or a Data Safety Monitoring Board, or DSMB, if one is used for our clinical trials, may require that we suspend or terminate our clinical trials for various reasons, including noncompliance with regulatory requirements, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, or a finding that the participants are being exposed to unacceptable health risks;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient;
- the FDA or comparable foreign regulatory authorities may require us to submit additional data or impose other requirements before permitting us to initiate a clinical trial; or
- changes in governmental regulations or administrative actions.

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 marketing approval for our product candidates. Further, the FDA or comparable foreign 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 it has reviewed and commented on the design for our clinical trials.

If we are required to conduct additional clinical trials or other nonclinical studies of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other studies, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our product candidates;
- not obtain marketing approval for our product candidates at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings that would reduce the potential market for our products or inhibit our ability to successfully commercialize our products;

- be subject to additional post-marketing restrictions and/or requirements, including post-marketing testing; or
- have the product removed from the market after obtaining marketing approval.

We cannot be certain as to what type and how many clinical trials the FDA or comparable foreign regulatory authorities will require us to conduct before we may successfully gain approval to market inebilizumab. Prior to approving a new product, the FDA generally requires that the efficacy of the product be demonstrated in two adequate and well-controlled clinical trials. In some situations, the FDA approves products on the basis of a single well-controlled clinical trial. Based on our discussions with the FDA and the EMA, we conducted only a single pivotal trial of inebilizumab for the treatment of patients with NMOSD. However, if the FDA or EMA determines that our pivotal trial results do not demonstrate a clinically meaningful benefit and an acceptable safety profile, or if the FDA or EMA requires us to conduct additional pivotal trials of inebilizumab in order to gain approval, we will incur significant additional development costs, commercialization of inebilizumab would be prevented or delayed and our business would be adversely affected.

Our product development costs will also increase if we experience delays in nonclinical and clinical development or receiving the requisite marketing approvals. We do not know whether any of our nonclinical studies or clinical trials will need to be restructured or will be completed on schedule, or at all. Significant nonclinical or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

If we experience delays or difficulties in the enrollment of patients in clinical trials, development of our product candidates may be delayed or prevented, which would have a material adverse effect on our business.

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities. Patient enrollment is a significant factor in the timing of clinical trials. In particular, because certain of our clinical trials are focused on indications with small patient populations, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. For example, based on an estimated prevalence of myasthenia gravis of 20 per 100,000 in the United States, we estimate the patient population to be approximately 56,000 and based on an estimated prevalence of systemic sclerosis of 13.5 to 44.3 per 100,000 in Europe and North America, we estimate the patient population to be approximately 300,000.

Patient enrollment may be affected if our competitors have ongoing clinical trials for product candidates that are under development for the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' product candidates. Patient enrollment may also be affected by other factors, including:

- size and nature of the patient population;
- severity of the disease under investigation;
- patient eligibility criteria for the trial in question;
- nature of the trial protocol;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- perceived risks and benefits of the product candidate under study;
- the occurrence of adverse events attributable to our product candidates;
- efforts to facilitate timely enrollment in clinical trials;
- the number and nature of competing products or product candidates and ongoing clinical trials of competing product candidates for the same indication;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients; and
- continued enrollment of prospective patients by clinical trial sites.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our clinical trials may be del ayed or terminated. Any delays in completing our clinical trials will increase our costs, delay or prevent our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may harm our business, financial condition and prospects significantly.

The outcome of pre-clinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA or comparable foreign regulatory authorities.

We currently have no products approved for sale and we cannot guarantee that we will ever have marketable products. Clinical failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we or any future collaborators may decide, or regulators may require us, to conduct additional clinical trials or pre-clinical studies. We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek marketing approvals for their commercial sale. Success in pre-clinical studies and early-stage clinical trials does not mean that future larger registration clinical trials will be successful. This is because product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA and comparable foreign regulatory authorities despite having progressed through pre-clinical studies and early-stage clinical trials. In particular, no compound with the mechanism of action of VIB4920 or VIB7734 has been commercialized, and the outcome of pre-clinical studies and early-stage clinical trials may not be predictive of the success of later-stage clinical trials.

From time to time, we may publish or report interim or preliminary data from our clinical trials. Interim or preliminary data from clinical trials that we may conduct may not be indicative of the final results of the trial and 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. Interim or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim or preliminary data. As a result, interim or preliminary data should be viewed with caution until the final data are available.

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. For example, in a Phase 1b trial, we observed that VIB4920 decreased disease activity in patients with rheumatoid arthritis. In the second half of 2019, we expect to initiate a Phase 2 trial for VIB4920 in Sjögren’s syndrome and initiate a separate Phase 2 trial for VIB4920 in kidney transplant rejection. There is no assurance that VIB4920 will have a similar impact on disease activity in such planned Phase 2 trials.

We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market our product candidates.

If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the commercialization of inebilizumab or any additional product candidates may be delayed, and our business will be harmed.

For planning purposes, we sometimes estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings, or commercialization objectives. From time-to-time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of marketing approval or a commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions which, if not realized as expected, may cause the timing of achievement of the milestones to vary considerably from our estimates, including:

- our available capital resources or capital constraints we experience;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators;
- our ability to identify and enroll patients who meet clinical trial eligibility criteria;

- our receipt of approvals by the FDA and other regulatory authorities and the timing thereof;
- other actions, decisions or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of materials used in the manufacture of our product candidates;
- the efforts of our collaborators with respect to the commercialization of our products; and
- the securing of, costs related to, and timing issues associated with, product manufacturing as well as sales and marketing activities.

If we fail to achieve announced milestones in the timeframes we expect, the commercialization of inebilizumab and any additional product candidates may be delayed, and our business and results of operations may be harmed.

Risks Related to Marketing Approval and Other Legal Compliance Matters

If we are not able to obtain, or if there are delays in obtaining, required marketing approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

Our product candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by comparable authorities in other countries. Before we can commercialize any of our product candidates, each such product candidate must be approved by the FDA pursuant to a BLA in the United States or in the EU by the EMA pursuant to a marketing authorization application, or MAA.

The process of obtaining marketing approvals, both in the United States and abroad, is expensive and takes several years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Failure to obtain marketing approval for a product candidate will prevent us from commercializing the product candidate in the relevant market or country. We have not received approval to market any of our product candidates from regulatory authorities in any jurisdiction. We have limited experience in planning and conducting the clinical trials required for marketing approvals, and we have and expect to continue to rely on third-party CROs to assist us in this process. Obtaining marketing approval requires the submission of extensive nonclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy. Securing marketing approval also requires the submission of information about the product manufacturing process, and in many cases the inspection of manufacturing, processing, and packaging facilities by the regulatory authorities. Our product candidates may not be effective, may be only moderately effective or may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude our obtaining marketing approval or prevent or limit commercial use, or there may be deficiencies in cGMP compliance by us or by our CMOs that could result in the candidate not being approved. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional nonclinical studies or clinical trials. Inebilizumab for the treatment of NMOSD, or any of our other product candidates could be delayed in receiving, or fail to receive, marketing approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the acceptance for review of a BLA or other submission to obtain marketing approval in the United States or elsewhere;

- upon review of our clinical trial sites and data, the FDA or comparable foreign regulatory authorities may find our record keeping or the record keeping of our clinical trial sites to be inadequate;
- third-party manufacturers or our clinical or commercial product candidates may be unable to meet the FDA's cGMP requirements or similar requirements of foreign regulatory authorities; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may grant approval contingent on the performance of costly post-marketing clinical trials (referred to as "conditional" or "accelerated" approval depending on the jurisdiction) or may approve a product candidate with prescribing information that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Our clinical trials of inebilizumab have been designed for inebilizumab to be approved as a monotherapy that is dosed every six months, but there is no assurance that the FDA will agree that the data presented will be sufficient to approve inebilizumab with those dosing characteristics and we may need to conduct additional clinical trials if that were to occur. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

If we experience delays in obtaining approval or if we fail to obtain approval of our product candidates, the commercial prospects for our product candidates may be harmed and our ability to generate revenues will be materially impaired.

Our product candidates may cause undesirable side effects that could delay or prevent their marketing approval, limit their commercial potential, or result in significant negative consequences following marketing approval, if any.

Undesirable side effects caused by our product candidates could cause us or the FDA or other regulatory authorities to interrupt, delay or halt our clinical trials and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or other regulatory authorities of our product candidates. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our 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. In addition to this, the product-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

All of our product candidates modulate the immune system and carry risks, including the theoretical risk of serious infections and cancer. Some common side effects of inebilizumab include urinary tract infection, arthralgia, back pain, headache, fall, hypoesthesia, cystitis and eye pain. Specifically, in our pivotal clinical trial for inebilizumab in patients with NMOSD, adverse events were reported in 71.8% (125/174) of the patients receiving inebilizumab in the randomized control period and 73.2% (41/56) of the patients receiving placebo in the randomized control period. In addition, two deaths have been reported in the ongoing open-label period. One death occurred in a patient experiencing a myelitis attack and was considered unrelated to inebilizumab by the investigator. The second death was due to complications from mechanical ventilator-associated pneumonia in a patient who developed new neurological symptoms and seizures, the cause of which could not be definitively established. The possibility that the death was treatment-related could not be ruled out, and as a result, under the terms of the protocol for the trial, the death was assessed as treatment-related. There can be no assurance that the FDA or comparable foreign regulatory authority will agree with the classifications of the deaths made by the investigators or that we will not be required to conduct additional clinical trials of inebilizumab in order to establish an adequate safety database.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients, 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 our product candidates receive marketing approval and we or others identify undesirable side effects caused by such product candidates (or any other similar products) after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw or limit their approval of such product candidates;
- 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 may be required to change the way such product candidates are distributed or administered, or change the labeling of the product candidates;
- FDA may require a REMS plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools, and regulatory authorities in other jurisdictions may require comparable risk mitigation plans;
- we may be subject to regulatory investigations and government enforcement actions;
- the FDA or a comparable foreign regulatory authority may require us to conduct additional clinical trials or costly post-marketing testing and surveillance to monitor the safety and efficacy of the product;
- we may decide to recall such product candidates from the marketplace after they are approved;
- we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates; and
- our reputation may suffer.

We believe that any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of commercializing our product candidates, if approved, and significantly impact our ability to successfully commercialize our product candidates and generate revenues.

A Breakthrough Therapy Designation by the FDA may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our product candidates will receive marketing approval.

The FDA recently granted Breakthrough Therapy Designation to inebilizumab for the treatment of NMOSD, and we may seek such designation in the future for other product candidates. A Breakthrough Therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor can help to identify the most efficient path for development. Drugs designated as Breakthrough Therapies are also eligible for accelerated approval.

FDA has discretion to determine whether the criteria for a Breakthrough Therapy has been met and whether to grant a Breakthrough Therapy Designation to an investigational product. Accordingly, even if we believe, after completing early clinical trials, that one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or approval compared to product candidates considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even after granting Breakthrough Therapy Designation to our product candidates, the FDA may later decide that such product candidates no longer meet the conditions for qualification and withdraw such designation.

A Fast Track Designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.

We do not currently have Fast Track Designation for any of our product candidates, but may seek such designation in the future. 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 drug sponsor may apply for FDA Fast Track Designation. The FDA has broad discretion whether to grant this designation. 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. Many drugs that have received Fast Track Designation have failed to obtain regulatory approval.

Any product candidate for which we obtain marketing approval will be subject to extensive post-marketing regulatory requirements and could be subject to post-marketing restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products, when and if any of them are approved.

If the FDA or a comparable foreign regulatory authority approves any of our product candidates, activities such as the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. The FDA or a comparable foreign regulatory authority may also impose requirements for costly post-marketing nonclinical studies or clinical trials (often called "Phase 4 trials") and post-marketing surveillance to monitor the safety or efficacy of the product. If we or a regulatory authority discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, production problems or issues with the facility where the product is manufactured or processed, such as product contamination or significant not-compliance with applicable cGMPs, a regulator may impose restrictions on that product, the manufacturing facility or us. If we or our third-party providers, including our CMOs, fail to comply fully with applicable regulations, then we may be required to initiate a recall or withdrawal of our products.

We must also comply with requirements concerning advertising and promotion for any of our product candidates for which we obtain marketing approval. Promotional communications with respect to prescription drugs and biologics are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we will not be able to promote any products we develop for indications or uses for which they are not approved. The FDA closely regulates the post-approval marketing and promotion of drugs to ensure drugs are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding use of their products, and if we promote our products beyond their approved indications, we may be subject to enforcement actions or prosecution arising from that off-label promotion. Violations of the Federal Food, Drug, and Cosmetic Act relating to the promotion of prescription drugs and biologics may lead to investigations alleging violations of federal and state healthcare fraud and abuse laws, as well as state consumer protection laws. Accordingly, to the extent we receive marketing approval for one or more of our product candidates, we and our CMOs and other third-party partners will continue to expend time, money and effort in all areas of regulatory compliance, including promotional and labeling compliance, manufacturing, production, product surveillance, and quality control. If we are not able to comply with post-approval regulatory requirements, we could have marketing approval for any of our products withdrawn by regulatory authorities and our ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Thus, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

In addition, later discovery of previously unknown adverse events or other problems with any of our approved products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning or untitled letters from the FDA or comparable notice of violations from foreign regulatory authorities;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- suspension of any of our ongoing clinical trials;
- imposition of restrictions on our operations, including closing our contract manufacturers' facilities;
- refusal to permit the import or export of our products;

- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Non-compliance with European Union requirements regarding safety monitoring or pharmacovigilance can also result in significant financial penalties. Similarly, failure to comply with the European Union's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay marketing approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Our relationships with prescribers, purchasers, third-party payors and patients will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Although we do not currently have any products on the market, upon commercialization of our product candidates, if approved, we will be subject to additional healthcare statutory and regulatory requirements and oversight by federal and state governments as well as foreign governments in the jurisdictions in which we conduct our business. Physicians, other healthcare providers and third-party payors will play a primary role in the recommendation, prescription and use of any product candidates for which we obtain marketing approval. Our future arrangements with such third parties may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain our business or financial arrangements and relationships through which we market, sell and distribute any products for which we may obtain marketing approval. Restrictions under applicable domestic and foreign healthcare laws and regulations include the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons 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 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;
- U.S. federal false claims, false statements and civil monetary penalties laws, including the U.S. False Claims Act, which impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government; actions may be brought by the government or a whistleblower and may include an assertion that a claim for payment by federal healthcare programs for items and services which results from a violation of the federal Anti-Kickback Statue constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the U.S. federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, that imposes criminal and civil liability for executing 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 U.S. 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;
- analogous state and foreign laws and regulations relating to healthcare fraud and abuse, 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;
- the U.S. federal physician payment transparency requirements, sometimes referred to as the "Sunshine Act," which requires manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report to the Centers for Medicare & Medicaid Services, or CMS, information related to physician payments and other transfers of value to physicians and teaching hospitals (and, beginning in 2021, for transfers of value to other healthcare providers), as well as the ownership and investment interests of physicians and their immediate family members;

- analogous state and foreign laws that require pharmaceutical companies to track, report and disclose to the government and/or the public information related to payments, gifts, and other transfers of value or remuneration to physicians and other healthcare providers, marketing activities or expenditures, or product pricing or transparency information, or that require pharmaceutical companies to implement compliance programs that meet certain standards or to restrict or limit interactions between pharmaceutical manufacturers and members of the healthcare industry;
- the U.S. federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under federal healthcare programs;
- HIPAA, which imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the 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
- state and foreign laws that govern the privacy and security of health information in certain circumstances, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. If the FDA or a comparable foreign regulatory authority approves any of our product candidates, we will be subject to an expanded number of these laws and regulations and will need to expend resources to develop and implement policies and processes to promote ongoing compliance. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations, resulting in government enforcement actions.

If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from federal healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from federal healthcare programs.

We may face difficulties from changes to current regulations and future legislation.

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 significant legislative initiatives to contain healthcare costs. Federal and state governments continue to propose and pass legislation designed to reform delivery of, or payment for, healthcare, which include initiatives to reduce the cost of healthcare. For example, in March 2010, the United States Congress enacted the Patient Protection and Affordable Care Act and the Healthcare and Education Reconciliation Act, or the ACA, which expanded healthcare coverage through Medicaid expansion and the implementation of the individual mandate for health insurance coverage and which included changes to the coverage and reimbursement of drug products under federal healthcare programs. The ACA contains a number of provisions that affect coverage and reimbursement of drug products and/or that could potentially reduce the demand for pharmaceutical products such as increasing drug rebates under state Medicaid programs for brand name prescription drugs and extending those rebates to Medicaid managed care and assessing a fee on manufacturers and importers of brand name prescription drugs reimbursed under certain government programs, including Medicare and Medicaid. Under the Trump administration, there have been ongoing efforts to modify or repeal all or certain provisions of the ACA. For example, tax reform legislation was enacted at the end of 2017 that eliminates the tax penalty established under the ACA for individuals who do not maintain mandated health insurance coverage beginning in 2019. In a May 2018 report, the Congressional Budget Office estimated that, compared to 2018, the number of uninsured individuals in the United States will increase by three million in 2019 and

six million in 2028, in part due to the elimination of the individual mandate. The AC A has also been subject to judicial challenge. In December 2018, a federal district court, in a challenge brought by a number of state attorneys general, found the ACA unconstitutional in its entirety because, once Congress repealed the individual mandate provision, there was no longer a basis to rely on Congressional taxing authority to support enactment of the law. Pending appeals, which could take some time, the ACA is still operational in all respects.

Additional legislative actions to control U.S. healthcare or other costs have passed. The Budget Control Act, as amended, resulted in the imposition of 2% reductions in Medicare (but not Medicaid) payments to providers in 2013 and will remain in effect through 2027 unless additional Congressional action is taken.

Recently, there has been considerable public and government scrutiny in the United States of pharmaceutical pricing and proposals to address the perceived high cost of pharmaceuticals. The current presidential administration has indicated an intent to address prescription drug pricing and recent Congressional hearings have brought increased public attention to the costs of prescription drugs and biologics. State governments also have sought to put in place limits and caps on pharmaceutical prices and have also requested rebates for certain pharmaceutical products.

We expect that current or future healthcare reform measures may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations for biological products will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by the U.S. Congress of the FDA's approval and decision-making processes may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.*

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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

Our future profitability may depend, in part, on our ability to commercialize our product candidates in foreign markets. In order to market and sell products in the European Union and many other jurisdictions, separate marketing approvals must be obtained and numerous and varying regulatory requirements must be complied with. The approval procedure varies among countries and economic areas and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The marketing approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. In addition, in many countries outside the United States, it is required that the product be approved for reimbursement before the product can be approved for sale in these countries. Approval from regulatory authorities outside the United States may not be obtained on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. Additionally, a failure or delay in obtaining marketing approval in one jurisdiction may have a negative effect on the marketing approval process in others. Obtaining foreign marketing approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs could delay or prevent the introduction of products in certain countries. Failure to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, will result in the reduced ability to realize the full market potential of product candidates.

We may not be able to file for marketing approvals and may not receive necessary approvals to commercialize our products in any foreign market. If we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for our product candidates in foreign markets;
- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- the existence of additional potentially relevant third-party intellectual property rights;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of our product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and tariffs. In order to access certain foreign markets we anticipate entering into collaborations with third parties to develop and obtain certain products. For example, in May 2019, we entered into a collaboration agreement with Hansoh Pharmaceutical Group, or Hansoh Pharma, to co-develop and market inebilizumab in China, Hong Kong and Macau, and in October 2019, we entered into a license agreement with Mitsubishi Tanabe Pharma Corporation, or MTPC, for co-development and commercialization of inebilizumab in Japan, Thailand, South Korea, Indonesia, Vietnam, Malaysia, Philippines, Singapore, and Taiwan.

We may be subject to, or may in the future become subject to, U.S. federal and state, and foreign laws and regulations imposing obligations on how we collect, use, disclose, store and process personal information. Our actual or perceived failure to comply with such obligations could result in liability or reputational harm and could harm our business. Ensuring compliance with such laws could also impair our efforts to maintain and expand our customer base, and thereby decrease our revenue.

In many activities, including the conduct of clinical trials, we are subject to laws and regulations governing data privacy and the protection of health-related and other personal information. These laws and regulations govern our

processing of personal data, including the collection, access, use, analysis, modification, storage, transfer, security breach notification, d estruction and disposal of personal data.

The privacy and security of personally identifiable information stored, maintained, received or transmitted, including electronically, is subject to significant regulation in the United States and abroad. While we strive to comply with all applicable privacy and security laws and regulations, legal standards for privacy continue to evolve and any failure or perceived failure to comply may result in proceedings or actions against us by government entities or others, or could cause reputational harm, which could have a material adverse effect on our business.

Numerous foreign, federal and state laws and regulations govern collection, dissemination, use and confidentiality of personally identifiable health information, including state privacy and confidentiality laws (including state laws requiring disclosure of breaches), federal and state consumer protection and employment laws; HIPAA and European and other foreign data protection laws. These laws and regulations are increasing in complexity and number and may change frequently and sometimes conflict. The European Union's omnibus data protection law, the General Data Protection Regulation, or GDPR, took effect on May 25, 2018. GDPR imposes numerous requirements on entities that process personal data in the context of an establishment in the European Economic Area, or EEA, or that process the personal data of data subjects who are located in the EEA. These requirements include, for example, establishing a basis for processing, providing notice to data subjects, developing procedures to vindicate expanded data subject rights, implementing appropriate technical and organizational measures to safeguard personal data, and complying with restrictions on the cross-border transfer of personal data from the EEA to countries that the European Union does not consider to have in place adequate data protection legislation, such as the United States. GDPR additionally establishes heightened obligations for entities that process "special categories" of personal data, such as health data. Nearly all clinical trials involve the processing of these "special categories" of personal data, and thus processing of personal data collected during the course of clinical trials is subject to heightened protections under GDPR. Violations of GDPR can lead to penalties of up to $20 million or 4% of an entity's annual turnover.

As a means to transfer personal data from the EEA to the U.S., U.S.-based companies may certify compliance with the privacy principles of the EU-U.S. Privacy Shield, or the Privacy Shield. Certification to the Privacy Shield, however, is not mandatory. If a U.S.-based company does not certify compliance with the Privacy Shield, it may rely on other authorized mechanisms to transfer personal data. Notably, the Privacy Shield is currently subject to challenge in the EU courts, and it is possible that it will be invalidated, which was the fate of its predecessor, the EU-U.S. Safe Harbor. In the event of invalidation of the Privacy Shield, U.S. companies that currently rely on the Privacy Shield as the basis for cross-border transfer of personal data will need to establish another basis for cross-border transfer of personal data.

HIPAA establishes a set of national privacy and security standards for the protection of individually identifiable health information, including protected health information, or PHI, by health plans, certain healthcare clearinghouses and healthcare providers that submit certain covered transactions electronically, or covered entities, and their "business associates," which are persons or entities that perform certain services for, or on behalf of, a covered entity that involve creating, receiving, maintaining or transmitting PHI. While we are not currently a covered entity or business associate under HIPAA, we may receive identifiable information from these entities. Failure to receive this information properly could subject us to HIPAA's criminal penalties, which may include fines up to $250,000 per violation and/or imprisonment. In addition, responding to government investigations regarding alleged violations of these and other laws and regulations, even if ultimately concluded with no findings of violations or no penalties imposed, can consume company resources and impact our business and, if public, harm our reputation.

In addition, various states, such as California and Massachusetts, have implemented similar privacy laws and regulations, such as the California Confidentiality of Medical Information Act, that impose restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. In addition to fines and penalties imposed upon violators, some of these state laws also afford private rights of action to individuals who believe their personal information has been misused. California's patient privacy laws, for example, provide for penalties of up to $250,000 and permit injured parties to sue for damages. The interplay of federal and state laws may be subject to varying interpretations by courts and government agencies, creating complex compliance issues for us and potentially exposing us to additional expense, adverse publicity and liability. Further, as regulatory focus on privacy issues continues to increase and laws and regulations concerning the protection of personal information expand and become more complex, these potential risks to our business could intensify.

The legislative and regulatory landscape for privacy and data security continues to evolve, and there has been an increasing focus on privacy and data security issues which may affect our business. Failure to comply with current and future laws and regulations could result in government enforcement actions (including the imposition of significant

penalties), criminal and/or civil liability for us and our officers and directors, private litigation and/or adverse publicity that negatively affects our business.

In the United States, California recently adopted the California Consumer Privacy Act of 2018, or CCPA, which will come into effect beginning in January 2020. The CCPA has been characterized as the first "GDPR-like" privacy statute to be enacted in the United States because it mirrors a number of the key provisions of the EU General Data Protection Regulation. The CCPA establishes a new privacy framework for covered businesses in the State of California, by creating an expanded definition of personal information, establishing new data privacy rights for consumers imposing special rules on the collection of consumer data from minors, and creating a new and potentially severe statutory damages framework for violations of the CCPA and for businesses that fail to implement reasonable security procedures and practices to prevent data breaches.

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

In some countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially.

If we or our third-party contractors fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could harm our business.

We and our third-party contractors are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our operations and those of our third-party contractors involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations and those of our third-party contractors also produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from the use of hazardous materials by us or our third-party service contractors, we could be held liable for any resulting damages, and the amount of the liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

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 hazardous materials, this insurance may not provide adequate coverage against other potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our discovery, nonclinical development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our business activities may be subject to the Foreign Corrupt Practices Act and similar anti-bribery and anti-corruption laws of other countries in which we operate.

We have conducted and have ongoing studies in international locations, and may in the future initiate additional studies in countries other than the United States. Our business activities may be subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits offering, promising, giving or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, the healthcare providers who prescribe pharmaceuticals are employed by their governments, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. Recently the SEC and Department of

Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products, if approved, in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees and our business, prospects, operating results and financial condition.

Biologics carry unique risks and uncertainties, which could have a negative impact on future results of operations.

The successful discovery, development, manufacturing and sale of biologics is a long, expensive and uncertain process. There are unique risks and uncertainties with biologics. For example, access to and supply of necessary biological materials, such as cell lines, may be limited and governmental regulations restrict access to and regulate the transport and use of such materials. In addition, the development, manufacturing and sale of biologics is subject to regulations that are often more complex and extensive than the regulations applicable to other pharmaceutical products. Manufacturing biologics, especially in large quantities, is often complex and may require the use of innovative technologies. Such manufacturing also requires facilities specifically designed and validated for this purpose and sophisticated quality assurance and quality control procedures. Biologics are also frequently costly to manufacture because production inputs are derived from living animal or plant material, and some biologics cannot be made synthetically. Failure to successfully discover, develop, manufacture and sell our biological product candidates would adversely impact our business and future results of operations.

Risks Related to Our Dependence on Third Parties

We are reliant on AstraZeneca for a period of time for certain services and for the clinical supplies of our product candidates and the commercial supplies of inebilizumab.

We were incorporated in December 2017 and, in February 2018, we acquired six molecules from MedImmune. Following the assets purchase, we entered into several agreements with AstraZeneca and MedImmune, including a license agreement, sublicense agreements, a transition services agreement, a master supply and development services agreement, a clinical supply agreement and a commercial supply agreement. AstraZeneca has no obligation to assist our operations and growth strategy, other than providing certain services or rights pursuant to these agreements. Pursuant to the transition services agreement, we are, and for a period of time will be, reliant on AstraZeneca for certain services, including, but not limited to, financial services, procurement activities, information technology services, clinical data management and statistical programming, clinical operations and development and commercial activities. AstraZeneca is obligated to provide each of these services for a designated period of time ranging from several months to approximately five years, depending upon the nature of the service provided.

We are, and for a period of time will be, substantially reliant on AstraZeneca to provide these services, and if AstraZeneca is unable or unwilling to satisfy its obligations under these agreements, we could incur operational difficulties or losses that could have a material and adverse effect on our business, prospects, financial condition and results of operations.

Furthermore, the services provided by AstraZeneca under these agreements do not include every service that is necessary to successfully operate our business, and AstraZeneca is only obligated to provide these services for limited periods of time. Accordingly, we must develop internal capabilities to perform these services, or obtain from other third parties services we currently receive from AstraZeneca. If we are unable to efficiently implement our own systems and services, or if we are unable to negotiate agreements with third-party providers of these services in a timely manner or on terms and conditions as favorable as those we receive from AstraZeneca, we may not be able to operate our business effectively and our financial condition may decline. Furthermore, if we fail to develop high-quality internal capabilities from third-party providers, in a cost-effective manner, we may be unable to operate our existing business or execute our strategic priorities successfully and efficiently, and our operating results and financial condition may be materially harmed.

We rely on, and expect to continue to rely on, third parties to conduct ou r clinical trials for our product candidates. If these third parties do not successfully carry out their contractual duties, comply with regulatory requirements or meet expected deadlines, we may not be able to obtain marketing approval for or commercialize our product candidates, and our business could be substantially harmed.

We do not have the ability to independently conduct clinical trials. We rely on and expect to continue to rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct or otherwise support clinical trials for our product candidates. In addition, we rely on AstraZeneca for certain operational and regulatory services with respect to each of our product candidates and their clinical trials and pre-clinical studies.

We have and expect to continue to rely heavily on these parties to conduct clinical trials for our product candidates. Nevertheless, we will be responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards.

We and our CROs will be required to comply with regulations, including good clinical practice, or GCP, and other related requirements for conducting, monitoring, recording and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate, and that the trial patients are adequately informed of the potential risks of participating in clinical trials and their rights are protected. These regulations are enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for any drugs in clinical development. The FDA and comparable foreign regulatory authorities enforce GCPs through periodic inspections of clinical trial sponsors, principal investigators and trial sites. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be called into question and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before considering our marketing applications for approval. We cannot assure you that, upon inspection, the FDA or a comparable foreign regulatory authority will determine that any of our future clinical trials will comply with GCPs. In addition, our clinical trials must be conducted with product candidates produced under cGMPs. Our failure or the failure of our CROs to comply with these regulations may require us to repeat clinical trials, which would delay the marketing approval process and could also subject us to enforcement action. We also are required to register certain clinical trials and post the results of such completed clinical trials involving product candidates for which we receive marketing approval on a government-sponsored database, www.ClinicalTrials.gov, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

Although we intend to design the clinical trials for our product candidates, CROs have administered and will continue to administer all of the clinical trials. As a result, many important aspects of our development programs, including their conduct and timing, will be outside of our direct control. Our reliance on third parties to conduct future clinical trials will also result in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with outside parties can also be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Outside parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues;
- undergo changes in priorities or become financially distressed;
- make errors in the design, management or retention of our data or data systems; and/or
- form relationships with other entities, some of which may be our competitors.

These factors may materially adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. If the CROs have not or do not conduct clinical trials in a satisfactory manner, breach their obligations to us or fail to comply with regulatory requirements, the development, marketing approval and commercialization of our product candidates may be delayed, we may not be able to obtain marketing approval and commercialize our product candidates, or our development program may be materially and irreversibly harmed. If we are unable to rely on clinical data collected by our CROs, we could be required to repeat, extend the duration of, or increase the size of any clinical trials we conduct and this could significantly delay commercialization and require significantly greater expenditures.

If any of our relationships with these third-party CROs terminat e, we may not be able to enter into arrangements with alternative CROs. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, any clinical trials such CROs are associated with may be extended, delayed or terminated, and we may not be able to obtain marketing approval for or successfully commercialize our product candidates. As a result, we believe that our financial results and the commercial prospects for our product candidates in the subject indication would be harmed, our costs could increase and our ability to generate revenue could be delayed.

We contract with third parties for the manufacture of our product candidates for nonclinical studies and clinical trials and expect to continue to do so for commercialization. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently own or operate, nor do we have any plans to establish in the future, any manufacturing facilities or personnel. We rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for nonclinical studies and clinical trials, as well as for the commercial manufacture of our approved products if any of our product candidates receives marketing approval. In particular, we rely on AstraZeneca for the manufacture of the current clinical and potential future commercial supplies of inebilizumab and for the current clinical and nonclinical supplies of our other product candidates. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or approved products or such quantities at an acceptable cost or quality, which could delay, prevent or impair our development or commercialization efforts.

The facilities used to manufacture our product candidates must be evaluated by the FDA or a comparable foreign regulatory authority pursuant to inspections that will be conducted after we submit our marketing applications to the FDA to ensure compliance with cGMP. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturers for compliance with cGMPs in connection with the manufacture of our product candidates. If AstraZeneca or other contract manufacturers we may engage in the future cannot successfully manufacture material that conforms to our specifications and the regulatory requirements of the FDA or a comparable foreign regulatory authority, we will not be able to use the product candidates or products produced at their manufacturing facilities. In addition, we have no control over the ability of AstraZeneca or other contract manufacturers we may engage in the future to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Further, our failure, or the failure of AstraZeneca or other third party manufacturers we may engage in the future, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, if approved, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect our business and supplies of our product candidates.

We may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third party manufacturers, reliance on third party manufacturers entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Our current and future product candidates may compete with other product candidates and approved products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates, we may incur added costs and delays in identifying and qualifying any such replacement. For example, AstraZeneca currently manufactures inebilizumab for us using their proprietary methods in certain steps of the manufacturing process. If we were to replace AstraZeneca for the manufacture of inebilizumab, we may incur additional costs and delays while the replacement manufacturer developed its own independent methods of manufacturing inebilizumab. Moreover, we would need to confirm that the drug product from the replacement manufacturer is comparable to the drug product that AstraZeneca is currently manufacturing for us.

Our current and anticipated future dependence upon others for the manufacture of our product candidates or products, if approved, may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

We, or our third-party manufacturers, may be unable to successfully scale-up manufacturing of our product candidates in sufficient quality and quantity, which would delay or prevent us from developing our product candidates and commercializing approved products, if any.

In order to conduct large-scale clinical trials of or commercialize our product candidates, we will need to manufacture them in large quantities. We, or any of our current or future manufacturing partners, including AstraZeneca, may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all. In addition, quality issues may arise during scale-up activities. Further, in order to release product and demonstrate stability of product candidates for use in late-stage clinical trials (and any subsequent products for commercial use), our analytical methods must be validated in accordance with regulatory guidelines. We may not be able to successfully validate, or maintain validation of, our analytical methods or demonstrate adequate purity, stability or comparability of the product candidates in a timely or cost-effective manner, or at all. For example, in connection with the potential commercialization of inebilizumab, AstraZeneca is in the process of scaling up and optimizing the manufacturing process for inebilizumab. While we believe the optimized manufacturing process meets all of the regulatory manufacturing requirements, the FDA will review the optimized process as part of the review of the BLA for inebilizumab. If we, or any current or future manufacturing partners, including AstraZeneca, are unable to successfully scale up the manufacture of our product candidates, including inebilizumab, in sufficient quality and quantity, or if we encounter validation issues, the development, testing and clinical trials of that product candidate, including inebilizumab, may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product, including inebilizumab, may be delayed or not obtained, which could significantly harm our business.

The third parties upon which we rely for the supply of source materials, cell cultures and biological products are our sole sources of supply and have limited capacity, and the loss of any of these suppliers could harm our business.

Manufacturing biological products like our product candidates, especially in large quantities, is often complex and may require the use of innovative technologies to handle living microorganisms. Each lot of an approved biologic must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing biologics such as monoclonal antibodies and complex protein products requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process or any steps in the production and purification processes, we may be required to provide pre-clinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. Biologics are frequently more complex than chemical drugs to manufacture because production ingredients are derived from living animal or plant material, and most biologics cannot be made synthetically. Manufacturers of biological products often encounter difficulties in production, which include difficulties with production costs and yields, quality control and assurance and shortages of qualified personnel, as well as compliance with strictly enforced federal, state and foreign regulations.

The source materials and cell cultures used to produce our product candidates are supplied to us from single-source suppliers with limited capacity. Our ability to successfully develop our product candidates, and to ultimately supply our commercial products, if approved in quantities sufficient to meet the market demand, depends in part on our ability to obtain the source materials and biological products in accordance with cGMP regulatory requirements and in sufficient quantities for commercialization and clinical trials. We do not currently have arrangements in place for a redundant or second-source supply of any source material or biological product in the event any of our current suppliers cease their operations for any reason.

We do not know whether our suppliers will be able to meet our demand, either because of the nature of our agreements with those suppliers, our limited experience with those suppliers or our relative importance as a customer to those suppliers. It may be difficult for us to assess their ability to timely meet our demand in the future based on past performance. While our suppliers have generally met our demand for their products on a timely basis in the past, they may subordinate our needs in the future to their other customers.

For some of our product candidates, we intend to identify and qualify additional contract manufacturers prior to submission of a BLA to the FDA and/or an MAA to the EMA. Establishing additional or replacement suppliers for our product candidates, if required, may not be accomplished quickly. If we are able to find a replacement supplier, such replacement supplier would need to be qualified and may require additional marketing approval, which could result in further delay. While we seek to maintain adequate inventory of the source materials, cell cultures and other components needed to produce our product candidates, any interruption or delay in the supply of components or materials, or our inability to obtain such materials from alternate sources at acceptable prices in a timely manner could impede, delay, limit or prevent our development efforts, which could harm our business, results of operations, financial condition and prospects.

We may seek to establish collaborations, and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.*

Our product candidate development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. For some of our product candidates, we may decide to collaborate with pharmaceutical and biotechnology companies for the development and potential commercialization of those product candidates. In particular, we initially plan to seek partnerships to pursue regulatory approval and commercialization of our product candidates outside the United States. For example, in May 2019, we entered into a collaboration agreement with Hansoh Pharma to co-develop and market inebilizumab in China, Hong Kong and Macau, and in October 2019, we entered into a license agreement with MTPC for co-development and commercialization of inebilizumab in Japan, Thailand, South Korea, Indonesia, Vietnam, Malaysia, Philippines, Singapore, and Taiwan.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities, 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 and market conditions generally. The collaborator may also 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. The terms of any collaborations or other arrangements that we may enter into may not be favorable to us.

We may also be restricted under existing or future collaboration agreements from entering into future agreements on certain terms with potential collaborators. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on

acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to marke t and generate product revenue.

In addition, any collaboration that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these collaborations. Any such collaboration 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, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration or integration costs, write-down of assets or goodwill or impairment charges, increased amortization expenses and difficulty and cost in facilitating the collaboration.

Lastly, disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision-making authority. Collaborations with pharmaceutical or biotechnology companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration would adversely affect us financially and could harm our business reputation.

Risks Related to the Commercialization of Our Product Candidates

Even if any of our product candidates receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any of our product candidates receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the timing of our receipt of any marketing approvals;
- the terms of any approvals and the countries in which approvals are obtained;
- the efficacy and safety and potential advantages and disadvantages compared to alternative treatments, including future alternative treatments;
- the prevalence and severity of any side effects associated with our product candidates;
- the indications for which our products are approved and the scope of risk information required to be included in the product labeling;
- adverse publicity about our products or favorable publicity about competing products;
- the approval of other products for the same indications as our products;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the success of our physician education programs;
- the strength of our marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement;
- the extent of patient cost-sharing obligations, including copays and deductibles;
- the availability of products and their ability to meet market demand, including a reliable supply for long-term treatment; and

- any restrictions on the use of our products together with other medications.

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 operation and prospects.

We face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition with respect to our current product candidates, and expect to face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Specifically, there are a number of companies developing or marketing treatments for autoimmune diseases, including many major pharmaceutical and biotechnology companies. If inebilizumab is approved, it would compete with eculizumab from Alexion Pharmaceuticals, Inc., or Alexion, to be marketed as Soliris®, and satralizumab from Chugai Pharmaceuticals Co., Ltd., each for the treatment of patients with NMOSD. Both products have achieved successful pivotal studies in NMOSD and in June 2019, Alexion received FDA approval of Soliris for the treatment of adults with NMOSD. If VIB4920 is approved, it would compete with: (a) if approved, dapirolizumab pegol, an investigational anti-CD40L pegylated Fab being developed in SLE jointly by UCB and Biogen, (b) Belatacept (NULOJIX®), a selective T cell costimulation blocker indicated for prophylaxis of organ rejection in adult patients receiving a kidney transplant, developed by Bristol-Myers Squib, (c) if approved, BI 655064, a humanized mouse anti-human mAb being developed in SLE as part of a global collaboration of AbbVie and Boehringer Ingelheim, (d) if approved, CFZ533, a mAb being developed in primary Sjögren's syndrome by Novartis and (e) multiple approved drugs or drugs that may be approved in the future for indications for which we may develop VIB4920. If VIB7734 is approved, it would compete with: (a) if approved for lupus, BIIB059, a mAb targeting BDCA2, which is a protein present in specific cells within the immune system, being developed by Biogen, (b) if approved for systemic sclerosis, Nintedanib, a tyrosine kinase inhibitor being developed by Boehringer Ingelheim and (c) multiple approved drugs or drugs that may be approved in the future for indications for which we may develop VIB7734.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other marketing approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market and/or slow our marketing approval. For example, in June 2019 Alexion received FDA approval of Soliris for the treatment of adults with NMOSD. Some of the important competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price and the availability of reimbursement from government and other third-party payors.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, nonclinical studies, conducting clinical trials, obtaining marketing approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Our product candidates for which we intend to seek approval may face generic or biosimilar competition sooner than anticipated.

Even if we are successful in achieving regulatory approval to commercialize a product candidate ahead of our competitors, our product candidates may face competition from biosimilar products. In the United States, our product candidates are regulated by the FDA as biological products and we intend to seek approval for these product candidates pursuant to the BLA pathway. The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created an abbreviated pathway for FDA approval of biosimilar and interchangeable biological products based on a previously licensed reference product. Under the BPCIA, an application for a biosimilar biological product cannot be approved by the FDA until 12 years after the original reference biological product was approved under a BLA. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our product candidates.

We believe that any of our product candidates approved as a biological product under a BLA should qualify for the 12-year period of exclusivity available to reference biological products. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference biological products pursuant to its interpretation of the exclusivity provisions of the BPCIA for competing products, potentially creating the opportunity for generic follow-on biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar product, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing including whether a future competitor seeks an interchangeability designation for a biosimilar of one of our products. Under the BPCIA as well as state pharmacy laws, only interchangeable biosimilar products are considered substitutable for the reference biological product without the intervention of the health care provider who prescribed the original biological product. However, as with all prescribing decisions made in the context of a patient-provider relationship and a patient's specific medical needs, healthcare providers are not restricted from prescribing biosimilar products in an off-label manner. In addition, a competitor could decide to forego the abbreviated approval pathway available for biosimilar products and to submit a full BLA for product licensure after completing its own preclinical studies and clinical trials. In such a situation, any exclusivity to which we may be eligible under the BPCIA would not prevent the competitor from marketing its biological product as soon as it is approved.

In Europe, the European Commission has granted marketing authorizations for several biosimilar products pursuant to a set of general and product class-specific guidelines for biosimilar approvals issued over the past few years. In addition, companies may be developing biosimilar products in other countries that could compete with our products, if approved.

If competitors are able to obtain marketing approval for biosimilars referencing our product candidates, if approved, our future products may become subject to competition from such biosimilars, whether or not they are designated as interchangeable, with the attendant competitive pressure and potential adverse consequences. Such competitive products may be able to immediately compete with us in each indication for which our product candidates may have received approval.

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

The regulations that govern marketing 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 pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product candidate, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product candidate 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 marketing approval.

Our ability to commercialize any product candidates successfully also will depend in part on the extent to which coverage and reimbursement for these product candidates and related treatments will be available from government authorities, private health insurers and other organizations. In the United States, reimbursement varies from payor to payor. Reimbursement agencies in Europe may be more conservative than federal healthcare programs or private health plans in the U.S. For example, a number of cancer drugs are generally covered and paid for in the United States, but have not been approved for reimbursement in certain European countries. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of payments for particular products. For example, payors may limit coverage to specific drug products on an approved list, also known as a formulary, which might not include all of the FDA-approved drugs for a particular indication. Payors may require use of alternative therapies or a demonstration that a product is medically necessary for a particular patient before use of a product will be covered. Additionally, payors may seek to control utilization by imposing prior authorization requirements. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for products. We cannot be sure that coverage will be available for any product candidate that we commercialize and, if coverage is available, what the level of reimbursement will be. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. Patients are unlikely to use our or our partners' products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of such products. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

In addition to CMS and private payors, professional organizations such as the American Autoimmune Related Diseases Association, Inc. can influence decisions about reimbursement for new medicines by determining standards of care. In addition, many private payors contract with commercial vendors who sell software that provide guidelines that attempt to limit utilization of, and therefore reimbursement for, certain products deemed to provide limited benefit to existing alternatives. Such organizations may set guidelines that limit reimbursement or utilization of our products.

There may be significant delays in obtaining reimbursement for newly approved drugs and biologics, and coverage may be more limited than the purposes for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for 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 not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by discounts or rebates required by federal 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. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

We currently have a limited marketing and sales force. If we are unable to establish effective sales or marketing capabilities or enter into agreements with third parties to sell or market our product candidates, we may not be able to effectively sell or market our product candidates, if approved, or generate product revenues.

We currently have a limited sales and marketing infrastructure. To achieve commercial success for any approved product candidate for which we retain sales and marketing responsibilities, we must build our sales, marketing, managerial, and other non-technical capabilities or make arrangements with third parties to perform these services. For example, we are currently exploring the use of sales representatives for the marketing of inebilizumab in patients with NMOSD in the United States, if approved. There are risks involved with both establishing our own sales and marketing capabilities and entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our product candidates on our own include:

- our inability to recruit, hire, retain and incentivize adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future products;

- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with establishing an independent sales and marketing organization.

If we enter into arrangements with third parties to perform sales, marketing and distribution services, as we are currently exploring for the marketing of inebilizumab in the United States, if approved, our product revenues or the profitability of these product revenues to us are likely to be lower than if we were to market and sell any product candidates that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market inebilizumab or any of our other product candidates or may be unable to do so when needed or on terms that are favorable to us. We likely will have more limited control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our product candidates effectively, or they may fail to comply with promotional requirements for prescription products that could render our products misbranded in violation of FDA regulations and thus potentially subject to enforcement. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing inebilizumab or any of our other product candidates that receive marketing approval or any such commercialization may experience delays or limitations. If we are not successful in commercializing inebilizumab or any of our other product candidates, either on our own or through collaborations with one or more third parties, our business, results of operations, financial condition and prospects will be materially adversely affected.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the evaluation of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- regulatory investigations, product recalls or withdrawals, or labeling, marketing or promotional restrictions;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to successfully commercialize any products that we may develop.

Our current product liability insurance coverage may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

The sizes of the patient populations suffering from some of the diseases we are targeting are small and based on estimates that may not be accurate.

Our projections of both the number of people who have some of the diseases we are targeting, as well as the subset of people with these diseases who have the potential to benefit from treatment with inebilizumab and any other future product candidates, are estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, physician interviews, patient foundations and market research, and may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. Additionally, the potentially addressable patient population for inebilizumab and any other future product candidates may be limited or may not be amenable to treatment with inebilizumab and any other products, if and when approved. Even if we obtain significant market share for inebilizumab and any other products (if and when they are approved), small potential target populations for certain indications means we may never achieve profitability without obtaining market approval for additional indications.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain intellectual property protection for our technology and products, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could commercialize technology and products similar or identical to ours, and our ability to successfully commercialize our technology and products may be impaired.

Our success depends in large part on our ability to obtain and maintain patents in the United States and other countries that adequately protect our proprietary technology and products. We seek to protect our proprietary position by filing patent applications in the United States and in foreign countries that cover our novel technologies and product candidates. Our patent portfolio currently includes both patents and patent applications, most of which were acquired from MedImmune.

The patent prosecution process is expensive and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. We may choose not to seek patent protection for certain innovations and may choose not to pursue patent protection in certain jurisdictions. Under the laws of certain jurisdictions, patents or other intellectual property rights may be unavailable or limited in scope. It is also possible that we will fail to identify patentable aspects of our research and development before it is too late to obtain patent protection.

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. 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 know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability, term and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued which protect our technology or products, in whole or in part, or which effectively prevent others from commercializing competitive technologies and products. For example, to date, none of our U.S. patent applications directed to VIB7734 have issued as patents. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. On September 16, 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. The U.S. Patent and Trademark Office, or U.S. PTO, recently developed new regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first-to-file provisions, became effective on March 16, 2013. The Leahy-Smith Act also created certain new administrative adversarial proceedings, discussed below. It is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

The U.S. Supreme Court has issued opinions in patent cases in the last few years that many consider may weaken patent protection in the United States, either by narrowing the scope of patent protection available in certain circumstances, holding that certain kinds of innovations are not patentable or generally otherwise making it easier to invalidate patents in court. Additionally, there have been recent proposals for additional changes to the patent laws of the United States and other countries that, if adopted, could impact our ability to obtain patent protection for our proprietary technology or our ability to enforce our proprietary technology. Depending on future actions by the U.S. Congress, the U.S. courts, the U.S. PTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and in other countries. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. 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.

During patent prosecution in the United States and in most foreign countries, a third party can submit prior art or arguments to the reviewing patent office to attempt to prevent the issuance of a competitor's patent. For example, our pending patent applications may be subject to a third-party preissuance submission of prior art to the U.S. PTO or an Observation in Europe. Such submission may convince the receiving patent office not to issue the patent. In addition, if the breadth or strength of protection provided by our patents and patent applications is reduced by such third party submission, it could affect the value of our resulting patent or dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

The risks described here pertaining to our patents and other intellectual property rights also apply to any intellectual property rights that we may license in the future, and any failure to obtain, maintain and enforce these rights could have a material adverse effect on our business. In some cases we may not have control over the prosecution, maintenance or enforcement of the patents that we license, and our licensors may fail to take the steps that we believe are necessary or desirable in order to obtain, maintain and enforce the licensed patents. In addition, even where we now have the right to control patent prosecution of patents and patent applications we have licensed from third parties or the patents and patent applications we acquired from others, we may still be adversely affected or prejudiced by actions or inactions of our licensors or the previous owners of such patents or patent applications. Any inability on our part to protect adequately our intellectual property may have a material adverse effect on our business, operating results and financial position.

Some intellectual property has been discovered through government funded programs and thus may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights, and limit our ability to contract with non-U.S. manufacturers.

Some of our intellectual property rights, specifically, intellectual property rights related to inebilizumab that are in-licensed from Duke University, were generated through the use of U.S. government funding and are therefore subject to certain federal regulations. As a result, the U.S. government may have certain rights to intellectual property embodied in certain of our current or future product candidates pursuant to the Bayh-Dole Act of 1980, or the Bayh-Dole Act. These U.S. government rights in certain inventions developed under a government-funded program include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (i) adequate steps have not been taken to commercialize the invention; (ii) government action is necessary to meet public health or safety needs; or (iii) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). To our knowledge, however, the U.S. government has, to date, not exercised any march-in rights on any patented technology that was generated using U.S. government funds. The U.S. government also has the right to take title to these inventions if we or the applicable grantee fail to disclose the invention to the government and fail to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying the subject invention or produced through the use of the subject invention be manufactured substantially in the United States. The manufacturing preference requirement can be waived if the owner of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. manufacturers may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property. To the extent any of our current or future intellectual property is generated through the use of U.S. government funding, the provisions of the Bayh-Dole Act may similarly apply.

We may become involved in administrative adversarial proceedings in the U.S. PTO or in the patent offices of foreign countries brought by a third party to attempt to cancel or invalidate our patent rights, which could be expensive, time consuming and cause a loss of patent rights.

The Leahy-Smith Act created new and additional procedures to challenge issued patents in the U.S. PTO, including post-grant review, derivation proceedings and *inter partes* review proceedings, which some third parties have been using to invalidate selected or all claims of issued patents of competitors. For a patent with a priority date of March 16, 2013 or later, a petition for post-grant review can be filed by a third party in a nine month window from issuance of the patent. A petition for *inter partes* review can be filed immediately following the issuance of a patent (or at any time thereafter) if the patent was filed prior to March 16, 2013. A petition for *inter partes* review can be filed after the nine month period for filing a post-grant review petition has expired for a patent with a priority date of March 16, 2013 or later. Post-grant review proceedings can be brought on any ground of challenge, whereas *inter partes* review proceedings can only be brought to raise a challenge based on published prior art. These administrative adversarial actions at the U.S. PTO review patent claims without the presumption of validity afforded to U.S. patents in lawsuits in U.S. federal courts, use a lower burden of proof than used by U.S. federal courts. Moreover, any third party can request an *inter partes* review or post-grant review and does not have to satisfy the traditional requirements for standing to challenge the validity of an issued U.S. patent. Because of these differences between U.S. administrative and judicial adversarial patent proceedings, it is generally considered easier for a competitor or third party to have one or more U.S. patent claims cancelled in a patent office post-grant review or *inter partes* review proceeding than invalidated in a litigation in a U.S. federal court. If any of our patents are challenged by a third party in such a U.S. patent office proceeding, there is no guarantee that we will be successful in defending the patent, which would result in a loss of the challenged patent right to us.

Opposition or invalidation procedures are also available in most foreign countries. Many foreign authorities, such as the authorities at the European Patent Office, have only post-grant opposition proceedings, however, certain countries, such as India, have both pre-grant and post-grant opposition proceedings. If any of our patents are challenged in a foreign opposition or invalidation proceeding, we could face significant costs to defend our patents, and we may not be successful. Uncertainties resulting from the initiation, continuation or loss of such proceedings could have a material adverse effect on our ability to compete in the market place. Further, in many foreign jurisdictions, the losing party must pay the attorneys' fees of the winning party, which can be substantial.

We may have to file one or more lawsuits in court to prevent a third party from selling a product or using a product in a manner that infringes our patent, which could be expensive, time consuming and unsuccessful, and ultimately result in the loss of our proprietary market.

Because competition in our industry is intense, competitors may infringe or otherwise violate our issued patents, patents of our licensors or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement lawsuits, which can be expensive and time consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. We may also elect to enter into license agreements in order to settle patent infringement claims or to resolve disputes prior to litigation, and any such license agreements may require us to pay royalties and other fees that could be significant. 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.

A number of pharmaceutical companies have been the subject of intense review by the U.S. Federal Trade Commission or a corresponding agency in another country based on how they have conducted or settled drug patent litigation, and certain reviews have led to an allegation of an anti-trust violation, sometimes resulting in a fine or loss of rights. We cannot be sure that we would not also be subject to such a review or that the result of the review would be favorable to us, which could result in a fine or penalty.

The U.S. Federal Trade Commission, or FTC, and various private plaintiff class actions have brought a number of lawsuits in federal court in recent years to challenge Hatch Waxman Abbreviated New Drug Application, or ANDA, litigation settlements between innovator companies and generic companies as anti-competitive violations of the Sherman Act. The FTC has successfully argued that if an innovator firm, as part of a patent litigation settlement with a generic company, agrees to provide anything of value to a generic firm to not launch or to delay launch of an authorized generic during the 180-day period granted to the first generic company to challenge an Orange Book listed patent covering an innovator drug, or negotiates a delay to a generic company's entry, the FTC may consider it an unlawful "reverse payment" that violates the antitrust laws. In 2013, the U.S. Supreme Court, in a five-to-three decision in *FTC v. Actavis, Inc.* held that whether a "reverse payment" settlement involving the exchange of consideration for a delay in entry is subject to an anticompetitive analysis depends on five considerations: (a) the potential for genuine adverse effects on competition; (b) the justification of payment; (c) the patentee's ability to bring about anticompetitive harm; (d) whether the size of the payment is a workable surrogate for the patent's weakness; and (e) that antitrust liability for large unjustified payments does not prevent litigating parties from settling their lawsuits, for example, by allowing the generic to enter the market before the patent expires without the patentee's paying the generic. Furthermore, whether a reverse payment is justified depends upon its size, its scale in relation to the patentee's anticipated future litigation costs, its independence from other services for which it might represent payment, as was the case in *Actavis*, and the lack of any other convincing justification. The Court held that reverse payment settlements can potentially violate antitrust laws and are subject to the standard antitrust rule-of-reason analysis, with the burden of proving that an agreement is unlawful on the FTC and leaving to lower courts the structuring of such rule of reason analysis. In the wake of that decision, lower courts continue to adjudicate government enforcement and private actions challenging "reverse payments" as violations of the antitrust laws. If we are faced with product patent litigation challenging the validity of any patents we own, including Hatch Waxman litigation with a generic company, any settlement of that litigation could later be challenged by the FTC or private plaintiffs as unlawful, and we could face a significant expense or penalty.

Third parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights covering our products and technology, including interference or derivation proceedings before the U.S. PTO. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. We may, in the future, receive letters or other threats or claims from third parties inviting us to take licenses under, or alleging that we infringe, their patents. We cannot be certain that we have identified all pending or issued patents of potential relevance to our product candidates or technologies. We may fail to identify relevant patent rights, or incorrectly conclude that an issued patent is invalid or not infringed by our activities. If any third-party patents were asserted against us, even if we believe such claims are without merit, there is no assurance that a court would find in our favor on questions of infringement, validity, enforceability or priority. A court of competent jurisdiction could hold that the asserted third party patents are valid, enforceable and infringed, which could materially and adversely affect our ability to commercialize our products. We may choose to or, if we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or product. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

Even if we are successful in defending against intellectual property claims, litigation or other legal proceedings relating to such claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. 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 ordinary shares. Such litigation or proceedings could substantially increase our operating losses and reduce our resources available for development 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 substantially greater financial resources. Uncertainties resulting from the initiation and continuation of litigation or other intellectual property related proceedings could have a material adverse effect on our ability to compete in the marketplace.

The patent protection and patent prosecution for some of our product candidates is dependent on third parties.

While we normally seek and gain the right to fully prosecute the patents relating to our product candidates, there may be times when patents relating to our product candidates are controlled by our licensors. This is the case with current patents and patent applications licensed from MedImmune related to VIB4920, and those licensed from Duke University related to inebilizumab. If we, or any of our future licensing partners fail to appropriately file, prosecute and maintain patent protection for patents covering any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using, and selling competing products. In addition, even where we now have the right to control patent prosecution of patents and patent applications we have licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensors.

If we fail to comply with our obligations in the agreements under which we license intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are a party to a number of intellectual property license agreements that are important to our business and expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, we may be required to make certain payments to the licensor, we may lose the exclusivity of our license, or the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license. This includes (i) our licenses with Duke University and Dana-Farber Cancer Institute related to inebilizumab, (ii) our license with SBI Biotech related to VIB7734, (iii) our license with MedImmune related to VIB4920, (iv) our sublicense with MedImmune for its license with Lonza related to inebilizumab and VIB7734, (v) our sublicense with MedImmune for its license with BioWa related to inebilizumab, and (vi) our sublicense with MedImmune for its license with BioWa and Lonza related to VIB7734. Additionally, the milestone and other payments associated with these licenses and other agreements will make it less profitable for us to develop our drug candidates.

In some cases, patent prosecution of our licensed technology is controlled solely by the licensor. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. In certain cases, we control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. Licensing of intellectual property is of critical importance to our business and involves complex legal, business, and scientific issues. Disputes may arise regarding intellectual property subject to a licensing agreement, including but not limited to:

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

- the priority of invention of patented technolog y; and
- the fulfilment of our obligations under the license.

If disputes over intellectual property and other rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

Our intellectual property in-licenses with third parties may be subject to disagreements over contract interpretations, which could narrow the scope of our rights to the relevant intellectual property or technology or increase our financial or other obligations to our licensors.

The agreements under which we currently in-license intellectual property 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 harm our business, financial condition, results of operations and prospects. If any of our current or future licenses or material relationships or any in-licenses upon which our current or future licenses are based are terminated or breached, we may:

- lose our rights to develop and market our current product candidates or any future product candidates;
- lose patent protection for our current product candidates or any future product candidates;
- experience significant delays in the development or commercialization of our current product candidates or any future product candidates;
- not be able to obtain any other licenses on acceptable terms, if at all; or
- incur liability for damages.

If we experience any of the foregoing, it could harm our business, financial condition and results of operations.

We may not be able to effectively enforce our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on our product candidates in all countries throughout the world would be prohibitively expensive, and therefore we only file for patent protection in selected countries. The requirements for patentability may differ in certain countries, particularly in developing countries. Moreover, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. For example, Europe, India, China and certain other countries do not allow patents for methods of treating the human body. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions that do not favor patent protection on drugs. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own drugs and, further, may export otherwise infringing drugs to territories where we have patent protection, if our ability to enforce our patents to stop infringing activities is inadequate. These drugs may compete with our product candidates, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in the major markets for our product candidates, we cannot ensure that we will be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our product candidates. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

A number of foreign countries have stated that they are willing to issue compulsory licenses to patents held by innovator companies on approved drugs to allow the government or one or more third party companies to sell the approved drug without the permission of the innovator patentee where the foreign government concludes it is in the public interest. India, for example, has used such a procedure to allow domestic companies to make and sell patented drugs without innovator approval. There is no guarantee that patents covering any of our products will not be subject to a compulsory license in a foreign country, or that we will have any influence over if or how such a compulsory license is granted. Further, Brazil allows its regulatory agency ANVISA to participate in deciding whether to grant a drug patent in Brazil, and patent grant decisions are made based on several factors, including whether the patent meets the requirements for a patent and whether such a patent is deemed in the country's interest. In addition, several other countries have created laws that make it more difficult to enforce drug patents than patents on other kinds of technologies. Further, under the treaty on the Trade-Related Aspects of Intellectual Property, or TRIPS, as interpreted by the Doha Declaration, countries in which drugs are manufactured are required to allow exportation of the drug to a developing country that lacks adequate manufacturing capability. Therefore, our product markets in the United States or foreign countries may be affected by the influence of current public policy on patent issuance, enforcement or involuntary licensing in the healthcare area.

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 U.S. PTO 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 rely on our outside counsel to pay these fees due to non-U.S. patent agencies. 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.

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

Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and is 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. 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 by third parties asserting that our employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these employees or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. Litigation may be necessary to defend against these claims.

In addition, while it is our policy to require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Our and their assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

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

In addition to seeking patents for some of our technology and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, contract manufacturers, consultants, advisors and other third parties. We seek to protect our confidential proprietary information, in part, by entering into confidentiality and invention or patent assignment agreements with our employees and consultants, however, we cannot be certain that such agreements have been entered into with all relevant parties. Moreover, to the extent we enter into such agreements, 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 inside and outside the United States 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, or those to whom they communicate it, 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.

Risks Related to Employee Matters, Managing Growth and Other Risks Related to Our Business

We currently have a limited number of employees, and our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.*

We are a clinical-stage company, and, as of September 30, 2019, had 95 employees. We are highly dependent on the research and development, clinical and business development expertise of Zhengbin (Bing) Yao, Ph.D., our President and Chief Executive Officer, and Jörn Drappa, M.D., Ph.D., our Chief Medical Officer, as well as the other principal members of our management, scientific and clinical team. Although we have entered into employment agreements with our executive officers, each of them may terminate his or her employment with us at any time. We do not maintain “key person” insurance for any of our executives or other employees. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Recruiting and retaining qualified scientific, clinical, manufacturing, sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, obtain marketing approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also face competition for the hiring of scientific and clinical personnel from universities and research institutions. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

We expect to expand our development and regulatory capabilities and potentially implement sales, marketing and distribution capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

To manage our anticipated development and expansion, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. This may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of our product candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize our product candidates, if approved, and compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our company.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. The last global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn, such as the last global financial crisis, could result in a variety of risks to our business, including our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruptions. Any of the foregoing could harm our business, and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Our employees, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.*

We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities to us that violate the regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the United States and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, 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. These laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our nonclinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third parties, 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 these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. 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 significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

We may expend our limited resources to pursue a particular product candidate an d 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 on specific product candidates. 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 may acquire businesses or products, or form strategic alliances, in the future, and we may not realize the benefits of such acquisitions or alliances.

We may acquire additional businesses or products, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products resulting from a strategic alliance or acquisition that delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure you that, following any such acquisition, we will achieve the expected synergies to justify the transaction.

We rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology, including any cyber security incidents, could harm our ability to operate our business effectively.

Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber-attacks, computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. System failures, accidents or security breaches could cause interruptions in our operations, and could result in a material disruption of our clinical activities and business operations, in addition to possibly requiring substantial expenditures of resources to remedy. The loss of clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur a liability and our research and development programs and the development of our product candidates could be delayed.

We or the third parties upon which we depend may be adversely affected by earthquakes or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Earthquakes or other natural disasters could severely disrupt our operations and have a material adverse effect on our business, results of operations, financial condition 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 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.

Risks Related to Our Common Stock

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses stockholders.*

The market price of shares of our common stock could be subject to wide fluctuations in response to many risk factors listed in this section and many others beyond our control, including:

- results of nonclinical and clinical trials of our product candidates, including inebilizumab, VIB4920 and VIB7734;
- results of clinical trials of our competitors' products;

- regulatory actions with respect to our products or our competitors' products, including the approval by the FDA of our BLA for inebilizumab in patients with NMOSD;
- actual or anticipated fluctuations in our financial condition and operating results;
- publication of research reports by securities analysts about us or our competitors or our industry;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, collaborations, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- the passage of legislation or other regulatory developments in the United States and other countries affecting us or our industry;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- sales of our common stock by us, our insiders or our other stockholders;
- speculation in the press or investment community;
- announcement or expectation of additional financing efforts;
- changes in accounting principles;
- changes in the structure of healthcare payment systems;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters and other calamities;
- overall performance of the equity markets;
- changes in market conditions for pharmaceutical and biopharmaceutical stocks;
- changes in general market, industry and economic conditions; and
- the other factors described in this "Risk Factors" section.

In addition, the stock market has experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. The volatility of pharmaceutical, biotechnology and other life sciences company stocks often does not relate to the operating performance of the companies represented by the stock. In the past, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management's attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation.

Our executive officers, directors and principal stockholders and their affiliates, if they choose to act together, will continue to have the ability to exercise significant influence over all matters submitted to stockholders for approval.*

Our executive officers and directors, combined with our stockholders who own more than 5% of our outstanding common stock, in the aggregate, beneficially own shares representing a majority of our outstanding capital stock. As a result, if these stockholders were to choose to act together, they would be able to influence our management and affairs and the outcome of matters submitted to our stockholders for approval, including the election of directors and any sale, merger, consolidation, or sale of all or substantially all of our assets. This concentration of ownership control may adversely affect the market price of our common stock by:

- delaying, deferring or preventing a change in control;
- entrenching our management and the board of directors;
- impeding a merger, consolidation, takeover or other business combination involving us that other stockholders may desire; and/or

- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management.*

Provisions in our third amended and restated certificate of incorporation and our amended and restated bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Although we believe these provisions collectively provide for an opportunity to obtain greater value for stockholders by requiring potential acquirers to negotiate with our board of directors, they would apply even if an offer rejected by our board of directors were considered beneficial by some stockholders. Among other things, these provisions:

- establish a classified board of directors such that only one of three classes of directors is elected each year;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a “poison pill” that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the voting power of all of the then-outstanding shares of capital stock that would be entitled to vote generally in the election of directors to amend or repeal specified provisions of our third amended and restated certificate of incorporation or amended and restated bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

If securities or industry analysts do not publish research or reports about our business, or if they publish negative evaluations of our stock or negative reports about our business, our stock price and trading volume could decline.

The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. We may never obtain research coverage by industry or financial analysts. If no or few analysts commence coverage of us, the trading price of our stock would likely decrease. Even if we do obtain analyst coverage, there can be no assurance that analysts will cover us or provide favorable coverage. If one or more of the analysts who covers us downgrades our stock or changes his or her opinion of our stock, our stock price would likely decline. If one or more of these analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our stock price or trading volume to decline.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.*

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

Substantially all of our pre-IPO stockholders are subject to lock-up agreements with the underwriters of the IPO that restrict their ability to transfer shares of our common stock or securities convertible into or exercisable or exchangeable for shares of our common stock until March 31, 2020. The lock-up agreements limit the number of shares of common stock that may be sold immediately following the IPO. As of November 14, 2019, there are 50,962,060 shares of common stock outstanding. Subject to certain limitations, approximately 41,682,060 shares, which are currently subject to a lock-up agreement, will become eligible for sale upon expiration of the lock-up period. Sales of stock by these stockholders could have a material adverse effect on the trading price of our common stock.

Certain holders of our securities are entitled to rights with respect to the registration of their shares under the Securities Act, subject to the 180-day lock-up agreements described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

We have registered on Form S-8 all shares of common stock that are issuable under our 2018 Amended and Restated Equity Incentive Plan. As a consequence, these shares can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described above.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may 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. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the date of the completion of the IPO; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved.

We may choose to take advantage of some, but not all, of the available exemptions. We will continue to take advantage of these reduced reporting requirements for as long as we remain an emerging growth company. In particular, we have not included all of the executive compensation information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we 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 stock price may be more volatile.

In addition, pursuant to the JOBS Act, as an "emerging growth company" we have elected to take advantage of an extended transition period for complying with new or revised accounting standards. This effectively permits us to delay adoption of certain accounting standards until those standards would otherwise apply to private companies. As a result, our financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make our common stock less attractive to investors.

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 Stock 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, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance.

We are evaluating these rules and regulations, and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. 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 have identified material weaknesses in our internal control over financial reporting related to our control environment. If we do not remediate the material weaknesses in our internal control over financial reporting, or if we fail to establish and maintain effective internal control, we may not be able to accurately report our financial results, which may cause investors to lose confidence in our reported financial information and may lead to a decline in the market price of our stock.*

As a public company, we will be required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. Pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, we will first be required to furnish a report by our management on our internal control over financial reporting for the year ending December 31, 2020. 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. 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. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented, or detected and corrected on a timely basis.

In preparation for our IPO, we identified material weaknesses in our internal control over financial reporting related to our control environment. More specifically, we have determined that we have not maintained adequate formal accounting policies, processes and controls related to complex transactions as a result of a lack of finance and accounting staff with the appropriate GAAP technical expertise needed to identify, evaluate and account for complex and non-routine transactions. We also determined that we have not maintained sufficient staffing or written policies and procedures for accounting and financial reporting, which contributed to the lack of a formalized process or controls for management's timely review and approval of financial information.

Over the next several months, we plan to implement a number of measures to address the material wea knesses we have identified. We plan to hire additional accounting personnel with appropriate GAAP technical accounting expertise. We are also designing additional controls around identification, documentation and application of technical accounting guidance with particular emphasis on complex and non-routine transactions. These controls are expected to include the implementation of additional supervision and review activities by qualified personnel, and the adoption of additional policies and procedures related to accounting and financial reporting. We intend to complete the implementation of our remediation plan during 2019. In addition, we have engaged a third-party provider to help us assess and improve our internal controls in preparation for compliance with the Sarbanes-Oxley Act. However, we cannot assure you that we will be successful in remediating the material weaknesses we identified or that our internal control over financial reporting, as modified, will enable us to identify or avoid material weaknesses in the future.

We cannot assure you that management will be successful in identifying and retaining appropriate personnel; that newly engaged staff or outside consultants will be successful in identifying material weaknesses in the future; or that appropriate personnel will be identified and retained prior to these deficiencies resulting in material and adverse effects on our business.

Any failure to remediate the material weaknesses we identified or develop or maintain effective controls, or any difficulties encountered in their implementation or improvement, could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods. Any failure to remediate the material weaknesses we identified or implement and maintain effective internal control over financial reporting could also adversely affect the results of management reports and independent registered public accounting firm audits of our internal control over financial reporting that we will eventually be required to include in our periodic reports that will be filed with the SEC. Ineffective disclosure controls and procedures, and internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the market price of our common stock.

Our ability to use our net operating loss carryforwards and certain other tax attributes to offset future taxable income may be limited.*

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Internal Revenue Code, a corporation that undergoes an “ownership change,” is subject to limitations on its ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research tax credits) to offset its post-change income or taxes. For these purposes, an ownership change generally occurs where the equity ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation’s stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a three year period. We have not determined if we have experienced Section 382 ownership changes in the past and if a portion of our NOLs is subject to an annual limitation under Section 382. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of the IPO or subsequent shifts in our stock ownership, some of which are outside of our control. These ownership changes may subject our existing NOLs or credits to substantial limitations under Sections 382 and 383. Accordingly, we may not be able to utilize a material portion of our NOLs or credits. As of December 31, 2018, we had federal NOLs of approximately $57.5 million. Limitations on our ability to utilize those NOLs to offset U.S. federal taxable income could potentially result in increased future tax liability to us. In addition, at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed.

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 of our business. In addition, the terms of any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Our third amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.*

Pursuant to our third amended and restated certificate of incorporation, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Chancery Court does not have

jurisdiction, the federal district court for the District of Delaware or othe r state courts of the State of Delaware) will be the sole and exclusive forum for state law claims for (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty by any of our directors, officers, employees or agents to us or our stockholders; (iii) any action asserting a claim against us or any of our current or former directors, officers or employees arising pursuant to any provision of the Delaware General Corporation Law or our third amended and restated certificate of incorporation or amended and restated bylaws; (iv) any action to interpret, apply, enforce or determine the validity of our third amended and restated certificate of incorporation or amended and restated bylaws; (v) any action as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; or (vi) any action asserting a claim governed by the internal affairs doctrine. This exclusive forum provision will not apply to any causes of action arising under the Securities Act or the Exchange Act. The forum selection clauses in our third amended and restated certificate of incorporation may limit our stockholders' ability to obtain a favorable judicial forum for disputes with us.

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

Set forth below is information regarding shares of equity securities sold, and options granted, by us during the three months ended September 30, 2019 that were not registered under the Securities Act.

Recent Sales of Unregistered Equity Securities

During the period between July 1, 2019 and September 30, 2019, we issued to certain of our employees, consultants and directors, options to purchase an aggregate of 977,700 shares of our common stock at a weighted-average exercise price of $13.62 per share. We deemed these issuances to be exempt from registration under the Securities Act either in reliance on Rule 701 of the Securities Act as sales and offers under compensatory benefit plans and contracts relating to compensation in compliance with Rule 701, or in reliance on Section 4(a)(2), as transactions by an issuer not involving a public offering. All recipients either received adequate information about our company or had access, through employment or other relationships, to such information. No underwriters were involved in the foregoing issuances of securities. We filed a registration statement on Form S-8 under the Securities Act on October 11, 2019 to register all of the shares of our common stock subject to outstanding options and all shares of our common stock otherwise issuable pursuant to our equity compensation plan.

In September 2019, we issued an aggregate of 4,705,882 shares of our Series A-3 preferred stock at a purchase pr ice of $17.00 per share for an aggregate gross consideration of $80 million, or the Series A-3 Financing to certain investors. We deemed this transaction to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) as a transaction by an issuer not involving a public offering.

Use of Proceeds from Initial Public Offering

In October 2019, we completed the IPO of our common stock and issued and sold in aggregate 9,085,000 shares of common stock, which included 1,185,000 shares of our common stock issued pursuant to the underwriters' option to purchase additional shares, at a public offering price of $19.00 per share, for net proceeds of $157.2 million after deducting underwriting discounts and commissions and other offering costs.

The offer and sale of all of the shares of our common stock in our IPO were registered under t he Securities Act pursuant to a registration statement on Form S-1 (File No. 333- 233528), which was declared effective by the SEC on October 2, 2019. Following the sale of all of the shares offered in the offering, the offering terminated. Goldman Sachs & Co. LLC, Morgan Stanley & Co. LLC and Cowen and Company, LLC acted as joint book-running managers for our IPO.

None of the underwriting discounts and commissions or offering expenses were incurred or paid to directors or officers of ours or their associates or to persons owning 10% or more of our common stock or to any of our affiliates.

We had not used any of the net proceeds from the IPO as of September 30, 2019 because the IPO closed on October 7, 2019. We have invested the net proceeds from the IPO in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities. There has been no material change in our planned use of the net proceeds from the IPO as described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on October 4, 2019.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Amended and Restated Certificate of Incorporation of Viela Bio, Inc. (incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K (File No. 001-39067) filed with the SEC on October 7, 2019)
3.2	Restated Bylaws of Viela Bio, Inc. (incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K (File No. 001-39067) filed with the SEC on October 7, 2019)
10.1	Amended and Restated 2018 Equity Incentive Plan, and forms of award agreements thereunder (incorporated by reference to Exhibit 10.2 of the Registrant's Registration Statement on Form S-1/A (File No. 333-233528) filed September 23, 2019)
10.2	Executive Severance Plan (incorporated by reference to Exhibit 10.23 of the Registrant's Registration Statement on Form S-1 (File No. 333-233528) filed August 29, 2019)
10.3	Non-Employee Director Compensation Plan (incorporated by reference to Exhibit 10.24 of the Registrant's Registration Statement on Form S-1 (File No. 333-233528) filed August 29, 2019)
10.4	Employment Agreement, by and between the Registrant and Zhengbin (Bing) Yao, Ph.D., dated August 28, 2019 (incorporated by reference to Exhibit 10.3 of the Registrant's Registration Statement on Form S-1 (File No. 333-233528) filed August 29, 2019)
10.5	Employment Agreement, by and between the Registrant and Jörn Drappa, Ph.D., dated August 28, 2019 (incorporated by reference to Exhibit 10.4 of the Registrant's Registration Statement on Form S-1 (File No. 333-233528) filed August 29, 2019)
10.6	Employment Agreement, by and between the Registrant and Aaron Ren, Ph.D., dated August 28, 2019 (incorporated by reference to Exhibit 10.5 of the Registrant's Registration Statement on Form S-1 (File No. 333-233528) filed August 29, 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.
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.
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.
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.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

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.

Company Name

Date: November 14, 2019

By: /s/ Mitchell Chan
Mitchell Chan
Chief Financial Officer

Date: November 14, 2019

By: /s/ Zhengbin (Bing) Yao, Ph.D.
Zhengbin (Bing) Yao, Ph.D.
Chairman, President and
Chief Executive Officer

Exhibit 31.1

CERTIFICATION 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

I, Zhengbin (Bing) Yao, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Viela Bio, 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

5. The registrant's other certifying officer(s) 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 14, 2019

By: /s/ Zhengbin (Bing) Yao, PH.D.
Zhengbin (Bing) Yao, PH.D.
Chairman, President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION 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

I, Mitchell Chan, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Viela Bio, 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(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

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

5. The registrant's other certifying officer(s) 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 14, 2019

By: /s/ Mitchell Chan
Mitchell Chan
Chief 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

In connection with the Quarterly Report of Viela Bio, Inc. (the "Company") on Form 10-Q for the three months ended September 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 14, 2019

By: /s/ Zhengbin (Bing) Yao, PH.D.
Zhengbin (Bing) Yao
Chairman, President and Chief 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

In connection with the Quarterly Report of Viela Bio, Inc. (the "Company") on Form 10-Q for the three months ended September 30, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: November 14, 2019

By: /s/ Mitchell Chan
Mitchell Chan
Chief Financial Officer