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 June 30, 2020

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 August 12, 2020, the registrant had 54,724,991 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 maintain regulatory approval of Uplizna™, and if approved, our other product candidates;
- our ability to successfully commercialize and market Uplizna™, and if approved, our other product candidates;
- 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 Uplizna™, and if approved, our other product candidates;
- our ability to build our own sales and marketing capabilities, or seek collaborative partners, to commercialize Uplizna™ outside the United States, and if approved, our other product candidates;
- 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 reimbursement for Uplizna™ and, if approved, our other product candidates;
- the degree of market acceptance of Uplizna™ 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 Uplizna™, and if approved, our other product candidates;
- 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;
- the development of major public health concerns, including the novel coronavirus outbreak or other pandemics arising globally, and the current and future impact of it and COVID-19 on our clinical trials, commercialization efforts, business operations and funding requirements; 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.

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

	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 131,551	$ 200,851
Marketable securities	293,995	113,945
Accounts receivable	—	30,000
Prepaid and other current assets	11,261	6,242
Total current assets	436,807	351,038
Marketable securities, non-current	22,832	31,415
Property and equipment, net	1,517	1,499
Capital lease assets	1,017	—
Intangible assets	19,700	—
Other assets	122	102
Total assets	$ 481,995	$ 384,054
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 6,337	$ 7,459
Accrued expenses and other current liabilities	29,930	9,192
Related party liability	4,490	12,892
Capital lease liability - current	184	—
Total current liabilities	40,941	29,543
Capital lease liability - non-current	836	—
Total liabilities	41,777	29,543
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized as of June 30, 2020 and December 31, 2019; no shares issued or outstanding as of June 30, 2020 and December 31, 2019	—	—
Common stock, $0.001 par value; 200,000,000 shares authorized as of June 30, 2020 and December 31, 2019; 54,722,948 and 50,617,868 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	54	51
Additional paid-in capital	795,842	631,154
Accumulated other comprehensive income	655	5
Accumulated deficit	(356,333)	(276,699)
Total stockholders' equity	440,218	354,511
Total liabilities and stockholders' equity	$ 481,995	$ 384,054

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

VIELA BIO, INC.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Revenue:				
License revenue	$ —	$ 20,000	$ —	$ 20,000
Total revenue	—	20,000	—	20,000
Operating expenses:				
Research and development	25,412	16,811	52,241	33,426
General and administrative	14,408	9,296	29,690	14,333
Total operating expenses	39,820	26,107	81,931	47,759
Loss from operations	(39,820)	(6,107)	(81,931)	(27,759)
Other income:				
Interest income	963	634	2,297	1,310
Total other income	963	634	2,297	1,310
Net loss	$ (38,857)	$ (5,473)	$ (79,634)	$ (26,449)
Net loss per share attributable to common stockholders—basic and diluted	$ (0.74)	$ (8.94)	$ (1.55)	$ (72.06)
Weighted average common shares outstanding—basic and diluted	52,212,006	612,059	51,482,502	367,041
Other comprehensive income				
Unrealized gains on marketable securities, net	$ 776	$ —	$ 650	$ —
Total other comprehensive income	776	—	650	—
Total comprehensive loss	$ (38,081)	$ (5,473)	$ (78,984)	$ (26,449)

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

VIELA BIO, INC.

CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)
(In thousands, except share and per share amounts)
(Unaudited)

	Redeemable convertible preferred stock												
	Series A-1		Series A-2		Series B		Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity (deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at April 1, 2020	—	$ —	—	$ —	—	$ —	50,997,300	$ 51	$ 633,967	$ (121)	$ (317,476)	$ 316,421
Stock-based compensation expense	—	—	—	—	—	—	—	—	3,086	—	—	3,086
Issuance of common stock for stock options exercised	—	—	—	—	—	—	125,648	—	454	—	—	454
Issuance of common stock, net	—	—	—	—	—	—	3,600,000	3	158,335	—	—	158,338
Other comprehensive income	—	—	—	—	—	—	—	—	—	776	—	776
Net loss	—	—	—	—	—	—	—	—	—	—	(38,857)	(38,857)
Balances at June 30, 2020	—	$ —	—	$ —	—	$ —	54,722,948	$ 54	$ 795,842	$ 655	$ (356,333)	$ 440,218
Balances at April 1, 2019	14,225,324	$ 142,253	17,000,000	$ 170,000	—	$ —	363,799	$ —	$ 2,518	$ —	$ (211,246)	$ (208,728)
Stock-based compensation expense	—	—	—	—	—	—	—	—	648	—	—	648
Issuance of common stock for stock options exercised	—	—	—	—	—	—	360,996	—	1,025	—	—	1,025
Issuance of common stock upon vesting of RSAs	—	—	—	—	—	—	8	1	(1)	—	—	—
Issuance of preferred stock	—	—	—	—	4,687,500	75,000						—
Net loss	—	—	—	—	—	—	—	—	—	—	(5,473)	(5,473)
Balances at June 30, 2019	14,225,324	$ 142,253	17,000,000	$ 170,000	4,687,500	$ 75,000	724,803	$ 1	$ 4,190	$ —	$ (216,719)	$ (212,528)

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

	Redeemable convertible preferred stock											
	Series A-1		Series A-2		Series B		Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity deficit
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at January 1, 2020	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**50,617,868**	**$ 51**	**$ 631,154**	**$ 5**	**$ (276,699)**	**$ 354,511**
Stock-based compensation expense	—	—	—	—	—	—	—	—	5,797	—	—	5,797
Issuance of common stock for stock options exercised	—	—	—	—	—	—	147,923	—	556	—	—	556
Issuance of common stock upon vesting of RSAs	—	—	—	—	—	—	357,157	—	—	—	—	—
Issuance of common stock, net	—	—	—	—	—	—	3,600,000	3	158,335	—	—	158,338
Other comprehensive income	—	—	—	—	—	—	—	—	—	650	—	650
Net loss	—	—	—	—	—	—	—	—	—	—	(79,634)	(79,634)
Balances at June 30, 2020	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**54,722,948**	**$ 54**	**$ 795,842**	**$ 655**	**$ (356,333)**	**$ 440,218**
Balances at January 1, 2019	**14,225,324**	**$ 142,253**	**17,000,000**	**$ 170,000**	**—**	**$ —**	**10**	**$ —**	**$ 1,879**	**$ —**	**$ (190,270)**	**$ (188,391)**
Stock-based compensation expense	—	—	—	—	—	—	—	—	1,287	—	—	1,287
Issuance of common stock for stock options exercised	—	—	—	—	—	—	360,996	—	1,025	—	—	1,025
Issuance of common stock upon vesting of RSAs	—	—	—	—	—	—	363,797	1	(1)	—	—	—
Issuance of preferred stock	—	—	—	—	4,687,500	75,000	—	—	—	—	—	—
Net loss	—	—	—	—	—	—	—	—	—	—	(26,449)	(26,449)
Balances at June 30, 2019	**14,225,324**	**$ 142,253**	**17,000,000**	**$ 170,000**	**4,687,500**	**$ 75,000**	**724,803**	**$ 1**	**$ 4,190**	**$ —**	**$ (216,719)**	**$ (212,528)**

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

VIELA BIO, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Six Months Ended June 30,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (79,634)	$ (26,449)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	193	25
Stock-based compensation expense	5,797	1,287
Amortization of premium on marketable securities, net	80	—
Amortization of capital lease asset	17	—
Changes in operating assets and liabilities:		
Accounts receivable	30,000	(5,000)
Prepaid and other assets	(5,032)	(418)
Accounts payable and other liabilities	(8,983)	4,899
Net cash used in operating activities	(57,562)	(25,656)
Cash flows from investing activities:		
Purchase of marketable securities	(237,792)	—
Sales and maturities of marketable securities	66,895	—
Purchase of property and equipment	(296)	(60)
Net cash used in investing activities	(171,193)	(60)
Cash flows from financing activities:		
Proceeds from exercise of common stock options	549	856
Proceeds from issuance of redeemable convertible preferred stock	—	87,000
Proceeds from issuance of common stock	169,200	—
Payments of common stock offering costs	(10,280)	—
Payments of capital lease liability	(14)	—
Net cash provided by financing activities	159,455	87,856
Net (decrease) increase in cash and cash equivalents	(69,300)	62,140
Cash and cash equivalents at beginning of period	200,851	126,898
Cash and cash equivalents at end of period	$ 131,551	$ 189,038
Supplemental disclosure of non-cash financing and investing activities:		
Receivable from sale of preferred stock	$ —	$ 169
Purchases of property and equipment included in accounts payable and accrued expenses	24	—
Milestone payments for in-licensed rights included in accounts payable and accrued expenses	19,700	
Receivable from exercise of common stock options	7	—
Common stock offering costs included in accounts payable and accrued expenses	582	—
Capital lease assets obtained in exchange for capital lease liabilities	1,034	—

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

1. Nature of the business and basis of presentation

Viela Bio, Inc. ("Viela" or the "Company") is a 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. The Company's lead molecule, 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, the Company reported positive pivotal clinical trial data for inebilizumab in patients with neuromyelitis optica spectrum disorder, or 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. The Company received Breakthrough Therapy Designation for the treatment of this disease from the U.S. Food and Drug Administration (the "FDA") in April 2019 and in August 2019, the FDA accepted for review the Company's Biologics License Application ("BLA") for inebilizumab. On June 11, 2020, the FDA approved Uplizna™ (inebilizumab-cdon) for the treatment of adult patients with NMOSD who are anti-AQP4 antibody positive as a twice-a-year maintenance regimen following initial doses. The Company commercially launched Uplizna™ following the FDA approval in June.

In addition, the Company has 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 Sjögren's syndrome and lupus, as well as other conditions such as kidney transplant rejection. A Phase 2b trial in Sjögren's syndrome, which is designed as Phase 3-enabling, is ongoing and in 2019, the Company initiated a separate Phase 2 trial in kidney transplant rejection. In light of the COVID-19 pandemic, in order to prioritize patient health and that of the investigators at clinical trial sites, the Company has paused enrollment of new patients in certain of its clinical trials, including its Phase 2b trial of VIB4920 in Sjögren's syndrome, which the Company anticipates resuming in the fourth quarter of 2020.

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, successfully commercializing its approved product Uplizna™ for the treatment of patients with NMOSD, 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. The Company expects to continue to incur expenses related to commercialization activities, including marketing expenses, as well as manufacturing and distribution costs for Uplizna™ for treatment in patients in the US with NMOSD. 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.

In October 2019, the Company completed an initial public offering (the "IPO") of its common stock and issued and sold 9,085,000 shares of common stock, which included 1,185,000 shares issued in pursuant to the underwriters' option to purchase additional shares, at a public offering price of $19.00 per share, for aggregate gross proceeds of $172,615 and net proceeds after deducting underwriting discounts and commissions and other offering costs of $156,927. 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.

In June 2020, the Company completed an underwritten public offering of its common stock and issued and sold 3,600,000 shares of common stock, at a public offering price of $47.00 per share, for aggregate gross proceeds of $169,200 and net proceeds after deducting underwriting discounts and commissions and other offering costs of $158,338.

In April 2020, Viela Bio BV, a wholly-owned subsidiary of the Company (the "Subsidiary"), was established as a legal entity domiciled in the Netherlands, for the purpose of import and export of drug substances and drug products in connection with development and commercialization of medicines. The Subsidiary did not have any operations during the interim period and as of June 30, 2020.

COVID-19

In December 2019 an outbreak of a novel strain of coronavirus was identified in Wuhan, China. This virus continues to spread globally, has been declared a pandemic by the World Health Organization and has spread to over 100 countries, including the United States. The impact of this pandemic has been and will likely continue to be extensive in many aspects of society, which has resulted in and will likely continue to result in significant disruptions to businesses

and capital markets around the world. The extent to which the coronavirus impacts the Company will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. At present, the Company is not experiencing significant impact or delays from COVID-19 on its business, operations and commercialization plans. However, in order to prioritize patient health and that of the investigators at clinical trial sites, the Company has paused enrollment of new patients in certain of its clinical trials, including its Phase 2b trial of VIB4920 in Sjögren's syndrome, its Phase 2 trial of VIB4920 in rheumatoid arthritis and its Phase 2 trial of inebilizumab in kidney transplant desensitization. The Company's ability to re-open enrollment, and continue enrollment, in these clinical trials will be dependent on many factors, including the progression of the pandemic and its impact on patients and the investigators at its clinical trial sites. Furthermore, the Company's ability to re-open enrollment in each of these clinical trials will require collaboration with, and permission from, each of the clinical trial sites. Over the coming weeks and months, the Company will continue to monitor carefully the situation with respect to each of its clinical trials and follow guidance from local and federal health authorities. The Company anticipates resuming enrollment of patients in its Phase 2b trial of VIB4920 in Sjögren's syndrome and its Phase 2 trial of VIB4920 in rheumatoid arthritis in the fourth quarter of 2020. Furthermore, with respect to the Company's commercial launch of Uplizna™, the Company believes that the pandemic has resulted in a decrease in patient visits to prescribing physicians, as well as challenges in coordination and communication between patients and prescribing physicians. The Company plans to continue to adapt its commercialization efforts to address the uncertainty presented by this treatment environment.

Basis of Presentation

The accompanying unaudited consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles ("GAAP"), and pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial statements. Accordingly, certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP are omitted. In the opinion of our management, all adjustments (consisting solely of normal recurring accruals) necessary for the fair statement of financial statements for the interim period have been included. The interim financial statements and accompanying notes should be read in conjunction with the financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2019, as filed with the SEC on March 25, 2020 (the "Form 10-K") . The results for any interim period are not necessarily indicative of results to be expected for any other interim periods or for a full fiscal year.

The accompanying unaudited interim consolidated financial statements include the accounts of the Company and its wholly-owned Subsidiary. All intercompany accounts and transactions have been eliminated in consolidation.

2. Summary of significant accounting policies

Use of estimates

The preparation of the Company's consolidated 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.

Revenue Recognition for Contract with Customers

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

Product Revenues, net

The Company's contracts with its specialty distributor (the "SD") and specialty pharmacy (the "SP"), referred to as its customers, are within the scope of ASC 606. Contractual performance obligations are limited to transfer of control of Uplizna™ to the customer. The Company recognizes product revenues, net of variable consideration related to certain allowances and accruals, in our consolidated financial statements upon transfer of control of Uplizna™ to the customer. The transfer of control occurs at a point-in-time upon the customer's receipt of the product after considering when the customer obtains legal title to the product and the customer has accepted the product. At this point, customers can direct the use of and obtain substantially all of the remaining benefits of the product.

The customer is initially invoiced at the contractual list price for Uplizna™. Revenue is reduced from contractual list price at the time of recognition for expected chargebacks, rebates, discounts, and certain fees, which are referred to as gross to net adjustments, or GTN adjustments. These reductions are primarily attributed to government programs such as the Federal Supply Schedule, Tricare, Medicare, Medicaid and the 340B Drug Pricing Program containing various pricing implications such as mandatory discounts and pricing protection below the wholesaler list price. In addition, the reductions also include expected copay assistance for commercially insured patients, prompt-pay discounts and certain fees paid to the specialty distributor and specialty pharmacy based on contractually determined rates. The GTN adjustments are generally reflected as either a reduction to receivables (and settled through the issuance of credits), or, are reflected as a liability and settled through cash payments. The Company does not offer a general right of return and accordingly does not include product returns within the GTN adjustments.

Significant judgment is required in estimating GTN adjustments considering legal interpretations of applicable laws and regulations, current experience, current contract prices under applicable programs, unbilled claims, and processing time lags.

The Company also reduces product revenue for cash payments (e.g., distribution fees) made to entities within the distribution channel (including the customer) where the Company does not receive a distinct good or service in exchange for such payments. Shipping and handling activities represent fulfillment activities and the Company records such costs within cost of goods sold on the consolidated statements of operations and comprehensive loss. In addition, the Company has elected to exclude taxes collected from customers and remitted to governmental authorities from the measurement of the transaction price.

License revenue

Refer to Note 11 for additional discussion of license and collaboration agreements.

Accounts Receivable, net

The Company's accounts receivable arise from product sales and license revenues. They are generally stated at the invoiced amount and do not bear interest. Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established and which result from certain government programs, copay assistance, prompt-pay discounts and certain distribution fees. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if no payments are required of the Company) for certain chargebacks, prompt pay discounts and certain distribution fees, or a current liability (if a payment is required of us), for government rebates, co-pay assistance and certain distribution fees.

The Company monitors the financial performance and creditworthiness of its customers so that it can properly assess and respond to changes in the customers' credit profiles. The Company provides reserves against trade receivables for estimated credit losses that may result from a customer's inability to pay. Amounts determined to be uncollectible are written-off against the established reserve.

As of June 30, 2020, the Company did not record any accounts receivable.

Inventory

The Company capitalizes inventory costs that are expected to be sold commercially once it's determined there is a probable future economic benefit such that the inventory costs will be recovered through commercial sale based on the review of several factors, as applicable, including (i) the likelihood that all required regulatory approvals will be obtained, (ii) the expected timing of validation (if not yet completed) of manufacturing processes in the associated facility, (iii) the expected expiration of the inventory, (iv) logistical or commercial constraints that may impede the timely distribution and sale of the product, including transport requirements and reimbursement status, (v) history of approvals of similar products or formulations and (vi) potential legal challenges.

The Company began capitalizing inventories upon FDA approval of Uplizna™ on June 11, 2020. Once capitalized, inventories are stated at the lower of cost or net realizable value with cost determined under the first-in-first-out ("FIFO") cost method. Inventories consist of raw materials, work in process and finished goods. Costs incurred prior to the FDA approval of Uplizna™ have been recorded as research and development expenses because of the uncertainty as described above. The Company included within research and development expenses approximately $94,798 of cost associated with the manufacture of Uplizna™, including raw materials, work in process and finished goods prior to FDA approval. As of June 30, 2020, the Company did not have any inventory as all costs were incurred prior to FDA approval.

The Company analyzes its inventory levels on a periodic basis to determine if any inventory is at risk for expiration prior to sale or has a cost basis that is greater than its estimated future net realizable value. Any adjustments are recognized through cost of sales in the period in which they are incurred.

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.

Prior to the IPO, the Company followed the two-class method when computing net loss per share, 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 Company's Preferred Stock contained participating rights in any dividend paid by the Company and were deemed to be participating securities. Net income 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 anti-dilutive effect, the calculation of diluted net loss per share for the three and six months ended June 30, 2019 does not include 31,225,324 shares of Series A Preferred Stock and 4,687,500 shares of Series B Preferred Stock.

Subsequent to the IPO, basic net loss per common share is computed by dividing the net loss by the weighted average number of shares of common stock outstanding for the period. Diluted net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding for the period, including potential dilutive common shares assuming the dilutive effect of outstanding stock options. Accordingly, in periods in which the Company reported a net loss, dilutive common shares were not included in the calculation as their effect was anti-dilutive, and as a result, diluted net loss per common share was the same as basic net loss per common share for the six months ended June 30, 2020 and 2019.

For the three and six months ended June 30, 2020 and 2019, there were no reconciling items between basic and diluted net loss per share.

Leases

Lease arrangements are evaluated and classified as either an operating lease or a capital lease pursuant to ASC 840, Leases ("ASC 840"). A lease is classified as a capital lease if any of the following criteria are met: transfer of ownership to the lessee by the end of the lease term; the lease contains a bargain purchase option; the lease term is equal to 75% or greater of the asset's useful economic life; or the present value of the future minimum lease payments is

equal to or greater than 90% of the asset's fair market value. Capital leases are recorded at the lower of the net present value of the total amount of rent payable under the leasing agreement (excluding finance charges) or fair market value of the leased asset. Capital lease assets are depreciated on a straight-line basis, over a period consistent with our normal depreciation policy for tangible fixed assets, but generally not exceeding the lease term. Operating lease expense is recognized ratably over the entire lease term.

Intangible assets, net

The Company's intangible assets consist of in-licensed rights, which are stated in the Company's consolidated balance sheets net of accumulated amortization and impairments, if applicable, and are amortized using a straight-line method over their useful lives. Additionally, the intangible assets are reviewed for impairment when certain triggering events occur.

The in-licensed rights relate to agreements with previous developers of Uplizna™. As a result of the FDA approval of Uplizna™ on June 11, 2020, the Company is required to make milestone payments of $19,700. As these represent payments securing the Company's rights with respect to an acquired in-process R&D asset that is now considered complete based on its approval by the FDA, the Company has capitalized such payments as intangible assets. The in-licensed rights are being amortized on a straight-line basis over the remaining life of the related patents which is the expected time period that the Company will benefit from the in-licensed rights. Amortization related to the in-licensed rights for the three and six months ended June 30, 2020 was immaterial given the timing of FDA approval in proximity to the period end.

The following table summarizes the estimated future amortization for the in-licensed rights:

Year Ending December 31,		
2020 (remaining six months)	$	1,020
2021		1,884
2022		1,884
2023		1,884
2024		1,884
Thereafter		11,144
Total	$	19,700

Recently adopted accounting pronouncements

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. The Company adopted this guidance effective January 1, 2020. The adoption of the standard did not have an impact on the Company's consolidated 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 public entities, ASU 2016-02 is effective for annual reporting periods beginning after December 15, 2018, including interim periods within those fiscal years. For all other entities, the ASU is effective for annual periods beginning after December 15, 2020, including interim periods within those fiscal years. The Company is currently evaluating the impact the adoption of the guidance will have on its consolidated financial statements and expects to adopt this standard in its annual financial statements for the year ended December 31, 2020.

3. Cash, cash equivalents and marketable securities

The following is a summary of the Company's cash, cash equivalents and available-for-sale marketable securities by significant investment category (unaudited):

	June 30, 2020						
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	Cash and Cash Equivalents	Current Marketable Securities	Non-Current Marketable Securities
Cash	$ 55,682	$ —	$ —	$ 55,682	$ 55,682	$ —	$ —
Level 1							
Money market funds	64,870	—	—	64,870	64,870	—	—
Subtotal	64,870	—	—	64,870	64,870	—	—
Level 2							
U.S. Treasury securities	53,355	115	(4)	53,466	5,000	42,357	6,109
Commercial paper	144,198	56	(19)	144,235	5,999	138,236	—
Corporate debt securities	129,618	515	(8)	130,125	—	113,402	16,723
Subtotal	327,171	686	(31)	327,826	10,999	293,995	22,832
Total	$ 447,723	$ 686	$ (31)	$ 448,378	$ 131,551	$ 293,995	$ 22,832

	December 31, 2019						
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	Cash and Cash Equivalents	Current Marketable Securities	Non-Current Marketable Securities
Cash	$ 26,821	$ —	$ —	$ 26,821	$ 26,821	$ —	$ —
Level 1							
Money market funds	157,777	—	—	157,777	157,777	—	—
Subtotal	157,777	—	—	157,777	157,777	—	—
Level 2							
U.S. Treasury securities	9,623	7	—	9,630	—	4,805	4,825
Commercial paper	55,021	4	(9)	55,016	13,050	41,966	—
Corporate debt securities	96,964	28	(25)	96,967	3,203	67,174	26,590
Subtotal	161,608	39	(34)	161,613	16,253	113,945	31,415
Total	$ 346,206	$ 39	$ (34)	$ 346,211	$ 200,851	$ 113,945	$ 31,415

The maturities of the Company's long-term marketable securities ranges from one to two years.

4. Common stock

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 June 30, 2020, no cash dividends had been declared or paid.

5. Redeemable convertible preferred stock

Prior to the IPO, the authorized capital stock of the Company included 40,618,706 shares of Preferred Stock, of which 35,931,206 shares were designated as Series A Preferred Stock and, 4,687,500 shares were designated as Series B Preferred Stock. Upon the closing of the IPO, the Company's outstanding Preferred Stock converted into 40,618,706 shares of common stock.

6. Stock-based compensation

During the six months ended June 30, 2020, the Company granted 1,467,747 stock options with a weighted average exercise price of $41.10 per share and a weighted average grant date fair value of $22.54 per share. The Company reserved 7,565,938 shares of common stock for issuance under the Equity Incentive Plan.

As of June 30, 2020, there was approximately $41,389 total unrecognized compensation expense, related to the unvested stock options, which is expected to be recognized over a weighted average period of 3.37 years.

During the six months ended June 30, 2020, 357,157 restricted stock awards were vested.

As of June 30, 2020, there was approximately $10 of total unrecognized compensation expense, related to the restricted stock awards, which is expected to be recognized over a weighted average period of 0.23 years.

Stock-based compensation

Stock-based compensation expense for the three and six months ended June 30, 2020 and 2019 was comprised of the following (unaudited):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Research and development	$ 1,362	$ 317	$ 3,005	$ 651
General and administrative	1,724	331	2,792	636
Total	$ 3,086	$ 648	$ 5,797	$ 1,287

7. Income taxes

During the six months ended June 30, 2020 and 2019, 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 generation of any revenue from product sales since inception through June 30, 2020 and has concluded that it is more likely than not that the Company will not realize the benefits of the deferred tax assets. Management reevaluates the positive and negative evidence at each reporting period. As of June 30, 2020 and December 31, 2019, no facts or circumstances arose that affected the Company's determination as to the full valuation allowance established against the net deferred tax assets. Accordingly, a full valuation allowance has been established against the net deferred tax assets as of June 30, 2020 and December 31, 2019.

As of June 30, 2020 and December 31, 2019, 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 June 30, 2020 and December 31, 2019, 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., Maryland and certain other states, 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.

On March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act"). The CARES Act, among other things, includes provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations, increased limitations on qualified charitable contributions, and technical corrections to tax depreciation methods for qualified improvement property. The Company is examining the impact that the CARES Act may have on its business. The Company is also evaluating its ability to use the refundable payroll tax credits and deferment of employer side social security payments. The Company does not believe that the income tax modifications mentioned above will affect its deferred tax assets or liabilities based on the Company's facts and circumstances.

8. 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 $241 and $87, during the three months ended June 30, 2020 and 2019, respectively, and $580 and $243 during the six months ended June 30, 2020 and 2019, respectively.

9. 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 recorded approximately $19,700 of regulatory milestone payments related to in-licensed rights as an intangible asset in June 2020, in connection with the approval of Biologics License Application by the FDA for Uplizna™ for the treatment of NMOSD. See Note 2 for further discussion.

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.

Operating Leases

The Company's operating leases primarily include office and lab leases in Gaithersburg and Rockville, Maryland.

In July 2018, the Company entered into an operating lease agreement with a related party for its headquarters in Gaithersburg, Maryland. The lease became effective July 1, 2018 and expires in June 2021 with the option to extend it by one year.

In October 2019, the Company entered into an operating lease agreement with a third party for an additional office space in Rockville, Maryland. The lease became effective October 1, 2019 and expires in June 2021.

In October 2019, the Company entered into an operating lease agreement with a third party for an additional lab space in Rockville, Maryland. The lease became effective October 15, 2019 and expires in February 2025.

Rent expense was $188 and $52 for the three months ended June 30, 2020 and 2019, respectively, and $341 and $103 for the six months ended June 30, 2020 and 2019, respectively.

The following table summarizes the Company's future contractual payments for operating leases as of June 30, 2020:

Year Ending December 31,		
2020 (remaining six months)	$	465
2021		537
2022		138
2023		138
2024		138
Thereafter		23
Total	$	1,437

Capital Lease Commitments

In December 2019, the Company entered into a non-cancelable capital lease agreement for lab equipment. The lease term is 60 months with a commencement date of June 1, 2020.

Future minimum lease payments under non-cancelable capital lease as of June 30, 2020 are as follows:

Year Ending December 31,		
2020 (remaining six months)	$	119
2021		239
2022		239
2023		239
2024		239
Thereafter		99
Total minimum lease payments		1,174
Less: Amount representing interest		(154)
Present value of net minimum lease payments	$	1,020

The present value of net minimum lease payments of $1,020 is reflected in the consolidated balance sheet as current and non-current capital lease liabilities of $184 and $836, respectively, as of June 30, 2020. There was no capital lease liability as of December 31, 2019.

10. Related party transactions

In connection with the acquisition of a portfolio of clinical molecules and pre-clinical molecules for potential therapies for autoimmune diseases and inflammation from MedImmune, LLC, MedImmune Limited (collectively, "MedImmune"), and AstraZeneca Collaboration Ventures, LLC (together with MedImmune, the "AZ Parties"), 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 three and six months ended June 30, 2020, the Company incurred $4,081 and $13,143 of costs under these agreements, respectively. As of June 30, 2020 and December 31, 2019, the Company recorded $4,490 and $12,892 as related party liabilities on the consolidated balance sheet, respectively. During the three and six months ended June 30, 2019, the Company incurred $5,804 and $15,635 of costs under these agreements, respectively.

11. Collaboration agreements

Commercial license and collaboration agreement with Hansoh

On May 24, 2019 (the "Hansoh 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, among other things, the Company promised to deliver to Hansoh an exclusive, sub-licensable, license to commercialize any pharmaceutical product that includes inebilizumab, in the mainland of the People's Republic of China, Hong Kong and Macau.

The Company received a non-refundable upfront payment of $15,000 in June 2019 and an additional $5,000 in December 31, 2019. 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 and 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 Hansoh Territory, subject to customary potential reductions.

As a result of the Hansoh transaction, the Company recognized the associated revenue of $20,000 at the Hansoh Effective Date.

Commercial license and collaboration agreement with Mitsubishi Tanabe Pharma Corporation

On October 8, 2019 (“MTPC Transaction Date”), the Company entered into an exclusive commercial license agreement with Mitsubishi Tanabe Pharma Corporation (“MTPC”). By entering into this agreement, among other things, the Company promised to transfer to MTPC an exclusive, sub-licensable, license to develop and commercialize any pharmaceutical product that includes inebilizumab, in Japan, Thailand, South Korea, Indonesia, Vietnam, Malaysia, Philippines, Singapore and Taiwan.

The agreement required MTPC to pay to the Company a non-refundable upfront payment of $30,000. The entire upfront payment was received in January 2020 and was included within accounts receivable as of December 31, 2019 as the Company had a contractual right to bill for the entire amount as of December 31, 2019 and the Company recognized the associated revenue of $30,000 at the MTPC Transaction Date. In addition, the Company can receive additional payments upon achieving certain sales milestones related to life cycle management indications.

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 Annual Report on Form 10-K for the year ended December 31, 2019 filed with Securities and Exchange Commission, or SEC, on March 25, 2020 (the "Annual Report"). Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on 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 Quarterly Report on 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 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 molecule, 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 U.S. Food and Drug Administration (the "FDA") in April 2019 and in August 2019, the FDA accepted for review our BLA for inebilizumab. On June 11, 2020, the FDA approved Uplizna™ (inebilizumab-cdon) for the treatment of adult patients with NMOSD who are anti-AQP4 antibody positive as a twice-a-year maintenance regimen following initial doses. We commercially launched Uplizna™ following FDA approval in June.

Furthermore, we plan to initiate, pending the development of clinical study protocols and subject to regulatory feedback, a Phase 3 trial of inebilizumab in the fourth quarter of 2020 for myasthenia gravis, a neuromuscular disorder caused by autoantibodies against acetylcholine receptors or muscle specific kinase and a Phase 3 trial of inebilizumab in the fourth quarter of 2020 for IgG4-related disease, a group of disorders marked by tumor-like swelling and fibrosis of affected organs, which may be caused by infiltration of CD19-expressing plasmablasts and plasma cells that generate IgG4 antibodies.

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 Sjögren's syndrome and lupus, as well as other conditions such as kidney transplant rejection. A Phase 2b trial in Sjögren's syndrome, which is designed as Phase 3-enabling, is ongoing and in 2019, we initiated a separate Phase 2 trial in kidney transplant rejection. We are currently advancing two candidates through pre-clinical studies. For the first candidate, VIB1116, we expect to conduct pre-clinical toxicology studies to enable a submission of an IND in 2020.

We incorporated on December 11, 2017 under the laws of the State of Delaware. 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 have one product approved for sale, Uplizna™ in the US, and have not generated any significant revenue from product sales to date. To date, we have funded our operations primarily with proceeds from the private placement of convertible preferred stock, the initial public offering of our common stock, or the IPO, the underwritten public offering of our common stock in June 2020 and collaboration agreements.

We have incurred significant operating losses since our inception, which are mainly attributed to research and development costs, and employee payroll expense, professional services expense and other administrative expenses included in general and administrative expenses. Our net loss was $38.9 million and $79.6 million for the three and six months ended June 30, 2020, respectively. 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 clinical trials and our expenditures related to other research and development activities, as well as the timing of collaboration agreements and any future commercialization

success. 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. In addition, if we obtain marketing approval for any product candidate, we expect to incur additional 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.

In June 2020, we completed an underwritten public offering of our common stock and issued and sold 3,600,000 shares of common stock, at a public offering price of $47.00 per share, for aggregate gross proceeds of $169,200 and net proceeds after deducting underwriting discounts and commissions and other offering costs of $158,338.

In May 2020, we announced positive interim results from our Phase 1b trial of VIB7734 in patients with cutaneous lupus erythematosus, or CLE. This Phase 1b clinical trial enrolled a total of 31 patients in three cohorts of patients and is designed to evaluate the safety and tolerability of VIB7734 when given by three monthly subcutaneous doses at escalating dose levels. Cohort 1 enrolled patients with several autoimmune diseases thought to be driven by plasmacytoid dendritic cell, or pDCs. Cohorts 2 and 3 enrolled patients with CLE. In cohorts 2 and 3, skin biopsies were taken before and after treatment to enumerate pDCs and measure interferon mediated gene expression. A clinical disease activity score was also periodically measured in cohorts 2 and 3. The primary endpoint was safety and tolerability. Additional endpoints included pDC depletion in peripheral blood and skin lesions of patients with CLE, and Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI) scores. Interim results included safety data from cohorts 1, 2 and a subset of patients in cohort 3, pharmacodynamics results from cohort 2, and CLASI results from cohort 2 and a subset of patients in cohort 3. As of the date of database lock (April 24, 2020), which occurred after all skin biopsies in cohort 2 had been analyzed, we observed rates of adverse events comparable to placebo control across all cohorts and consistent with the Phase 1a trial of VIB7734. Results also indicated potent depletion of pDC both in peripheral blood and in inflamed CLE skin lesion biopsies in cohort 2, and a dose-dependent, increased proportion of subjects with reductions in CLASI scores of 4 points or more compared to placebo in cohorts 2 and 3. While the trial was not powered to detect statistically significant changes in pDC depletion or the CLASI scores between placebo and treatment arms, reductions in CLASI scores of 4 points or more compared to baseline are considered to be clinically meaningful. Subsequently, we have obtained additional efficacy and biomarker data on cohort 3, which confirmed highly efficient pDC depletion in tissues and reduction in CLASI scores that are considered to be clinically meaningful. Based on these positive interim results, we intend, subject to regulatory feedback, to progress to a Phase 2 clinical trial in patients with systemic lupus erythematosus. These data are preliminary and subject to change as further analyses are conducted. In addition, the clinical trial in cohort 3 is ongoing and the interim data from this cohort represents only a subset of the patients enrolled in the cohort. The interim data from cohort 3 are expected to change as further patient follow up occurs and more patient data become available.

We intend to initiate a Phase 1 trial with VIB7734, which has demonstrated an ability to regulate key inflammatory mediators, in patients with COVID-19-related acute lung injury in the third quarter of 2020. Results from this study are anticipated in the first quarter of 2021.

In December 2019 an outbreak of a novel strain of coronavirus was identified in Wuhan, China. This virus continues to spread globally, has been declared a pandemic by the World Health Organization and has spread to over 100 countries, including the United States. The impact of this pandemic has been and will likely continue to be extensive in many aspects of society, which has resulted in and will likely continue to result in significant disruptions to businesses and capital markets around the world. The extent to which the coronavirus impacts us will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. At present, we are not experiencing significant impact or delays from COVID-19 on our business, operations and, if approved, commercialization plans. However, in order to prioritize patient health and that of the investigators at clinical trial sites, we have paused enrollment of new patients in certain of our clinical trials, including our Phase 2b trial of VIB4920 in Sjögren's syndrome, our Phase 2 trial of VIB4920 in rheumatoid arthritis and our Phase 2 trial of inebilizumab in kidney transplant desensitization. Our ability to re-open enrollment, and continue enrollment, in these clinical trials will be dependent on many factors, including the progression of the pandemic and its impact on patients and the investigators at our clinical trial sites. Furthermore, our ability to re-open enrollment, and continue enrollment, in each of these clinical trials will require collaboration with, and permission from, each of the clinical trial sites. Over the coming weeks and

months, we will continue to monitor carefully the situation with respect to each of our clinical trials and follow guidance from local and federal health authorities. We anticipate resuming enrollment of patients in our 2b trial of VIB4920 in Sjögren's syndrome and our Phase 2 trial of VIB4920 in rheumatoid arthritis in the fourth quarter of 2020. Furthermore, with respect to our commercial launch of Uplizna™, we believe that the pandemic has resulted in a decrease in patient visits to prescribing physicians, as well as challenges in coordination and communication between patients and prescribing physicians. We plan to continue to adapt our commercialization efforts to address the uncertainty presented by this treatment environment.

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 significant 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.

Components of our Results of Operations

Revenue

We did not generate any revenue from the sale of products since our inception through June 30, 2020. We initiated the commercial launch of Uplizna™ and expect to generate revenue from the sale of products in the third quarter of 2020. We have generated revenue from commercial license and collaboration agreements related to the treatment of NMOSD with inebilizumab. We do not expect any revenues that we may generate in the near future to be significant enough to fund our operations.

Research and Development Expenses

To date, our research and development expenses, net of the acquisition of In Process Research & Development ("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. We outsource a substantial portion of our clinical trial activities, utilizing external entities such as Contract Research Organizations ("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;
- the efficacy and safety profile of the product candidate; and
- developments related to the coronavirus outbreak and impact of it and COVID-19 on the costs and timing associated with the conduct of our clinical trials and other related activities.

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 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.

Interest Income

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

Results of Operations

Comparison of the Three Months Ended June 30, 2020 and 2019

The following table summarizes our results of operations for the three months ended June 30, 2020 and 2019:

	Three Months Ended June 30,		
	2020	2019	Change
	(in thousands)		
Revenue:			
License Revenue	$ —	$ 20,000	$ (20,000)
Total Revenue	—	20,000	(20,000)
Operating expenses:			
Research and development	$ 25,412	$ 16,811	$ 8,601
General and administrative	14,408	9,296	5,112
Total operating expenses	39,820	26,107	13,713
Loss from operations	(39,820)	(6,107)	(33,713)
Other income			
Interest income	963	634	329
Total other income	963	634	329
Net loss	$ (38,857)	$ (5,473)	$ (33,384)

License Revenue. License revenue was $20.0 million for the three months ended June 30, 2019, due to the revenue recognized pursuant to the Co-Development and Commercial License Agreement by and between us and Hansoh Pharma dated May 24, 2019. There was no revenue generated during the three months ended June 30, 2020.

Research and Development Expenses. Research and development expenses were $25.4 million and $16.8 million for the three months ended June 30, 2020 and 2019, respectively. The increase of $8.6 million was primarily driven by an increase of $3.2 million in personnel related costs due to an increase in headcount, and $5.4 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 approval process, U.S. commercial launch of Uplizna™ 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 $14.4 million and $9.3 million for the three months ended June 30, 2020 and 2019, respectively. The increase of $5.1 million was due primarily to increases of $4.9 million in personnel related expenses, including stock-based compensation, due to an increase in headcount, and $1.6 million of facility related and other administrative expenses, partially offset by a decrease of $1.4 million in professional services related to accounting services, corporate legal fees and patent legal fees.

Interest Income. Interest income was $1.0 million and $0.6 million for the three months ended June 30, 2020 and 2019, respectively. The increase of $0.4 million was due primarily to higher cash and cash equivalents and marketable securities held during the three months ended June 30, 2020 compared to the corresponding period in 2019.

Comparison of the Six Months Ended June 30, 2020 and 2019

The following table summarizes our results of operations for the six months ended June 30, 2020 and 2019

	Six Months Ended June 30,		
	2020	2019	Change
	(in thousands)		
Revenue:			
License Revenue	$ —	$ 20,000	$ (20,000)
Total Revenue	—	20,000	(20,000)
Operating expenses:			
Research and development	52,241	33,426	18,815
General and administrative	29,690	14,333	15,357
Total operating expenses	81,931	47,759	34,172
Loss from operations	(81,931)	(27,759)	(54,172)
Other income			
Interest income	2,297	1,310	987
Total other income	2,297	1,310	987
Net loss	$ (79,634)	$ (26,449)	$ (53,185)

License Revenue. License revenue was $20.0 million for the six months ended June 30, 2019, due to the revenue recognized pursuant to the Co-Development and Commercial License Agreement by and between us and Hansoh Pharma dated May 24, 2019. There was no revenue generated during the six months ended June 30, 2020.

Research and Development Expenses. Research and development expenses were $52.2 million and $33.4 million for the six months ended June 30, 2020 and 2019, respectively. The increase of $18.8 million was primarily driven by an increases of $7.3 million in personnel related costs due to an increase in headcount, and $11.5 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 approval process, U.S. commercial launch of Uplizna™ 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 $29.7 million and $14.3 million for the six months ended June 30, 2020 and 2019, respectively. The increase of $15.4 million was due primarily to increases of $1.7 million in professional services related to accounting services, corporate legal fees and patent legal fees, $10.2 million in personnel related expenses, including stock-based compensation, due to an increase in headcount, and $3.5 million of facility related and other administrative expenses.

Interest Income. Interest income was $2.3 million and $1.3 million for the six months ended June 30, 2020 and 2019, respectively. The increase of $1.0 million was due primarily to higher cash and cash equivalents and marketable securities held during the six months ended June 30, 2020 compared to the corresponding period in 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 June 30, 2020, we had cash and cash equivalents of $131.6 million.

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

	Six Months Ended June 30,	
	2020	2019
	(in thousands)	
Net cash provided by (used in):		
Operating activities	$ (57,562)	$ (25,656)
Investing activities	(171,193)	(60)
Financing activities	159,455	87,856
Net increase (decrease) in cash	$ (69,300)	$ 62,140

Operating Activities

Net cash used in operating activities was $57.6 million and $25.7 million for the six months ended June 30, 2020 and 2019, respectively. The net cash used in operating activities for the six months ended June 30, 2020 was primarily due to our net loss of $79.6 million, partially offset by non-cash charges of $6.1 million related to depreciation, stock-based compensation expense and net amortization of premiums on marketable securities, lease expense, and cash provided by changes in our operating assets and liabilities of $16.0 million. The net cash used in operating activities for the six months ended June 30, 2019 was primarily due to our net loss of $26.4 million, partially offset by non-cash charges of $1.3 million related to stock-based compensation expense and depreciation.

Investing Activities

Net cash used in investing activities was $171.2 million for the six months ended June 30, 2020. The net cash used in investing activities was primarily due to purchases of marketable securities of $237.8 million, sales and maturities of marketable securities of $66.9 million, and purchase of property and equipment of $0.3 million. The net cash used in investing activities for the six months ended June 30, 2019 was due to purchases of property and equipment.

Financing Activities

Net cash provided by financing activities was $159.5 million for the six months ended June 30, 2020 primarily due to net proceeds received from issuance of 3,600,000 shares of common stock in the underwritten public offering of $158.9 million and proceeds from exercise of stock options of $0.6 million. Net cash provided by financing activities was $87.9 million for the six months ended June 30, 2019 primarily due to proceeds from the issuance of series A-2 redeemable convertible preferred stock and series B redeemable convertible preferred stock.

Funding Requirements

We believe that our existing cash, cash equivalents and marketable securities will be sufficient to meet our anticipated cash requirements into 2023. 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 revenue received from commercial sales of Uplizna™ or any potential commercial sales of our product candidates, if approved, and product pricing, as well as product coverage and the adequacy of reimbursement of third-party payors, relating to Uplizna™ or any such product, if approved;
- the cost of commercialization activities for and manufacturing of Uplizna™ and our 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;
- the costs of operating as a public company; and
- the extent to which our business is adversely impacted by the effects of the novel coronavirus outbreak or by other health epidemics or pandemics.

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 June 30, 2020.

	Payments Due by Period				
	Total	Less than 1 Year	1-3 Years	3-5 Years	More than 5 Years
	(in thousands)				
Operating lease obligations	$ 1,437	$ 933	$ 275	$ 229	$ —
Capital lease obligations	1,174	239	477	458	—
Regulatory milestone payment	19,700	19,700	—	—	—
Total	$ 22,311	$ 20,872	$ 752	$ 687	$ —

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.

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 consolidated 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 consolidated 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.

Except as described below with respect to revenue recognition for product revenue, accounts receivable and inventory, during the three months ended June 30, 2020, there have been no material changes to our critical accounting policies disclosed in our Annual Report for our fiscal year ended December 31, 2019.

Revenue Recognition for Contract with Customers

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

Product Revenues, net

Our contracts with a specialty distributor, or SD, and a specialty pharmacy, or SP, which we refer to as our customers, are within the scope of ASC 606. Contractual performance obligations are limited to transfer of control of Uplizna™ to the customer. We recognize product revenues, net of variable consideration related to certain allowances and accruals, in our consolidated financial statements upon transfer of control of Uplizna™ to the customer. The transfer of control occurs at a point-in-time upon the customer's receipt of the product after considering when the customer obtains legal title to the product and the customer has accepted the product. At this point, customers can direct the use of and obtain substantially all of the remaining benefits of the product.

The customer is initially invoiced at the contractual list price for Uplizna™. Revenue is reduced from contractual list price at the time of recognition for expected chargebacks, rebates, discounts, and certain fees, which are referred to as GTN adjustments. These reductions are primarily attributed to government programs such as the Federal Supply Schedule, Tricare, Medicare, Medicaid and the 340B Drug Pricing Program containing various pricing implications such as mandatory discounts and pricing protection below the wholesaler list price. In addition, the reductions also include expected copay assistance for commercially insured patients, prompt-pay discounts and certain fees paid to the specialty distributor and specialty pharmacy based on contractually determined rates. The GTN adjustments are generally reflected as either a reduction to receivables (and settled through the issuance of credits), or, are reflected as a liability and settled through cash payments. We do not offer a general right of return and accordingly do not include product returns within the GTN adjustments.

Significant judgment is required in estimating GTN adjustments considering legal interpretations of applicable laws and regulations, current experience, current contract prices under applicable programs, unbilled claims, and processing time lags.

We also reduce product revenue for cash payments (e.g., distribution fees) made to entities within the distribution channel (including the customer) where we do not receive a distinct good or service in exchange for such payments. Shipping and handling activities represent fulfillment activities and we record such costs within cost of goods sold on the consolidated statements of comprehensive loss. In addition, we have elected to exclude taxes collected from customers and remitted to governmental authorities from the measurement of the transaction price.

Accounts Receivable, net

Our accounts receivable arises from product sales and license revenues. They are generally stated at the invoiced amount and do not bear interest. Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which reserves are established and which result from certain government programs, copay assistance, prompt-pay discounts and certain distribution fees. These reserves are based on the amounts earned or to be claimed on the related sales and are classified as reductions of accounts receivable (if no

payments are required of the Company) for certain chargebacks, prompt pay discounts and certain distribution fees, or a current liability (if a payment is required of us), for government rebates, co-pay assistance and certain distribution fees.

We monitor the financial performance and creditworthiness of our customers so that we can properly assess and respond to changes in the customers' credit profiles. We provide reserves against trade receivables for estimated credit losses that may result from a customer's inability to pay. Amounts determined to be uncollectible are written-off against the established reserve.

Inventory

We capitalize inventory costs that are expected to be sold commercially once it's determined there is a probable future economic benefit such that the inventory costs will be recovered through commercial sale based on the review of several factors, as applicable, including (i) the likelihood that all required regulatory approvals will be obtained, (ii) the expected timing of validation (if not yet completed) of manufacturing processes in the associated facility, (iii) the expected expiration of the inventory, (iv) logistical or commercial constraints that may impede the timely distribution and sale of the product, including transport requirements and reimbursement status, (v) history of approvals of similar products or formulations and (vi) potential legal challenges.

We began capitalizing inventories upon FDA approval of Uplizna™ on June 11, 2020. Once capitalized, inventories are stated at the lower of cost or net realizable value with cost determined under the first-in-first-out (FIFO) cost method. Inventories consist of raw materials, work in process and finished goods. Costs incurred prior to the FDA approval of Uplizna™ have been recorded as research and development expenses because of the inherent risks as described above.

We analyze our inventory levels on a periodic basis to determine if any inventory is at risk for expiration prior to sale or has a cost basis that is greater than its estimated future net realizable value. Any adjustments are recognized through cost of sales in the period in which they are incurred.

Other Company Information

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

At December 31, 2019, we had federal and state net operating loss carryforwards of $114.6 million. Federal and state net operating losses generated in 2018 and future years can be carried forward indefinitely. As of December 31, 2019, we also had federal research credit carryforwards of $13.2 million. The federal research and development tax credit carryforwards expire beginning in 2039 unless previously utilized, and the state research and development tax credit carryforwards expire beginning in 2025.

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, 2019 and June 30, 2020. 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.

On March 27, 2020, President Trump signed into law the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act. The CARES Act, among other things, includes provisions relating to refundable payroll tax credits, deferment of employer side social security payments, net operating loss carryback periods, alternative minimum tax credit refunds, modifications to the net interest deduction limitations, increased limitations on qualified charitable contributions, and technical corrections to tax depreciation methods for qualified improvement property. The Company is examining the impact that the CARES Act may have on its business. The Company is also evaluating its ability to use the refundable payroll tax credits and deferment of employer side social security payments. The Company does not believe that the income tax modifications mentioned above will affect its deferred tax assets or liabilities based on the Company's facts and circumstances

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.

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 the 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. We expect that we will no longer be an emerging growth company on December 31, 2020.

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 purchase marketable securities which are generally investment grade, liquid, short-term fixed income securities and money-market instruments denominated in U.S. dollars. Our marketable securities consist of commercial paper, corporate notes and U.S. government agency notes. We have not experienced any significant 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. However, uncertain financial markets have resulted in a tightening in the credit markets, a reduced level of liquidity in many financial markets, and extreme volatility in fixed income and credit markets. The credit ratings of the securities we have invested in could deteriorate and may have an adverse impact on the carrying value of these investments.

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 and the returns from such instruments will vary as short-term interest rates change. While historical fluctuations in interest income have not been significant, in a financial environment with extremely low or negative interest rates, we could experience a significant reduction in the interest earned from such instruments.

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

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 effective as of June 30, 2020.

Changes in Internal Controls over Financial Reporting

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 June 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We have not experienced any material impact to our internal controls over financial reporting despite the fact that a large group of our employees are working remotely due to the COVID-19 pandemic. We are continually monitoring and assessing the impact the COVID-19 situation has on the operating effectiveness of our internal controls.

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 on Form 10-Q entitled "Management's Discussion and Analysis of Financial Condition and Results of Operation" and our consolidated 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 our Quarterly Report on Form 10-Q for the quarter ended March 31, 2020.

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 $38.9 million and $79.6 million for the three and six months ended June 30, 2020, respectively. To date, we have financed our operations through private placements of our preferred stock and public offering of our common stock. 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:

- pursue commercial activities and manufacturing for Uplizna™ 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;
- encounter developments related to the coronavirus pandemic and impact of it and COVID-19 on the costs and timing associated with the conduct of our clinical trials and other related activities; 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.

The revenue we generate 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 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. 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 continue transitioning from a company with a research focus to a company capable of supporting commercial activities while maintaining a research focus. 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 commercialize and manufacture Uplizna™ 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 other 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 June 30, 2020, we had $131.6 million in cash and cash equivalents. We believe that, based upon our current operating plan, our existing capital resources, will be sufficient to fund our anticipated operations into 2023. 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 costs of commercialization activities, including product sales, marketing, manufacturing and distribution, for Uplizna™ for treatment in patients in the US with NMOSD or any of our product candidates for which we receive marketing approval;
- revenue received from commercial sales of Uplizna™;
- 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 significant 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 and commercialization. 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 significant revenues from sales of any products. On June 11, 2020, the FDA approved Uplizna™ (inebilizumab-cdon) for the treatment of adult patients with NMOSD who are anti-AQP4 antibody positive as a twice-a-year maintenance regimen following initial doses. Even if we successfully commercialize Uplizna™ or any of our product candidates, if approved, our commercial opportunities may be limited.

Commencing clinical trials in the United States is subject to acceptance by the FDA of an Investigational New Drug Application, or IND, with respect to each product candidate in each indication, and finalizing the trial design based on discussions with the FDA. 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. On June 11, 2020, the FDA approved Uplizna™ (inebilizumab-

cdon) for the treatment of adult patients with NMOSD who are anti-AQP4 antibody positive as a twice-a-year maintenance regimen following initial doses. We commercially launched Uplizna™ in June following FDA approval. In 2019, we initiated a Phase 2b trial for VIB4920 in Sjögren's syndrome, which is designed as Phase 3-enabling, and initiated a separate Phase 2 trial for VIB4920 in kidney transplant rejection. Our Phase 1b multiple ascending dose trial for VIB7734 is ongoing and in May 2020, we announced positive interim results from Phase 1b trial for VIB7734. 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 and approved for the treatment of adult patients with NMOSD who are anti-AQP4 antibody positive as a twice-a-year maintenance regimen following initial doses, 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:

- 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, by 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.

Similar to Uplizna™, 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. The FDA approved Uplizna™ (inebilizumab-cdon) for the treatment of adult patients with NMOSD who are anti-AQP4 antibody positive as a twice-a-year maintenance regimen following initial doses. All our remaining product candidates are in clinical and pre-clinical development. 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. 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, or 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.

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. 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 our product candidates in order to gain approval, we will incur significant additional development costs, commercialization of our product candidates 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 delayed 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.*

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 2019, we initiated a Phase 2b trial for VIB4920 in Sjögren's syndrome and initiated 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 Phase 2b and 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 Uplizna™ or any additional product candidates, if approved, 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 Uplizna™ and clinical development of any of our 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 regulatory authorities, such as 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 and expect to continue to rely on third-party CROs to assist us in planning and conducting clinical trials required for marketing approval. 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. Our 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. 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. Across both the randomized and open-label treatment in our N-MOmentum trial for inebilizumab, the most common adverse reactions (greater than 10%) were urinary tract infection (20%), nasopharyngitis (13%), infusion reaction (12%), arthralgia (11%), and headache (10%). The most common infections reported by Uplizna™ -treated patients in the randomized and open-label periods included urinary tract infection (20%), nasopharyngitis (13%), upper respiratory tract infection (8%), and influenza (7%). In addition, two deaths were 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 a 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 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, with the marketing approval for Uplizna™ 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 and other jurisdiction's requirements regarding safety monitoring or pharmacovigilance can also result in significant financial penalties. Similarly, failure to comply with the European Union's and other jurisdiction'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.*

With the approval of Uplizna™, we are 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 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. With the approval of Uplizna™ by FDA, we are 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. If inebilizumab or any of our other product candidates are approved by comparable foreign regulatory authorities, we 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 ACA 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. The Trump administration has made proposals, which, if implemented, could place limits or caps on pharmaceutical prices. Similarly, 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, destruction 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 historically relied on compliance with the privacy principles of the EU-U.S. Privacy Shield, or the Privacy Shield. In July 2020, the Court of Justice for the European Union invalidated the Privacy Shield which was the fate of its predecessor, the EU-U.S. Safe Harbor. 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 in such jurisdictions, if any.*

In some countries, particularly the countries of the European Union, Japan and China, 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 Uplizna™.*

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 our 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 EEA 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 terminate, 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 Uplizna™. In particular, we rely on AstraZeneca for the manufacture of the current clinical and commercial supplies of Uplizna™, 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. If we, or any current or future manufacturing partners, including AstraZeneca, are unable to successfully scale up the manufacture of our product candidates, in sufficient quality and quantity, or if we encounter validation issues, the development, testing and clinical trials of that product candidate, may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product, 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 license and 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 market 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

Uplizna™, which received FDA approval in June 2020, or any of our product candidates that receive marketing approval, if any, 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.*

Uplizna™, which received FDA approval in June 2020, or any of our product candidates that receive marketing approval, if any, may fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If Uplizna™ or our product candidates, if approved, 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 Uplizna™ or 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 for our product candidates;
- 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. Uplizna™, our approved product for the treatment of patients with NMOSD, will compete with eculizumab from Alexion Pharmaceuticals, Inc., or Alexion, marketed as Soliris®, and satralizumab, if approved, 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.

Uplizna™, as well as any product candidates that we are able to commercialize, if any, 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 focused 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.*

To achieve commercial success for any approved product candidate for which we retain sales and marketing responsibilities, we must further build our sales, marketing, managerial, and other non-technical capabilities or make arrangements with third parties to perform these services. 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.

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 our other product candidates that receive marketing approval or any such commercialization may experience delays or limitations. If we are not successful in commercializing Uplizna™ 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 with the commercialization of Uplizna™. 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 and have increased our insurance coverage as we commence commercialization of Uplizna™. 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 Uplizna™ and any of our 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 Uplizna™ and any of our future product candidates may be limited or may not be amenable to treatment with Uplizna™ and any of our products, if and when approved. Even if we obtain significant market share for Uplizna™ and any of our 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). 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 standard 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 held in *FTC v. Actavis, Inc.* that reverse payment settlements can potentially violate antitrust laws and are subject to the standard antitrust rule-of-reason analysis. 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 technology; 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 commercial-stage company, and, as of June 30, 2020, had 152 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 some of 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 focused 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 and fail to capitalize on product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and managerial resources, we focus 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/or health epidemics 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, health epidemic, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters and/or lab space, 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.

A pandemic, epidemic, or outbreak of an infectious disease, such as COVID-19 may materially and adversely affect our business and our financial results.*

The novel coronavirus outbreak has affected segments of the global economy and may materially affect our operations, including potentially significant interruption of our clinical trial activities and pre-commercial launch activities. COVID-19 originated in Wuhan, China, in December 2019 the virus has since spread to multiple countries, including the United States, where we are currently conducting our clinical trials. The continued spread of the coronavirus may result in a period of business disruption, including material delays in our clinical trials or material delays or disruptions in our commercialization efforts. In addition, there could be a potential effect of COVID-19 to the business at FDA or other health authorities, which could result in delays of reviews and approvals, including with respect to our product candidates.

The continued spread globally could also have a material adverse effect our clinical trial operations in the United States and elsewhere, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography.

We are closely monitoring the potential impact of the coronavirus outbreak, and the associated restrictions on travel and work that have been implemented, on our business and clinical trials. The extent to which the coronavirus impacts us will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. At present, we are not experiencing significant impact or delays from COVID-19 on our business, operations and, if approved, commercialization plans. However, in order to prioritize patient health and that of the investigators at clinical trial sites, we have paused enrollment of new patients in certain of our clinical trials, including our Phase 2b trial of VIB4920 in Sjögren's syndrome, our Phase 2 trial of VIB4920 in rheumatoid arthritis and our Phase 2 trial of inebilizumab in kidney transplant desensitization. We anticipate resuming enrollment of patients in our 2b trial of VIB4920 in Sjögren's syndrome and our Phase 2 trial of VIB4920 in rheumatoid arthritis in the fourth quarter of 2020. The coronavirus outbreak may further delay enrollment in our planned or ongoing clinical trials due to prioritization of hospital resources toward the outbreak, the protection of the health of patients and investigators at the clinical trial sites, and restrictions on work and travel. In addition, some patients may be unwilling to enroll in our trials or be unable to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services. These and other factors could significantly delay our ability to conduct clinical trials or release clinical trial results. Our ability to re-open enrollment in these clinical trials will be dependent on many factors, including the progression of the pandemic and its impact on patients and the investigators at our clinical trial sites. Furthermore, our ability to re-open enrollment in each of these clinical trials will require collaboration with, and permission from, each of the clinical trial sites. Over the coming weeks and months, we will continue to monitor carefully the situation with respect to each of our clinical trials and follow guidance from local and federal health authorities.

Additionally, with respect to our commercial launch of Uplizna™, we believe that the pandemic has resulted in a decrease in patient visits to prescribing physicians, as well as challenges in coordination and communication between patients and prescribing physicians. We plan to continue to adapt our commercialization efforts to address the uncertainty presented by this treatment environment.

COVID-19 may also affect employees of third-party contract research organizations located in affected geographies that we rely upon to carry out our clinical trials. The spread of COVID-19, or another infectious disease, could also negatively affect the operations at our third-party manufacturers, which could result in delays or disruptions in the supply of our product candidates. In addition, we have taken precautionary measures, and may take additional measures, intended to help minimize the risk of the virus to our employees, including temporarily requiring all employees to work remotely, suspending all non-essential travel worldwide for our employees, and discouraging employee attendance at industry events and in-person work-related meetings, which could negatively affect our business.

We cannot presently predict the extent to which current or future business shutdowns and disruptions may impact or limit our ability or the ability of any of the third parties with which we engage to conduct business in the manner and on the timelines presently planned. Any such impacts or limitations could have a material adverse impact on our business and our results of operation and financial condition. While the potential economic impact brought by and the duration of the coronavirus outbreak may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock

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;
- 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 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. If few analysts commence coverage of us, the trading price of our stock would likely decrease. Even if we do obtain sufficient 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 were subject to lock-up agreements with the underwriters of the IPO that restricted 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. Furthermore, several of our stockholders were subject to lock-up agreements with the underwriters of the firm underwritten public offering of our common stock that occurred in June 2020 that restricted their ability to transfer shares of our common stock or securities convertible into or exercisable or exchangeable for shares of our common stock until July 11, 2020. The lock-up agreements limited the number of shares of common stock that may be sold immediately following the IPO and our underwritten public offering of common stock. 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. 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 Amended and Restated 2018 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. We expect that we will no longer be an emerging growth

company on December 31, 2020. 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 consolidated 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.

In the past, we have identified material weaknesses in our internal control over financial reporting. We may identify future material weaknesses in our internal control over financial reporting. If we are unable to implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports, and the market price of our common stock may be materially adversely affected.*

To date, we have not conducted a review of our internal control for the purpose of providing the reports required by the Sarbanes-Oxley Act of 2002. 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. We expect that we will no longer be an emerging growth company on December 31, 2020. Further, a system of controls can provide only reasonable, not absolute, assurance that the control objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected. 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.

In the past, we and our independent registered public accounting firm identified two material weaknesses in our internal control over financial reporting. A “material weakness” is a deficiency, or a 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 on a timely basis. We had determined that we had 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 had also determined that we did not maintain 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. Earlier in 2020, we implemented a number of remedial actions to address the underlying causes of the material weaknesses, which were subject to senior management review and Audit committee oversite, including the development and formal documentation of policies and procedures relating to our internal control over financial reporting; segregation of incompatible duties and hiring of additional accounting personnel with appropriate technical accounting and financial reporting experience; and revision of our internal controls to provide a more formal process for our review procedures during the financial statement close process, and enhancement of our internal controls to identify and evaluate significant and non-routine transactions. As a result of such remedial actions, we believe we have remediated the material weaknesses.

If in the future we identify a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our financial statements may be materially misstated. We may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we are required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from The Nasdaq Global Select Market or other adverse consequences that would materially harm our business. In addition, we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, and other regulatory authorities, and become subject to litigation from investors and stockholders, which could harm our reputation and our financial condition, or divert financial and management resources from our core business.

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, 2019, we had federal NOLs of approximately $114.6 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 other 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 June 30, 2020 that were not registered under the Securities Act.

Recent Sales of Unregistered Equity Securities

(a) Unregistered Sales of Equity Securities.

None.

(b) Use of Proceeds from Initial Public Offering of Common Stock.

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 $156.9 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 the 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 June 30, 2020. 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.

(c) *Purchases of Equity Securities By the Issuer and Affiliated Purchasers*.

We did not repurchase any of our equity securities during the quarter ended June 30, 2020.

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
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

* The certifications attached as Exhibit 32.1 and Exhibit 32.2 that accompany this Quarterly Report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Viela Bio, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of such Form 10-Q), irrespective of any general incorporation language contained in such filing.

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.

VIELA BIO, INC.

Date: August 12, 2020

By: /s/ Mitchell Chan

Mitchell Chan
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Date: August 12, 2020

By: /s/ Zhengbin (Bing) Yao, Ph.D.

Zhengbin (Bing) Yao, Ph.D.
Chairman, President and
Chief Executive Officer
(Principal 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: August 12, 2020

By: /s/ Zhengbin (Bing) Yao, PH.D.
Zhengbin (Bing) Yao, PH.D.
Chairman, President and Chief Executive Officer
(Principal 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: August 12, 2020

By: /s/ Mitchell Chan
Mitchell Chan
Chief Financial Officer
(Principal Financial Officer and Principal Accounting 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 quarter ended June 30, 2020, 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: August 12, 2020

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

Exhibit 32.2

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

In connection with the Quarterly Report of Viela Bio, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2020, 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: August 12, 2020

By: /s/ Mitchell Chan
Mitchell Chan
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)