UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended 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: 001-38692

EQUILLIUM, INC.

(Exact name of registrant as specified in its charter)

Delaware	**82-1554746**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification Number)**
2223 Avenida de la Playa, Suite 105, La Jolla, CA	**92037**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (858) 412-5302

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	EQ	The Nasdaq Global Market

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 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, 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 filer	☒
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 11, 2020, the registrant had 19,263,375 shares of common stock, par value $0.0001 per share, outstanding.

EQUILLIUM, INC.
TABLE OF CONTENTS

		Page No.
PART I	FINANCIAL INFORMATION	1
ITEM 1.	FINANCIAL STATEMENTS	1
	Condensed Consolidated Balance Sheets	1
	Condensed Consolidated Statements of Operations and Comprehensive Loss	2
	Condensed Consolidated Statements of Stockholders' Equity	3
	Condensed Consolidated Statements of Cash Flows	4
	Notes to Condensed Consolidated Financial Statements	5
ITEM 2.	MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS	15
ITEM 3.	QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK	23
ITEM 4.	CONTROLS AND PROCEDURES	23
PART II	OTHER INFORMATION	24
ITEM 1.	LEGAL PROCEEDINGS	24
ITEM 1A.	RISK FACTORS	24
ITEM 2.	UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS	74
ITEM 6.	EXHIBITS	75
SIGNATURES		76

PART I - FINANCIAL INFORMATION

Item 1. Financial Statements

Equillium, Inc.
Condensed Consolidated Balance Sheets
(In thousands, except share and par value data)

	June 30, 2020 (Unaudited)	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 24,083	$ 13,219
Short-term investments	18,523	39,924
Prepaid expenses and other current assets	1,572	2,288
Total current assets	44,178	55,431
Property and equipment, net	81	93
Other assets	-	15
Total assets	$ 44,259	$ 55,539
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,761	$ 1,873
Accrued expenses	1,626	2,010
Total current liabilities	3,387	3,883
Long-term notes payable	9,810	9,681
Other non-current liabilities	90	127
Total liabilities	13,287	13,691
Commitments and contingencies		
Stockholders' equity:		
Common stock, $0.0001 par value; 200,000,000 shares authorized; 17,723,850 and 17,425,654 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	1	1
Additional paid-in capital	86,284	82,938
Accumulated other comprehensive income	97	21
Accumulated deficit	(55,410)	(41,112)
Total stockholders' equity	30,972	41,848
Total liabilities and stockholders' equity	$ 44,259	$ 55,539

See accompanying notes.

Equillium, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(In thousands, except share and per share data)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	$ 3,893	$ 4,250	$ 8,599	$ 8,009
General and administrative	2,717	2,189	5,463	4,778
Total operating expenses	6,610	6,439	14,062	12,787
Loss from operations	(6,610)	(6,439)	(14,062)	(12,787)
Other income (expense), net:				
Interest expense	(274)	-	(547)	-
Interest income	122	375	342	773
Other income (expense), net	301	(5)	(31)	(5)
Total other income (expense), net	149	370	(236)	768
Net loss	$ (6,461)	$ (6,069)	$ (14,298)	$ (12,019)
Other comprehensive (loss) income, net:				
Unrealized (loss) gain on available-for-sale securities, net	(69)	39	69	83
Foreign currency translation (loss) gain	(308)	(1)	7	(1)
Total other comprehensive (loss) income, net	(377)	38	76	82
Comprehensive loss	$ (6,838)	$ (6,031)	$ (14,222)	$ (11,937)
Net loss per share, basic and diluted	$ (0.37)	$ (0.35)	$ (0.81)	$ (0.69)
Weighted-average common shares outstanding, basic and diluted	17,692,731	17,376,236	17,627,641	17,376,236

See accompanying notes.

Equillium, Inc.
Condensed Consolidated Statements of Stockholders' Equity
(In thousands, except share data)
(Unaudited)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2018	17,376,236	$ 1	$ 80,441	$ 5	$ (15,512)	$ 64,935
Vesting of restricted stock liability	-	-	19	-	-	19
Stock-based compensation expense	-	-	446	-	-	446
Other comprehensive income	-	-	-	44	-	44
Net loss	-	-	-	-	(5,950)	(5,950)
Balance at March 31, 2019	17,376,236	$ 1	$ 80,906	$ 49	$ (21,462)	$ 59,494
Vesting of restricted stock liability	-	-	19	-	-	19
Stock-based compensation expense	-	-	581	-	-	581
Other comprehensive income	-	-	-	38	-	38
Net loss	-	-	-	-	(6,069)	(6,069)
Balance at June 30, 2019	17,376,236	$ 1	$ 81,506	$ 87	$ (27,531)	$ 54,063

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2019	17,425,654	$ 1	$ 82,938	$ 21	$ (41,112)	$ 41,848
Issuance of common stock under ATM facility, net of issuance costs	174,649	-	825	-	-	825
Issuance of common stock	83,662	-	252	-	-	252
Vesting of restricted stock liability	-	-	18	-	-	18
Stock-based compensation expense	-	-	787	-	-	787
Other comprehensive income	-	-	-	453	-	453
Net loss	-	-	-	-	(7,837)	(7,837)
Balance at March 31, 2020	17,683,965	$ 1	$ 84,820	$ 474	$ (48,949)	$ 36,346
Issuance of common stock pursuant to employee stock purchase plan	39,885	-	96	-	-	96
Vesting of restricted stock liability	-	-	18	-	-	18
Stock-based compensation expense	-	-	1,350	-	-	1,350
Other comprehensive loss	-	-	-	(377)	-	(377)
Net loss	-	-	-	-	(6,461)	(6,461)
Balance at June 30, 2020	17,723,850	$ 1	$ 86,284	$ 97	$ (55,410)	$ 30,972

See accompanying notes.

Equillium, Inc.
Condensed Consolidated Statements of Cash Flows
(In thousands)
(Unaudited)

	Six Months Ended June 30,	
	2020	**2019**
Operating activities:		
Net loss	$ (14,298)	$ (12,019)
Adjustments to reconcile net loss to cash used in operating activities:		
Depreciation and amortization	15	11
Stock-based compensation	2,137	1,027
Net unrealized loss on foreign currency transactions	34	12
Non-cash consulting expense	81	-
Amortization of term loan discount and issuance costs	130	-
Realized gain on investments	(13)	-
Accretion of discount on investments, net	8	(241)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	890	318
Accounts payable	(100)	890
Accrued expenses	(334)	782
Net cash used in operating activities	(11,450)	(9,220)
Investing activities:		
Purchases of property and equipment	(15)	(56)
Purchases of short-term investments	(2,225)	(25,630)
Maturities of short-term investments	23,700	29,075
Net cash provided by investing activities	21,460	3,389
Financing activities:		
Proceeds from issuance of common stock under ATM facility, net of issuance costs	775	-
Proceeds from ESPP purchase	96	-
Net cash provided by financing activities	871	-
Effect of exchange rate changes on cash and cash equivalents	(17)	(16)
Net increase (decrease) in cash and cash equivalents	10,864	(5,847)
Cash and cash equivalents at beginning of period	13,219	28,508
Cash and cash equivalents at end of period	$ 24,083	$ 22,661
Supplemental disclosures of non-cash activities:		
Issuance of commitment shares to Lincoln Park pursuant to agreement	$ 171	$ -

See accompanying notes.

1. Organization and Accounting Pronouncements

Description of Business

Equillium, Inc. (the Company) was incorporated in the state of Delaware on March 16, 2017. The Company is engaged in the research and development of products for severe autoimmune and inflammatory disorders with high unmet medical need.

From inception through June 30, 2020, the Company has devoted substantially all of its efforts to organizing and staffing the Company, business planning, raising capital, in-licensing rights to itolizumab (EQ001), conducting preclinical research, filing two initial Investigational New Drug applications (INDs), commencing clinical development of the Company's initial product candidate, itolizumab (EQ001), conducting business development activities, and the general and administrative activities associated with operating as a public company. In addition, the Company has a limited operating history, has not generated revenues from its principal operations, and the sales and income potential of its business is unproven.

Liquidity and Business Risks

As of June 30, 2020, the Company had $42.6 million in cash, cash equivalents and short-term investments. The Company has incurred significant operating losses and negative cash flows from operations. The Company expects to use its cash, cash equivalents and short-term investments to fund research and development of itolizumab (EQ001) and for working capital and other general corporate purposes. The Company does not expect to generate any revenues from product sales unless and until the Company successfully completes development and obtains regulatory approval of itolizumab (EQ001) or any future product candidate, which will not be for at least the next several years, if ever. Accordingly, until such time as the Company can generate significant revenue from sales of its product candidates, if ever, the Company expects to finance its cash needs through a combination of equity offerings, debt financings, and collaboration and license agreements. However, the Company may not be able to secure additional financing or enter into such other arrangements in a timely manner or on favorable terms, if at all. As a result of the COVID-19 pandemic and actions taken to slow its spread, the global credit and financial markets have experienced extreme volatility, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. If equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult to obtain, more costly and/or more dilutive. The Company's failure to raise capital or enter into such other arrangements when needed would have a negative impact on the Company's financial condition and could force the Company to delay, reduce or terminate its research and development programs or other operations, or grant rights to develop and market product candidates that the Company would otherwise prefer to develop and market itself. Management believes that the Company's cash, cash equivalents and short-term investments as of June 30, 2020, together with capital raised subsequent to June 30, 2020, will be sufficient to fund operations for at least the next 12 months from the date this Quarterly Report on Form 10-Q is filed with the Securities and Exchange Commission (SEC).

In March 2020, as a result of impacts and risks associated with the COVID-19 pandemic, the Company decided to pause enrollment in its Phase 1b clinical trials of itolizumab (EQ001) in uncontrolled asthma and lupus nephritis. This decision was not based on any observed safety issues associated with itolizumab (EQ001) but rather out of an abundance of caution related to the COVID-19 pandemic and the Company's concern for the well-being of patients and their caregivers. In July 2020, the Company announced that patient enrollment in both of those trials had resumed. The Company is continuing efforts to enroll patients in the Phase 1b/2 clinical trial of itolizumab (EQ001) for the treatment of acute graft-versus-host disease (aGVHD) given the acute life-threatening severity of the disease, as the Company believes itolizumab (EQ001) represents a potentially life-saving treatment for these severely ill patients. However, there remains a risk that enrollment of that trial as well as enrollment in the Company's Phase 1b trials in uncontrolled asthma and lupus nephritis and the timing of topline data may also be adversely impacted by the COVID-19 pandemic.

The COVID-19 outbreak in the United States and the rest of the world has caused disruptions to the Company's business, which may delay results of the Company's clinical trials and adversely impact the Company's business. The Company cannot predict how legal and regulatory responses to concerns about COVID-19 or other major public health issues will impact the Company's business, nor can it predict potential adverse impacts related to the availability of capital to fund the Company's operations. Additionally, the Company's workforce and outside consultants may also be affected, which could result in an adverse impact on the Company's ability to conduct business. Any of these factors, alone or in combination with others, could harm the Company's business, results of operations, financial condition or liquidity. However, the magnitude, timing, and duration of any such potential financial impacts cannot be reasonably estimated at this time.

Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) and the rules and regulations of the SEC related to a quarterly report on Form 10-Q. Any reference in these notes to applicable guidance is meant to refer to GAAP as found in the Accounting Standards Codification (ASC) and Accounting Standards Updates (ASU) promulgated by the Financial Accounting Standards Board (FASB). Certain information and note disclosures normally included in annual financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to those rules and regulations. The condensed consolidated financial statements reflect all adjustments which, in the opinion of management, are necessary for a fair statement of the results for the periods presented. All such adjustments are of a normal and recurring nature. The operating results presented in these condensed consolidated financial statements are not necessarily indicative of the results that may be expected for any future periods. These condensed consolidated financial statements should be read in conjunction with the audited financial statements and the notes thereto for the year ended December 31, 2019 included in the Company’s Annual Report on Form 10-K filed with the SEC on March 26, 2020.

Principles of Consolidation

In January 2019, the Company created a new wholly-owned subsidiary in Australia with the Company serving as the sole shareholder through the subscription of shares. The accompanying condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary. All intercompany transactions and balances have been eliminated in consolidation.

Foreign Currency Translation

The Company’s wholly-owned subsidiary in Australia uses their local currency to be their functional currency. Assets and liabilities are translated into U.S. dollars at quarter-end exchange rates and revenues and expenses are translated at average exchange rates during the quarter and year-to-date periods. Foreign currency translation adjustments for the reported periods are included in accumulated other comprehensive income in the Company’s condensed consolidated statements of comprehensive loss, and the cumulative effect is included in the stockholders’ equity section of the Company’s condensed consolidated balance sheets. Realized and unrealized gains and losses denominated in foreign currencies are recorded in operating expenses in the Company’s condensed consolidated statements of operations. For the three months ended June 30, 2020, net realized and unrealized gains totaled $0.3 million. For the six months ended June 30, 2020, net realized and unrealized losses totaled $44,000. There were no material realized and unrealized gains and losses for the three and six months ended June 30, 2019.

Recently Issued Accounting Pronouncements

In February 2015, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which amends the FASB ASC 840 and creates Topic 842, Leases. The new topic supersedes Topic 840, Leases, and increases transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and requires disclosures of key information about leasing arrangements. For companies that are not emerging growth companies (EGCs), ASU 2016-02 is effective for fiscal years beginning after December 15, 2018. For EGCs, the ASU was to be effective for fiscal years beginning after December 15, 2019. However, in November 2019, the FASB issued ASU 2019-10, *Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815)* and *Leases (Topic 842*), *Effective Dates (ASU 2019-10),* which included a one-year deferral of the effective date of ASU 2016-02 for certain entities. As a result, the ASU is now effective for EGCs for fiscal years beginning after December 15, 2020, and interim periods within fiscal years beginning after December 15, 2021. The Company expects to adopt the new standard in the fourth quarter of 2021 using the modified retrospective method, under which the Company will apply Topic 842 to existing and new leases as of January 1, 2021, but prior periods will not be restated and will continue to be reported under Topic 840 guidance in effect during those periods. The Company anticipates that the adoption will not have a material impact on its condensed consolidated statements of operations and condensed consolidated comprehensive loss or its condensed consolidated statements of cash flows but expects to recognize right-of-use assets and liabilities for lease obligations associated with its operating leases.

In August 2018, the FASB issued ASU 2018-13, *Fair Value Measurement (Topic 820) – Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, which is designed to improve the effectiveness of disclosures by removing, modifying and adding disclosures related to fair value measurements. ASU 2018-13 is effective for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. Early adoption is permitted. The Company adopted this ASU on January 1, 2020. The adoption of this standard did not have a material impact on the Company’s condensed consolidated financial statements.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of the Company's condensed consolidated financial statements requires the Company to make estimates and assumptions that impact the reported amounts of assets, liabilities and expenses and the disclosure of contingent assets and liabilities in the condensed consolidated financial statements and accompanying notes. Significant estimates in the Company's condensed consolidated financial statements relate to clinical trial accruals and the valuation of equity awards. Management evaluates its estimates on an ongoing basis. Although estimates are based on the Company's historical experience, knowledge of current events, and actions it may undertake in the future, actual results may ultimately materially differ from these estimates and assumptions.

Accrued Research and Development Expense

The Company is required to estimate its expenses resulting from its obligations under contracts with vendors, consultants and contract research organizations, in connection with conducting research and development activities. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts. The Company reflects research and development expenses in its condensed consolidated financial statements by matching those expenses with the period in which services and efforts are expended. The Company accounts for these expenses according to the progress of the preclinical or clinical study as measured by the timing of various aspects of the study or related activities. The Company determines accrual estimates through review of the underlying contracts along with preparation of financial models taking into account discussions with research and development personnel and other key personnel as well as considering input from representatives of our contract service providers as to the progress of studies, or other services being conducted. During the course of a study, the Company adjusts its rate of expense recognition if actual results differ from its estimates. The Company classifies its estimates for accrued research and development expenses as accrued expenses on the accompanying condensed consolidated balance sheet.

Stock-Based Compensation

The Company measures employee and non-employee stock-based awards, including stock options and stock purchase rights, at grant-date fair value and records compensation expense on a straight-line basis over the vesting period of the award. The Company uses the Black-Scholes option pricing model to value its stock option awards. Estimating the fair value of stock option awards requires management to apply judgment and make estimates of certain assumptions, including the volatility of the Company's common stock, the expected term of the Company's stock options, the expected dividend yield and the fair value of the Company's common stock on the measurement date. As a result, if factors change and management uses different assumptions, stock-based compensation expense could be materially different for future awards.

Net Loss per Share

Basic net loss per share is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period. Diluted net loss per share is computed by dividing the net loss by the weighted average number of common shares and common share equivalents outstanding for the period. Common stock equivalents are only included when their effect is dilutive. The Company's potentially dilutive securities include outstanding options under the Company's equity incentive plan and outstanding warrants to purchase common stock, each of which have been excluded from the computation of diluted net loss per share as they would be anti-dilutive to the net loss per share. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position.

Potentially dilutive securities not included in the calculation of diluted net loss per share attributable to common stockholders because to do so would be anti-dilutive are as follows (in common stock equivalent shares):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Common stock options	2,414,461	1,203,483	2,414,461	1,203,483
Common stock warrants	80,428	-	80,428	
Total	2,494,889	1,203,483	2,494,889	1,203,483

3. Fair Value of Financial Instruments

The following tables summarize the Company’s assets that require fair value measurements on a recurring basis and their respective input levels based on the fair value hierarchy (in thousands):

		Fair Value Measurements Using		
	June 30, 2020	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Short-term investments:				
U.S. treasury securities	$ 13,601	$ 13,601	$ -	$ -
Certificates of deposit	4,922	4,922	-	-
Total	$ 18,523	$ 18,523	$ -	$ -

		Fair Value Measurements Using		
	December 31, 2019	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Short-term investments:				
U.S. treasury securities	$ 28,549	$ 28,549	$ -	$ -
Agency securities	5,994	-	5,994	-
Certificates of deposit	5,381	5,381	-	-
Total	$ 39,924	$ 33,930	$ 5,994	$ -

U.S. treasury securities and certificates of deposit are valued using Level 1 inputs. Level 1 securities are valued at unadjusted quoted prices in active markets that are observable at the measurement date for identical, unrestricted assets or liabilities. Fair values determined by Level 2 inputs, which utilize data points that are observable such as quoted prices, interest rates and yield curves, require the exercise of judgment and use of estimates, that if changed, could significantly affect the Company’s financial position and results of operations. Investments in agency securities are valued using Level 2 inputs. Level 2 securities are initially valued at the transaction price and subsequently valued and reported utilizing inputs other than quoted prices that are observable either directly or indirectly, such as quotes from third-party pricing vendors.

The carrying amounts of the Company’s financial instruments, including cash, prepaid and other current assets, accounts payable, and accrued liabilities, approximate fair value due to their short maturities. The carrying amount of the Company’s notes payable of $9.8 million at June 30, 2020 approximated their fair value as the terms of the notes are consistent with the market terms of transactions with similar profiles (Level 2 inputs). None of the Company’s non-financial assets or liabilities are recorded at fair value on a non-recurring basis.

At June 30, 2020 and December 31, 2019, the Company had investments in money market funds of $21.1 million and $10.3 million, respectively, that were measured at fair value using the net asset value per share (or its equivalent) that have not been classified in the fair value hierarchy. The funds invest primarily in U.S. government securities.

The Company did not hold any Level 1, 2 or 3 financial liabilities that are recorded at fair value on a recurring basis as of June 30, 2020 and December 31, 2019.

4. Certain Financial Statement Caption Information

Short-Term Investments

The following table summarizes the Company's short-term investments (in thousands):

	Maturity (in years)	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
June 30, 2020					
U.S. treasury securities	1 or less	$ 13,529	$ 72	$ -	$ 13,601
Certificates of deposit	1 or less	4,876	46	-	4,922
Total		$ 18,405	$ 118	$ -	$ 18,523
December 31, 2019					
U.S. treasury securities	1 or less	$ 23,513	$ 6	$ (4)	$ 23,515
U.S. treasury securities	>1 and <5	5,035	-	(1)	5,034
Agency securities	1 or less	5,976	19	(1)	5,994
Certificates of deposit	1 or less	4,131	22	-	4,153
Certificates of deposit	>1 and <5	1,220	8	-	1,228
Total		$ 39,875	$ 55	$ (6)	$ 39,924

All of the Company's available-for-sale securities are available to the Company for use in its current operations. As a result, the Company categorizes all of these securities as current assets even though the stated maturity of some individual securities may be one year or more beyond the balance sheet date. All of the Company's securities have a maturity within two years of the balance sheet date.

There were no impairments considered other-than-temporary during the periods presented, as it is management's intention and ability to hold the securities until a recovery of the cost basis or recovery of fair value. For the three and six months ended June 30, 2020, there were net gross realized gains on short-term investments totaling $0 and $13,000, respectively. There were no gross realized gains and losses on sales of short-term investments for the three and six months ended June 30, 2019. Unrealized gains and losses are included in accumulated other comprehensive income.

Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	June 30, 2020	December 31, 2019
Accrued payroll and other employee benefits	$ 994	$ 1,215
Clinical studies	404	442
Other accruals	111	267
Accrued interest	69	71
Preclinical research	48	15
Total accrued expenses	$ 1,626	$ 2,010

5. Notes Payable

On September 30, 2019 (the Effective Date), the Company entered into a Loan and Security Agreement (the Loan Agreement) with two lenders (the Lenders) whereby the Company can borrow up to $20.0 million in a series of term loans. Upon entering into the Loan Agreement, the Company borrowed $10.0 million from the Lenders (Term A Loan).

Under the terms of the Loan Agreement, the Company may, at its sole discretion, borrow from the Lenders (i) up to an additional $5.0 million (Term B Loan) upon the Company's achievement of positive topline data in either the Company's (a) Phase 1b aGVHD trial of itolizumab (EQ001) or (b) Phase 1b asthma trial of itolizumab (EQ001), supporting a formal decision to advance into Phase 2 development, and as confirmed by the Company's Board of Directors (the Term B Milestone) and (ii) up to an additional $5.0 million (Term C Loan and together with Term A Loan and Term B Loan, the Term Loans) upon the Company's achievement of positive topline data in both the Company's Phase 1b aGVHD trial of itolizumab (EQ001) and the Company's Phase 1b asthma trial of itolizumab (EQ001), supporting a formal decision to advance into Phase 2 development, and as confirmed by the Company's Board of Directors (the Term C Milestone). The Company may draw the Term B Loan during the period commencing on the date of the occurrence of the Term B Milestone and ending on the earliest of (i) December 31, 2020, (ii) 60 days after achieving the Term B Milestone, and (iii) the occurrence of an event of default and may draw the Term C Loan during the period commencing on the date of the occurrence of the Term C Milestone and ending on the earliest of (i) December 31, 2020, (ii) 60 days after achieving the Term C Milestone, and (iii) the occurrence of an event of default.

All of the Term Loans mature on June 1, 2024 (the Maturity Date) and will be interest-only payments through June 30, 2021, followed by 36 equal monthly payments of principal and interest; provided that if the Company draws the Term B Loan, the Term Loans will be interest-only payments through December 31, 2021, followed by 30 equal monthly payments of principal and interest. The Term Loans bear interest at a floating per annum rate equal to the greater of (i) 8.25% and (ii) the sum of (a) the prime rate reported in The Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue, plus (b) 3.00%.

The Company will be required to make a final payment of 4.50% of the original principal amount of the Term Loans drawn payable on the earlier of (i) the Maturity Date, (ii) the acceleration of any Term Loans, or (iii) the prepayment of the Term Loans (the Final Payment). The Company may prepay all, but not less than all, of the Term Loans upon 30 days' advance written notice to the Lenders, provided that the Company will be obligated to pay a prepayment fee equal to (i) 3.00% of the principal amount of the applicable Term Loan prepaid on or before the first anniversary of the applicable funding date, (ii) 2.00% of the principal amount of the applicable Term Loan prepaid between the first and second anniversary of the applicable funding date, and (iii) 1.00% of the principal amount of the applicable Term Loan prepaid thereafter, and prior to the Maturity Date (each, a Prepayment Fee).

In connection with entering into the Loan Agreement, the Company issued to the Lenders warrants exercisable for 80,428 shares of the Company's common stock (the Warrants). The Warrants are exercisable in whole or in part, immediately, and have a per share exercise price of $3.73, which was the closing price of the Company's common stock reported on the Nasdaq Global Market on the day prior to the Effective Date. The Warrants will terminate on the earlier of September 30, 2029 or the closing of certain merger or consolidation transactions. If the Company borrows under Term B Loan and/or Term C Loan, upon the funding of Term B Loan and/or Term C Loan, as applicable, the Company will issue to the Lenders additional warrants to purchase shares of the Company's common stock equal to 3.00% of each Term Loan amount divided by the lower of (i) the ten day average closing price of the Company's common stock reported on the Nasdaq Global Market prior to funding or (ii) the closing price of the Company's common stock reported on the Nasdaq Global Market on the day prior to funding. Such lower amount of (i) and (ii) above shall also be the exercise price per share for such warrants. The terms of such warrants would be substantially the same as those contained in the Warrants.

The Company recorded the Warrants as a debt discount, which is classified as a contra-liability against long-term notes payable on the condensed consolidated balance sheet, and is amortizing the balance over the life of the underlying debt. The offset to the contra-liability is recorded in additional paid-in capital in the Company's condensed consolidated balance sheet as the Warrants were determined to be an equity instrument. The Company determined the fair value of the Warrants at the date of issuance was $0.3 million using the Black-Scholes option pricing model based on significant unobservable inputs (Level 3) with an expected term of 10 years, volatility of 92.78%, risk free rate of 1.68% and expected dividend of 0%.

The costs incurred to issue the Term Loans of $0.1 million were deferred and are included in the discount to the carrying value of the Term Loans in the accompanying condensed consolidated balance sheet. The deferred costs and the Final Payment fee are amortized to interest expense over the expected term of the Term Loans using the effective interest method with an effective interest rate of 10.97%.

The aggregate carrying amounts of the Term Loans are comprised of the following (in thousands):

	June 30, 2020	December 31, 2019
Principal	$ 10,000	$ 10,000
Add: accreted liability for Final Payment fee	105	35
Less: unamortized discount	(295)	(354)
Total	$ 9,810	$ 9,681

Upon the occurrence of certain events, including but not limited to the Company's failure to satisfy its payment obligations under the Loan Agreement, the breach of certain of its other covenants under the Loan Agreement, or the occurrence of a material adverse change, cross defaults to other indebtedness or material agreements, judgment defaults and defaults related to failure to maintain governmental approvals failure of which to maintain could result in a material adverse effect, the Lenders will have the right, among other remedies, to declare all principal and interest immediately due and payable, to exercise secured party remedies, to receive the Final Payment and, if the payment of principal and interest is due prior to the Maturity Date, to receive the applicable Prepayment Fee. At June 30, 2020, the Company was in compliance with the covenants contained in the Loan Agreement.

Future maturities of the Term Loans, including the Final Payment fee, as of June 30, 2020 are as follows (in thousands):

	June 30, 2020
Remainder of 2020	$ -
Year ending December 31, 2021	1,667
Year ending December 31, 2022	3,333
Year ending December 31, 2023	3,333
Year ending December 31, 2024	2,117
	10,450
Unaccreted balance for Final Payment fee on Term Loans	(345)
Unamortized discounts	(295)
	9,810
Less current portion	-
Noncurrent portion	$ 9,810

6. Collaboration and License Agreement

In May 2017, the Company entered into a collaboration and license agreement (which was amended in September 2018, April 2019 and December 2019), clinical supply agreement, investor rights agreement, and common stock purchase agreement (collectively License Agreements) with Biocon SA (together with Biocon Limited, Biocon). Pursuant to the License Agreements, Biocon granted the Company an exclusive license to develop, make, have made, use, sell, have sold, offer for sale, import and otherwise exploit itolizumab and any pharmaceutical composition or preparation containing or comprising itolizumab that uses Biocon technology or Biocon know-how (collectively a Biocon Product) in the United States, Canada, Australia and New Zealand (collectively Company Territory). However, unless the Company achieves certain regulatory and development milestones within a specific time period, the licensed rights, other than development rights, are limited to the fields of orphan indications and the treatment of conditions related to asthma and lupus. The Company also has the right to sublicense through multiple tiers to third parties, provided such sublicenses comply with the terms of the License Agreements and the Company provides Biocon a copy of each sublicense agreement within 30 days of execution. If the Company grants a third party a sublicense of its rights to develop and commercialize Biocon Products in Australia or New Zealand, the Company will be required to pay Biocon a high double-digit percentage of any upfront payment the Company receives from such sublicensee for such sublicense, as well as a high double-digit percentage of any additional payments the Company receives from such sublicensee for such sublicense, including but not limited to royalty payments on net sales of Biocon Products by such sublicensee. Under the License Agreements, the Company granted back to Biocon a license to use its technology and know-how related to itolizumab and Biocon Products in certain countries outside of the Company's Territory. Pursuant to the License Agreements, Biocon agreed to be the Company's exclusive supplier of itolizumab clinical drug product. Biocon will provide clinical drug product at no cost for up to three concurrent orphan indications until the Company's first U.S. regulatory approval and all other clinical drug product at Biocon's cost.

In consideration of the rights granted to the Company by Biocon, the Company issued Biocon a total of 2,316,134 shares of common stock.

In addition, the Company is obligated to pay Biocon up to an aggregate of $30 million in regulatory milestone payments upon the achievement of certain regulatory approvals and up to an aggregate of $565 million in sales milestone payments upon the achievement of first commercial sale of product and specified levels of product sales. The Company is also required to pay royalties on tiers of aggregate annual net sales of Biocon Products by the Company, the Company's affiliates and the Company's sublicensees in the United States and Canada at percentages from the mid-single digits to sub-teen double-digits and on tiers of aggregate annual net sales of Biocon Products by the Company and the Company's affiliates (but not the Company's sublicensees) in Australia and New Zealand, in each case, subject to adjustments in certain circumstances. Biocon is also required to pay the Company royalties at comparable percentages for sales of itolizumab (EQ001) outside of the Company Territory if the approvals in such geographies included or referenced the Company's data including data from certain of the Company's clinical trials, subject to adjustments in certain circumstances. Under the License Agreements, net sales are calculated on a country-by-country basis and are subject to adjustments, including whether the Biocon Product is sold in the form of a combination product. As of June 30, 2020, the Company has not made or received payments in connection with the milestones or royalties within the agreement.

7. Stockholders' Equity

As of June 30, 2020, the Company's authorized capital stock consisted of 200,000,000 shares of common stock, par value $0.0001 per share, and 10,000,000 shares of preferred stock, par value $0.0001 per share.

The Company had 17,723,850 and 17,425,654 shares of common stock outstanding as of June 30, 2020 and December 31, 2019, respectively.

At-the-Market Offering Program

In November 2019, the Company entered into an Open Market Sales Agreement℠ with Jefferies LLC (Jefferies) under which the Company may offer and sell shares of its common stock from time to time, through an "at-the-market" (ATM) equity offering program under which Jefferies acts as sales agent (2019 ATM Facility). The Company sets certain parameters for the sale of shares, which may include but are not limited to the number of shares to be issued, the time period during which sales are requested to be made, and any minimum price below which sales may not be made. Jefferies is entitled to compensation for its services at a commission rate of 3.0% of the gross sales price per share of common stock sold plus reimbursement of certain expenses.

The maximum aggregate offering price of common stock that could be sold under the 2019 ATM Facility was $8.45 million. During the six months ended June 30, 2020, the Company sold 174,649 shares of its common stock and received net proceeds of $0.8 million under the 2019 ATM Facility. There were no sales of shares in the three months ended June 30, 2020.

On July 14, 2020, the Company entered into another Open Market Sales Agreement℠ with Jefferies for a new ATM equity offering (2020 ATM Facility). See Note 8 – *Subsequent Events* for further details.

Purchase Agreement

In March 2020, the Company entered into a purchase agreement (Purchase Agreement), with Lincoln Park Capital Fund, LLC (Lincoln Park), which provides that, upon the terms and subject to the conditions and limitations set forth therein, the Company may sell to Lincoln Park up to $15.0 million of shares of its common stock from time to time over the 36-month term of the Purchase Agreement. Upon execution of the Purchase Agreement, the Company issued 65,374 shares of its common stock to Lincoln Park as commitment shares in accordance with the closing conditions contained within the Purchase Agreement. The commitment shares were valued using the closing price of the Company's common stock on the effective date of the Purchase Agreement resulting in a fair market value of approximately $0.2 million. The fair market value of the commitment shares as well as other issuance costs associated with the Purchase Agreement totaled $0.4 million. These issuance costs are classified as prepaid expenses and other current assets in the accompanying condensed consolidated balance sheet. As shares of common stock are sold to Lincoln Park in accordance with the Purchase Agreement, the issuance costs, including the fair value of the commitment shares, will be reclassified to additional paid-in capital on the Company's condensed consolidated balance sheet. During the three and six months ended June 30, 2020, there were no sales of the Company's stock under this Purchase Agreement. There have been no sales of the Company's stock under this Purchase Agreement as of June 30, 2020 and through the date of the filing of this Quarterly Report on Form 10-Q.

Repricing of Outstanding Options

On April 22, 2020, the Board of Directors of the Company (the Board) approved a repricing of outstanding options to purchase 1,475,093 shares of the Company's common stock held by employees of the Company, including executive officers (but excluding any employees who serve on the Board) that had exercise prices in excess of the closing stock price on April 22, 2020 and were granted under the Company's 2017 Equity Incentive Plan or 2018 Equity Incentive Plan. As a result of the repricing, the exercise price of such options was lowered to $2.45 per share, the closing price of the Company's common stock on April 22, 2020. The vesting schedule and term of these options remained unchanged.

The Board effectuated the repricing to realign the value of such options with their intended purpose, which is to retain and motivate the holders of such options to continue to work in the best interests of the Company and its stockholders. Prior to the repricing, many of the options had exercise prices well above the recent market prices of the Company's common stock, including prior to the recent market volatility that has generally been associated with the COVID-19 pandemic.

The effect of the repricing generated a total incremental cost of approximately $0.4 million, of which approximately $0.1 million was recognized as stock-based compensation expense in the three months ended June 30, 2020, with the remainder to be expensed over the remaining vesting periods.

Stock Options

The following table summarizes the stock option activity during the six months ended June 30, 2020:

	Shares Subject to Options	Weighted-Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Options outstanding at December 31, 2019	1,821,093	$ 5.64		
Granted	593,368	$ 3.71		
Exercised	-	$ -		
Forfeitures and cancellations	-	$ -		
Options outstanding at June 30, 2020	2,414,461	$ 3.40	8.91	$ 770
Options exercisable at June 30, 2020	805,185	$ 3.45	8.54	$ 302

(a) Aggregate intrinsic value in this table was calculated as the positive difference, if any, between the closing price per share of the Company's common stock on June 30, 2020 of $2.95 and the price of the underlying options.

(b) The weighted-average exercise price per share of the options outstanding and exercisable as of June 30, 2020 includes the impact of the repricing of 1,475,093 options on April 22, 2020 at $2.45 per share.

At June 30, 2020, unamortized stock compensation for stock options was $8.5 million, with a weighted-average recognition period of 2.8 years.

On May 28, 2020, the Compensation Committee of the Company's Board of Directors issued to its Executive Chairman, Chief Executive Officer and two non-management directors retention stock options to purchase an aggregate of 169,368 shares of the Company's common stock. These stock option grants immediately vested at the date of grant. The non-cash stock-based compensation expense recognized in the three and six months ended June 30, 2020 associated with these stock option grants totaled $0.4 million. At the time, the Executive Chairman and Chief Executive Officer voluntarily agreed to a 65% and an 85% reduction, respectively, in their base salaries otherwise payable for the remainder of 2020. The two non-management directors voluntarily agreed to forego 100% of their annual cash retainers otherwise payable to such directors for the remainder of 2020.

Stock-Based Compensation Expense

The non-cash stock-based compensation expense for all stock awards, net of forfeitures recognized as they occur, that was recognized in the condensed consolidated statements of operations is as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Research and development	$ 488	$ 310	$ 902	$ 565
General and administrative	862	271	1,235	462
Total	$ 1,350	$ 581	$ 2,137	$ 1,027

Common Stock Reserved for Future Issuance

Common stock reserved for future issuance at June 30, 2020 is as follows:

	June 30, 2020	December 31, 2019
Stock options issued and outstanding	2,414,461	1,821,093
Warrants for common stock	80,428	80,428
Awards available under the 2018 Equity Incentive Plan	1,091,387	813,473
Employee stock purchase plan	638,087	503,716
Total	4,224,363	3,218,710

8. Subsequent Events

On July 14, 2020, the Company entered into the 2020 ATM Facility with Jefferies to sell shares of the Company’s common stock having aggregate sales proceeds of up to $150 million, from time to time, through an ATM equity offering program under which Jefferies acts as sales agent.

Subsequent to June 30, 2020 and through the date of the filing of this Quarterly Report on Form 10-Q, the Company has sold an aggregate of 1,539,525 shares of common stock under both of the 2019 ATM Facility and the 2020 ATM Facility, which includes shares sold pursuant to the 2020 ATM Facility, but not yet delivered to Jefferies, for gross proceeds of approximately $17.9 million. The Company paid cash commissions on the gross proceeds, plus reimbursement expenses to Jefferies and legal fees in the aggregate amount of approximately $0.6 million, resulting in net proceeds of $17.3 million.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes included in this Quarterly Report on Form 10-Q and the audited financial statements and notes thereto as of and for the year ended December 31, 2019 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations, both of which are contained in our Annual Report on Form 10-K filed with the Securities and Exchange Commission, or SEC, on March 26, 2020. Unless the context requires otherwise, references in this Quarterly Report on Form 10-Q to "we," "us," and "our" refer to Equillium, Inc.

Forward-Looking Statements

The information in this discussion contains forward-looking statements and information within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, which are subject to the "safe harbor" created by those sections. These forward-looking statements include, but are not limited to, statements concerning our strategy, future operations, future financial position, future revenues, projected costs, prospects and plans and objectives of management. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements that we make. These forward-looking statements involve risks and uncertainties that could cause our actual results to differ materially from those in the forward-looking statements, including, without limitation, the risks set forth in Part II, Item 1A, "Risk Factors" in this Quarterly Report on Form 10-Q and in our other filings with the SEC. The forward-looking statements are applicable only as of the date on which they are made, and we do not assume any obligation to update any forward-looking statements.

Overview

We are a clinical-stage biotechnology company leveraging deep understanding of immunobiology to develop products to treat severe autoimmune and inflammatory, or immuno-inflammatory, disorders with high unmet medical need. Our initial product candidate, itolizumab (EQ001), is a clinical-stage, first-in-class monoclonal antibody that selectively targets the novel immune checkpoint receptor CD6. CD6 plays a central role in the modulation of effector T cell, or T_{eff} cell, activity and trafficking. Activated T_{eff} cells drive a number of immuno-inflammatory diseases across therapeutic areas including transplant science, systemic autoimmunity, pulmonary, neurologic, gastrointestinal, renal, vascular, ophthalmic and dermatologic disorders. Therefore, we believe itolizumab (EQ001) may have broad therapeutic utility in treating a large and diverse set of severe immuno-inflammatory diseases.

Our pipeline is focused on developing itolizumab (EQ001) as a potential best-in-class, disease modifying treatment for multiple severe immuno-inflammatory disorders. Our Investigational New Drug application, or IND, with the U.S. Food and Drug Administration, or FDA, for acute graft-versus-host disease, or aGVHD, was accepted in July 2018. The FDA granted itolizumab (EQ001) Fast Track designation for the treatment of aGVHD in December 2018 and Orphan Drug designations for both the prevention and treatment of aGVHD in February 2019. In March 2019, we initiated a Phase 1b/2 clinical trial of itolizumab (EQ001) for the treatment of aGVHD and expect top-line data from the Phase 1b part of this trial in the second half of 2020. In June 2019, we initiated a Phase 1b proof-of-concept clinical trial in Australia for the treatment of uncontrolled asthma. Our IND for lupus nephritis was accepted by the FDA in July 2019, and we initiated a Phase 1b proof-of-concept clinical trial for the treatment of lupus nephritis in September 2019. The FDA granted itolizumab (EQ001) Fast Track designation for the treatment of lupus nephritis in December 2019. In March 2020, as a result of impacts and risks associated with the COVID-19 pandemic, we decided to pause enrollment in our Phase 1b clinical trials of itolizumab (EQ001) in uncontrolled asthma and lupus nephritis. This decision was not based on any observed safety issues associated with itolizumab (EQ001) but rather out of an abundance of caution related to the COVID-19 pandemic and our concern for the well-being of patients and their caregivers. In July 2020, we announced that patient enrollment in both of those trials had resumed. We are continuing efforts to enroll patients in the Phase 1b/2 clinical trial of itolizumab (EQ001) for the treatment of aGVHD given the acute life-threatening severity of the disease as we believe itolizumab (EQ001) represents a potentially life-saving treatment for these severely ill patients. However, there remains a risk that enrollment of that trial as well as enrollment in our Phase 1b trials in uncontrolled asthma and lupus nephritis, and the timing of topline data may also be adversely impacted by the COVID-19 pandemic. In August 2020, we announced positive data from the ongoing Phase 1b/2 clinical trial of itolizumab in aGVHD. Across the first two dose cohorts, itolizumab has been generally well tolerated, and five of seven patients achieved a complete response at the Day 29 endpoint.

We have ongoing translational biology programs to assess the therapeutic utility of itolizumab (EQ001) in additional indications where CD6 and its ligand, activated leukocyte cell adhesion molecule (ALCAM), play an important role in the pathogenesis of T cell mediated diseases. Our selection of current and future indications is driven by our analysis of the scientific, translational, clinical and commercial rationale for advancing itolizumab (EQ001) into further development.

We acquired rights to itolizumab (EQ001) for the territories of the United States and Canada in May 2017 pursuant to a collaboration and license agreement with Biocon SA (subsequently assigned to Biocon Limited, or together, Biocon), and the territories of Australia and New Zealand in December 2019, pursuant to an amendment to that agreement. Following completion of a Phase 3 clinical trial conducted by Biocon outside of North America, itolizumab was approved in India for the treatment of moderate to severe plaque psoriasis and is marketed by Biocon in India as ALZUMAb.

In July 2020, Biocon reported that a clinical trial conducted in India by Biocon demonstrated that itolizumab (ALZUMAb) significantly reduced mortality in patients hospitalized with COVID-19, and that the Drugs Controller General of India, or DCGI, has granted restricted emergency use approval of itolizumab in India for the treatment of cytokine release syndrome (CRS) in COVID-19 patients with moderate to severe acute respiratory distress syndrome (ARDS). In July 2020, based on the encouraging topline data reported by Biocon and subsequent DCGI approval of itolizumab for the treatment of COVID-19 patients, we announced that we are planning to conduct a global randomized, controlled clinical trial of itolizumab (EQ001) in COVID-19 patients for which we plan to file an IND after we complete our review of the Biocon data.

Our collaboration with Biocon includes an exclusive supply agreement for clinical and commercial drug product of itolizumab (EQ001). Biocon currently manufactures itolizumab (EQ001) at commercial scale in a facility in India regulated by the FDA. In August 2019, we entered into a letter agreement with Biocon that grants us exclusive rights to negotiate licensing rights with third parties to develop and commercialize itolizumab (EQ001) in select major markets outside of North America. This letter agreement allows us to represent itolizumab (EQ001) more broadly commercially and participate in value that may be created with strategic partners across geographies.

Since our inception, substantially all of our efforts have been focused on organizing and staffing our company, business planning, raising capital, in-licensing rights to itolizumab (EQ001), conducting preclinical research, filing two initial INDs, commencing clinical development of itolizumab (EQ001) and the general and administrative activities associated with operating as a public company. We have not generated any revenue from product sales or otherwise. Since inception, we have primarily financed our operations through our initial public offering, or IPO, private placements of convertible promissory notes, term loans and sales of our common stock through “at-the-market” sales agreements, or ATM offerings, with Jefferies LLC, or Jefferies. We have incurred losses since our inception. Our net losses were $14.3 million for the six months ended June 30, 2020 and $25.6 million for the year ended December 31, 2019. As of June 30, 2020, we had an accumulated deficit of $55.4 million. Substantially all of our operating losses resulted from expenses incurred in connection with our research and development activities, preclinical and clinical activities and general and administrative costs associated with our operations.

We expect to continue to incur significant expenses and increasing losses into the foreseeable future. We anticipate our expenses will increase substantially as we continue our research and development activities, including the ongoing and future clinical development of itolizumab (EQ001), potentially expand the indications in which we conduct clinical development of itolizumab (EQ001), potentially acquire additional products and/or product candidates, seek regulatory approval for and potentially commercialize any approved product candidates, hire additional personnel, protect our intellectual property, incur increasing expense associated with our outstanding debt, and incur general corporate costs. We expect that our existing cash, cash equivalents and short-term investments as of June 30, 2020, together with capital raised subsequent to June 30, 2020, will enable us to fund our currently planned operations for at least the next 12 months.

We do not expect to generate any revenues from product sales unless and until we successfully complete development and obtain regulatory approval for itolizumab (EQ001) or any future product candidate, which will not be for at least the next several years, if ever. Accordingly, 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 a combination of equity offerings, debt financings, and collaboration and license agreements. However, we may not be able to secure additional financing or enter into such other arrangements in a timely manner or on favorable terms, if at all. As a result of the COVID-19 pandemic and actions taken to slow its spread, the global credit and financial markets have experienced extreme volatility, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. If equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult to obtain, more costly and/or more dilutive. In addition, subject to limited exceptions, our loan and security agreement with Oxford Finance LLC and Silicon Valley Bank also prohibits us from incurring indebtedness without the prior written consent of the lenders, which consent may be withheld at their sole and absolute discretion. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could force us to delay, reduce or terminate our research and development programs or other operations, or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Financial Overview

Revenue

We currently have no products approved for sale, and we have not generated any revenues to date. In the future, we may generate revenue from collaboration or license agreements we may enter into with respect to our product candidates, as well as product sales from any approved product, which approval we do not expect to occur for at least the next several years, if ever. Our ability to generate product revenues will depend on the successful development and eventual commercialization of itolizumab (EQ001) and any future product candidates. If we fail to complete the development of itolizumab (EQ001) or any future product candidates in a timely manner, or to obtain regulatory approval for our product candidates, our ability to generate future revenue and our results of operations and financial position would be materially adversely affected.

Research and Development Expenses

Research and development expenses primarily consist of costs associated with our research and development activities, preclinical activities, and clinical development of itolizumab (EQ001). Our research and development expenses include:

- salaries and other related costs, including stock-based compensation and benefits, for personnel in research and development functions;
- external research and development expenses incurred under arrangements with third parties, such as consultants and advisors for research and development;
- costs of services performed by third parties, such as contract research organizations, or CROs, that conduct research and development and preclinical activities on our behalf;
- costs related to preparing and filing two INDs with the FDA and other regulatory interactions and submissions; and
- costs related to general overhead expenses such as travel, insurance and rent expenses associated with our research and development activities.

We expense research and development costs as incurred. We account for nonrefundable advance payments for goods and services that will be used in future research and development activities as expenses when the service has been performed or when the goods have been received.

Our direct research and development expenses consist principally of external costs, such as fees paid to CROs and consultants in connection with our preclinical and clinical development.

We plan to substantially increase our research and development expenses for the foreseeable future as we continue to advance the development of itolizumab (EQ001) and potentially expand the number of indications for which we are developing itolizumab (EQ001). The successful development of itolizumab (EQ001) is highly uncertain. At this time, due to the inherently unpredictable nature of preclinical and clinical development, which has been further exacerbated by the uncertain magnitude, extent and duration of impacts associated with the COVID-19 pandemic, we cannot reasonably estimate the nature, timing or costs of the efforts that will be necessary to complete the remainder of the development of itolizumab (EQ001) or the period, if any, in which material net cash inflows from itolizumab (EQ001) may commence. Clinical development timelines, the probability of success, and development costs can differ materially from expectations.

Completion of clinical trials may take several years or more, and the length of time generally varies according to the type, complexity, novelty, and intended use of a product candidate. The cost of clinical trials may vary significantly over the life of a project as a result of differences arising during clinical development, including, among others:

- managing the impact of COVID-19 pandemic and related precautions on the operation of our clinical trials;
- per patient clinical trial costs;
- the number of clinical trials required for approval;
- the number of sites and the number of countries included in our clinical trials;
- the length of time required to enroll suitable patients;
- the inefficiencies and additional costs related to any delays and potential restarts of clinical trials;
- the number of doses that patients receive;
- the number of patients that participate in our clinical trials;
- the drop-out or discontinuation rates of patients in our clinical trials;
- the duration of patient follow-up;
- potential additional safety monitoring or other studies requested by regulatory agencies;
- the number and complexity of procedures, analyses and tests performed during our clinical trials;
- the costs of procuring drug product for our clinical trials;
- the phase of development of the product candidate; and
- the efficacy and safety profile of the product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation and benefits, and consulting fees for executive, human resources, investor relations, finance, and accounting functions. Other significant costs include legal fees relating to patent and corporate matters, insurance, travel, board expenses, facility costs and taxes.

We anticipate that our general and administrative expenses will increase in future periods, reflecting an expanding infrastructure, increased legal, audit, tax and other professional fees associated with being a public company and maintaining compliance with stock exchange listing and SEC requirements, director and officer insurance premiums associated with being a public company, and accounting and investor relations costs. In addition, if we obtain regulatory approval for any product candidate, we expect to incur expenses associated with building the infrastructure and capabilities to commercialize such product. However, the timing of any such approval is highly uncertain, and it may be several years, if ever, that we receive any such regulatory approval.

Interest Expense

Interest expense consists of interest on our term loans payable.

Interest Income

Interest income consists primarily of interest income earned on cash, cash equivalents and short-term investments.

Other Expense, net

Other expense, net consists of net foreign currency transaction losses related to our Australian subsidiary.

Results of Operations

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

The following table sets forth our results of operations for the three and six months ended June 30, 2020 and 2019 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Research and development	$ 3,893	$ 4,250	$ 8,599	$ 8,009
General and administrative	2,717	2,189	5,463	4,778
Interest expense	(274)	-	(547)	-
Interest income	122	375	342	773
Other income (expense), net	301	(5)	(31)	(5)

Research and Development Expenses

Research and development expenses were $3.9 million and $8.6 million for three and six months ended June 30, 2020, respectively, compared to $4.3 million and $8.0 million for the three and six months ended June 30, 2019, respectively.

The decrease of $0.4 million in research and development expenses for the three months ended June 30, 2020 compared to the same period in 2019 primarily includes the following changes:

- $0.7 million decrease in clinical development activities, primarily related to higher start-up costs of clinical trials in the prior year;
- $0.4 million increase in employee compensation and benefits, primarily related to increased headcount partially offset by lower consulting expenses; and
- $0.1 million decrease in overhead expenses primarily related to decreased travel expenses associated with our research and development activities, much of which resulted from the impact associated with the COVID-19 pandemic.

The increase of $0.6 million in research and development expenses for the six months ended June 30, 2020, compared to the same period in 2019 primarily includes the following changes:

- $1.0 million increase in employee compensation and benefits, primarily related to increased headcount;
- $0.2 million decrease in preclinical research activities; and
- $0.2 million decrease in overhead expenses primarily related to decreased spending on travel and recruiting associated with our research and development activities, much of which resulted from the impact associated with the COVID-19 pandemic.

General and Administrative Expenses

General and administrative expenses were $2.7 million and $5.5 million for the three and six months ended June 30, 2020 and 2019, respectively, compared to $2.2 million and $4.8 million for the three and six months ended June 30, 2019, respectively.

On May 28, 2020, our board of directors issued retention stock options to purchase an aggregate of 169,368 shares of our common stock to our Executive Chairman, Chief Executive Officer and two non-management directors. These stock options immediately vested at the grant date and resulted in a $0.4 million charge to non-cash stock-based compensation in the three and six-months ended June 30, 2020. At the time, the Executive Chairman and Chief Executive Officer voluntarily agreed to a 65% and an 85% reduction, respectively, in their base salaries otherwise payable for the remainder of 2020. The two non-management directors voluntarily agreed to forego 100% of their annual cash retainers otherwise payable to such directors for the remainder of 2020. We expect that the voluntary reductions in salary and retainers will save us approximately $0.4 million in cash expenditures in calendar year 2020.

The increase of $0.5 million in general and administrative expenses for the three months ended June 30, 2020, compared to the same period in 2019, primarily includes the following changes:

- $0.6 million increase in employee compensation and benefits, primarily due to increased non-cash stock-based compensation totaling $0.4 million for fully-vested retention option grants issued to our Chief Executive Officer, our Executive Chairman and two non-management directors partially offset by lower salary expense;
- $0.1 million decrease in overhead expenses primarily related to decreased spending on travel associated with our general and administrative activities, much of which resulted from the impact associated with the COVID-19 pandemic; and
- $0.1 million decrease related to legal fees.

The increase of $0.7 million in general and administrative expenses for the six months ended June 30, 2020, compared to the same period in 2019, primarily includes the following changes:

- $0.8 million increase in employee compensation and benefits, primarily due to increased non-cash stock-based compensation expense totaling $0.4 million for fully-vested retention option grants issued to our Chief Executive Officer, our Executive Chairman and two non-management directors as well as higher consulting expenses; and
- $0.1 million decrease related to legal fees.

Interest Expense

Interest expense was $0.3 million and $0.5 million for the three and six months ended June 30, 2020, respectively, compared to no interest expense in the same periods in 2019. The increase consists of interest on our term notes payable.

Interest Income

Interest income was $0.1 million and $0.3 million for the three and six months ended June 30, 2020, respectively, compared to $0.4 million and $0.8 million for the three and six months ended June 30, 2019, respectively. The decrease in interest income was primarily due to both lower average cash, cash equivalents and short-term investment balances and lower interest rates during 2020 compared to 2019.

Other Income (Expense), Net

Other income (expense), net was $0.3 million of other income, net and $31,000 of other expense, net for the three and six months ended June 30, 2020, respectively, compared to $5,000 of other expense, net in both the three and six months ended June 30, 2019. The increase in other income (expense), net for the three months ended June 30, 2020 compared to the same period in 2019 relates primarily to net foreign currency transaction unrealized gains. For the six months ended June 30, 2020, compared to the same period in 2019, net foreign currency transaction losses increased approximately $39,000.

Liquidity and Capital Resources

From inception through June 30, 2020, we have raised an aggregate of approximately $92.0 million in gross proceeds pursuant to our IPO, private placements of convertible promissory notes, proceeds from term loans and proceeds from equity issuances under our ATM facility. As of June 30, 2020, we had $24.1 million in cash and cash equivalents and $18.5 million in short-term investments.

Sources of Liquidity

September 2019 Loan Agreement

In September 2019, we entered into a loan and security agreement, or Loan Agreement, with Oxford Finance LLC and Silicon Valley Bank, or together, the Lenders, pursuant to which we can borrow up to $20.0 million in a series of term loans. Upon entering into the Loan Agreement, we borrowed $10.0 million, or Term A Loan. Under the terms of the Loan Agreement, we may, at our sole discretion, borrow from the Lenders (i) up to an additional $5.0 million, or Term B Loan, upon our achievement of positive topline data in either our (a) itolizumab (EQ001) Phase 1b aGVHD trial or (b) itolizumab (EQ001) Phase 1b asthma trial, supporting a formal decision to advance into Phase 2 development, and as confirmed by our Board of Directors, or the Term B Milestone, and (ii) up to an additional $5.0 million, or Term C Loan and together with Term A Loan and Term B Loan, the Term Loans, upon our achievement of positive topline data in both our EQ001 Phase 1b aGVHD trial and our itolizumab (EQ001) Phase 1b asthma trial, supporting a formal decision to advance into Phase 2

development, and as confirmed by our Board of Directors, or the Term C Milestone. We may draw the Term B Loan during the period commencing on the date of the occurrence of the Term B Milestone and ending on the earliest of (i) December 31, 2020, (ii) 60 days after achieving the Term B Milestone, and (iii) the occurrence of an event of default and may draw the Term C Loan during the period commencing on the date of the occurrence of the Term C Milestone and ending on the earliest of (i) December 31, 2020, (ii) 60 days after achieving the Term C Milestone, and (iii) the occurrence of an event of default.

At-the-Market Offering Program

In November 2019, we entered into an Open Market Sales Agreement[SM] with Jefferies to sell shares of our common stock having aggregate sales proceeds of up to $8.45 million, from time to time, through an ATM equity offering program under which Jefferies acts as sales agent, or the 2019 ATM Facility. Under the 2019 ATM Facility, we set certain parameters for the sale of shares, which may include but are not limited to the number of shares to be issued, the time period during which sales are requested to be made, and any minimum price below which sales may not be made. Jefferies is entitled to compensation for its services at a commission rate of 3.0% of the gross sales price per share of common stock sold plus reimbursement of certain expenses. As of June 30, 2020, we sold an aggregate of 192,899 shares of our common stock under the 2019 ATM Facility for gross proceeds of $0.9 million.

On July 14, 2020, we entered into another Open Market Sales Agreement [SM] with Jefferies for a new ATM equity offering to sell shares of our common stock, from time to time, having aggregate sales proceeds of up to $150 million under which Jefferies would act as sales agent, or the 2020 ATM Facility. The 2020 ATM Facility provides that Jefferies will be entitled to compensation for its services at a commission rate of 3.0% of the gross sales price per share of common stock sold. We are not obligated to make any sales under the 2020 ATM Facility.

Subsequent to June 30, 2020 and through the date of the filing of this Quarterly Report on Form 10-Q, we sold an aggregate of 1,539,525 shares of common stock under both of the 2019 ATM Facility and the 2020 ATM Facility, which includes shares sold pursuant to the 2020 ATM Facility, but not yet delivered to Jefferies, for gross proceeds of approximately $17.9 million. We paid cash commissions on the gross proceeds, plus reimbursement expenses to Jefferies and legal fees in the aggregate amount of approximately $0.6 million resulting in net proceeds of $17.3 million.

2020 Purchase Agreement

In March 2020, we entered into a purchase agreement, or the Purchase Agreement, with Lincoln Park Capital Fund, LLC, or Lincoln Park, which provides that, upon the terms and subject to the conditions and limitations set forth therein, we may sell to Lincoln Park up to $15.0 million of shares of our common stock from time to time over the 36-month term of the Purchase Agreement. Upon execution of the Purchase Agreement, we issued 65,374 shares of our common stock to Lincoln Park as commitment shares in accordance with the closing conditions contained within the Purchase Agreement. We have not sold any shares of our common stock to Lincoln Park under the Purchase Agreement through the date of the filing of this Quarterly Report on Form 10-Q.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing and future activities, particularly as we advance and expand our clinical development of itolizumab (EQ001), including potential new indications. We expect that our primary uses of capital will be for clinical research and development services, preclinical research, manufacturing, legal and other regulatory compliance expenses, compensation and related expenses, risk management, and general overhead costs.

We expect that our existing cash, cash equivalents and short-term investments as of June 30, 2020, together with capital raised subsequent to June 30, 2020, will enable us to fund our currently planned operations for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we expect. Furthermore, our operating plans may change, and we may need additional funds sooner than planned. Additionally, the process of testing product candidates in clinical trials is costly, and the timing of progress in these trials is uncertain. Because the outcome of these efforts is uncertain, we cannot estimate the actual amounts necessary to successfully complete the development and commercialization of itolizumab (EQ001) or whether, or when, we may achieve profitability.

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

- the initiation, progress, timing, costs and results of our ongoing and future clinical trials of itolizumab (EQ001), including as such activities may be adversely impacted by the COVID-19 pandemic;
- the number and scope of indications we decide to pursue for itolizumab (EQ001) development;

- the cost, timing and outcome of regulatory review of any Biologics License Application, or BLA, we may submit for itolizumab (EQ001);
- the costs and timing of manufacturing for itolizumab (EQ001), if approved;
- 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, including personnel to support the development of itolizumab (EQ001);
- the costs associated with being a public company;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements;
- the extent to which we acquire or in-license other product candidates and technologies; and
- the cost associated with commercializing itolizumab (EQ001), if approved for commercial sale.

Until such time as we can generate substantial product revenues, if ever, we expect to finance our cash needs through a combination of equity offerings, debt financings, and collaboration and license agreements. The sale of additional equity or convertible debt could result in additional dilution to our stockholders and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing common stockholders. The incurrence of debt financing would result in debt service obligations and the governing documents would likely include operating and financing covenants that would restrict our operations. As a result of the COVID-19 pandemic and actions taken to slow its spread, the global credit and financial markets have experienced extreme volatility, including diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. If equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult to obtain, more costly and/or more dilutive. If we raise additional funds through collaboration or license agreements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us and/or that may reduce the value of our common stock. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or other operations. Any of these actions could have a material effect on our business, financial condition and results of operations. We have experienced net losses and negative cash flows from operating activities since our inception and expect to continue to incur net losses into the foreseeable future. We had an accumulated deficit of $55.4 million as of June 30, 2020. We expect operating losses and negative cash flows to continue for at least the next several years as we continue to incur costs related to the development of itolizumab (EQ001).

Cash Flows

The following table sets forth the primary sources and uses of cash for each of the periods set forth below (in thousands):

	Six Months Ended June 30,	
	2020	2019
Net cash provided by (used in):		
Operating activities	$ (11,450)	$ (9,220)
Investing activities	21,460	3,389
Financing activities	871	-
Effect of exchange rate changes on cash	(17)	(16)
Net increase (decrease) in cash and cash equivalents	$ 10,864	$ (5,847)

Operating Activities

Net cash used in operating activities was $11.5 million during the six months ended June 30, 2020, as compared to $9.2 million during the six months ended June 30, 2019. The increase is primarily due to an increase of $2.3 million in net loss for the six months ended June 30, 2020, as compared to the same period in 2019, offset by an increase in non-cash adjustments to net loss totaling $1.6 million primarily associated with an increase in non-cash stock-based compensation of $1.1 million. Furthermore, there were net unfavorable working capital changes due to a decrease of $2.1 million in accounts payable and accrued expenses offset by a decrease of $0.6 million in prepaid expenses and other current assets for the six months ended June 30, 2020 as compared to the same period in 2019.

Investing Activities

Net cash provided by investing activities was $21.5 million during the six months ended June 30, 2020. We purchased $2.2 million of short-term investments and $23.7 million of our short-term investments matured during the period. Purchases of property and equipment for the six months ended June 30, 2020 totaled $15,000.

Net cash provided by investing activities was $3.4 million during the six months ended June 30, 2019. We purchased $25.6 million of short-term investments and $29.1 million of our short-term investments matured during the period. Purchases of property and equipment for the six months ended June 30, 2019 totaled $0.1 million.

Financing Activities

Net cash provided by financing activities totaled $0.9 million during the six months ended June 30, 2020. We received net proceeds from the sale of shares under the 2019 ATM facility totaling $0.8 million and from the issuance of shares under our employee stock purchase plan totaling $0.1 million. There were no financing activities during the six months ended June 30, 2019.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules, and similarly did not and do not have any holdings in variable interest entities.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not required for smaller reporting companies.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As of June 30, 2020, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended. Based on this evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of June 30, 2020.

There has been no change in our internal control over financial reporting during our most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II - OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

You should carefully consider the following risk factors, as well as the other information in this report, before deciding whether to purchase, hold or sell shares of our common stock. The occurrence of any of the following risks could harm our business, financial condition, results of operations and/or growth prospects or cause our actual results to differ materially from those contained in forward-looking statements we have made in this report and those we may make from time to time. You should consider all of the factors described as well as the other information in our financial statements and the related notes and "Management's Discussion and Analysis of Financial Condition and Results of Operations" when evaluating our business. The risk factors set forth below that are marked with an asterisk (*) either are new risks to, or contain changes to the similarly titled risk factors included in, our Annual Report on Form 10-K for the year ended December 31, 2019. If any of the following risks actually occurs, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock would likely decline and you may lose all or part of your investments. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations.

Risks Related to Our Business and to the Development and Regulatory Approval of Itolizumab (EQ001)

The novel coronavirus global pandemic has adversely impacted our business, including our clinical trials, and could further impact other aspects of our business including our supply chain, personnel, and our business development activities, the magnitude and extent of which are uncertain.*

In December 2019, a novel strain of coronavirus, designated COVID-19, was first reported in Wuhan, China and has since become a global pandemic. The President of the United States declared the coronavirus pandemic a national emergency and many states and municipalities in the United States, including California, have announced aggressive actions to reduce the spread of the disease, including limiting non-essential gatherings of people, ceasing all non-essential travel, ordering certain businesses and government agencies to cease non-essential operations at physical locations and issuing "shelter-in-place" orders which direct individuals to shelter at their places of residence (subject to limited exceptions). As a result, we have implemented work-from-home policies for employees and have moved to a "virtual" model with respect to our partner support activities. The effects of government actions and our policies and those of third parties to reduce the spread of the coronavirus may negatively impact productivity, cause disruptions to our supply chain and ongoing and future clinical trials and impair our ability to execute our business development strategy. These and other disruptions in our operations and the global economy could negatively impact our business, operating results and financial condition.

Quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to the coronavirus or other infectious diseases could impact personnel at third-party manufacturing facilities upon which we rely, or the availability or cost of materials, which could disrupt the supply chain for our clinical trials. In particular, certain of our service providers involved in clinical trials are located in regions that have been subject to coronavirus-related actions and policies that limit the conduct of normal business operations. To the extent our suppliers and service providers are unable to comply with their obligations under our agreements with them or they are otherwise unable to deliver or are delayed in delivering goods and services to us due to the coronavirus, our ability to continue advancing development of our product candidates may become impaired.

In addition, our clinical trials have been and may continue to be affected by the coronavirus. In March 2020, as a result of impacts and risks associated with the COVID-19 pandemic, we decided to pause enrollment in our Phase 1b clinical trials of itolizumab (EQ001) in uncontrolled asthma and lupus nephritis. This decision was not based on any observed safety issues associated with itolizumab (EQ001) but rather out of an abundance of caution related to the current global pandemic and our concern for the well-being of patients and their caregivers. In July 2020, we announced that patient enrollment in both of those trials had resumed. We are continuing efforts to enroll patients in the Phase 1b/2 clinical trial of itolizumab (EQ001) for the treatment of aGVHD given the acute life-threatening severity of the disease as we believe itolizumab (EQ001) represents a potentially life-saving treatment for these severely ill patients. However, there remains a risk that enrollment of that trial as well as enrollment in our Phase 1b trials in uncontrolled asthma and lupus nephritis, and the timing of topline data, may also be adversely impacted by the COVID-19 pandemic. Clinical site initiation and patient enrollment for our ongoing aGVHD trial may be delayed due to prioritization of hospital resources toward the coronavirus. Current or future patients in our ongoing or planned clinical trials may also choose to not enroll, not participate in follow-up clinical visits or drop out of the trial as a precaution against contracting the coronavirus. Further, some patients may not be able or willing to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to the

coronavirus, may be adversely impacted. These events could delay our clinical trials, increase the cost of completing our clinical trials and negatively impact the integrity, reliability or robustness of the data from our clinical trials.

The spread of the coronavirus and actions taken to reduce its spread may also materially affect us economically. While the potential economic impact brought by, and the duration of, the coronavirus may be difficult to assess or predict, there could be a significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity and financial position.

The coronavirus continues to rapidly evolve. The extent to which the coronavirus may impact our clinical trials, our supply chain, our access to capital and our business development activities, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the pandemic, the duration of the pandemic and the efforts by governments and business to contain it, business closures or business disruptions and the impact on the economy and capital markets.

We have a very limited operating history and have never generated any revenues.*

We are an early-stage biotechnology company with a very limited operating history that may make it difficult to evaluate the success of our business to date and to assess our future viability. We were incorporated in March 2017 and our operations, to date, have consisted of organizing and staffing our company, business planning, raising capital, in-licensing rights to itolizumab (EQ001), conducting preclinical research, filing two initial INDs, commencing clinical development of itolizumab (EQ001), conducting business development activities, and the general and administrative activities associated with being a public company. We have not yet demonstrated an ability to successfully complete any clinical trials and have never completed the development of any product candidate, and we have never generated any revenue from product sales or otherwise. Consequently, we have no meaningful operations upon which to evaluate our business, and predictions about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing biopharmaceutical products.

We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability.*

Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that a product candidate will fail to gain regulatory approval or become commercially viable. We have never generated any revenues, and we cannot estimate with precision the extent of our future losses. For the six months ended June 30, 2020 and the year ended December 31, 2019, our net losses were $14.3 million and $25.6 million, respectively. As of June 30, 2020, we had an accumulated deficit of $55.4 million. We expect to incur increasing levels of operating losses for the foreseeable future as we execute our plan to continue our research and development activities, including the ongoing and future clinical development of itolizumab (EQ001), potentially expand the indications for which we conduct clinical development of itolizumab (EQ001), potentially acquire new products and/or product candidates, seek regulatory approvals of and potentially commercialize any approved product candidates, hire additional personnel and protect our intellectual property. In addition, if we obtain regulatory approval for itolizumab (EQ001), we expect to incur increased sales and marketing expenses. As a result, we expect to continue to incur significant and increasing operating losses and negative cash flows for the foreseeable future. These losses have had and will continue to have an adverse effect on our financial position and working capital.

To become and remain profitable, we must develop or acquire and eventually commercialize a product with significant market potential. This will require us to be successful in a range of challenging activities, including completing preclinical studies and clinical trials of itolizumab (EQ001), obtaining marketing approval for itolizumab (EQ001), manufacturing, marketing and selling itolizumab (EQ001) if we obtain marketing approval, and satisfying post-marketing requirements, if any. We may never succeed in these activities and, even if we succeed in obtaining approval for and commercializing itolizumab (EQ001), we may never generate revenues that are significant enough to achieve profitability. In addition, as a young business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges. Furthermore, because of the numerous risks and uncertainties associated with biopharmaceutical 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 profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis and we may 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 the value of the company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

We are highly dependent on the success of our product candidate, itolizumab (EQ001), which is in early stage clinical development, and we may not be able to successfully obtain regulatory or marketing approval for, or successfully commercialize, this product candidate in any of the indications for which we plan to develop it.*

Our future success will depend almost entirely on our ability to successfully develop, obtain regulatory approval for and then successfully commercialize itolizumab (EQ001), in any of the indications for which we initially plan to develop it, including treatment of COVID-19 patients, as well as treatment of uncontrolled asthma, aGVHD and lupus nephritis, which may never occur. We have no product candidates in our pipeline other than itolizumab (EQ001). We currently generate no revenues from sales of any biopharmaceutical products or otherwise, and we may never be able to develop or commercialize a marketable biopharmaceutical product.

Before we can market and sell itolizumab (EQ001) in the United States, we will need to manage research and development activities, commence and complete clinical trials, obtain necessary regulatory approvals from the FDA and build a commercial organization or enter into a marketing collaboration with a third party, among other things. We cannot assure you that we will be able to successfully complete the necessary clinical trials and/or obtain regulatory approval and develop sufficient commercial capabilities for itolizumab (EQ001). We have not submitted a BLA to the FDA for any product candidate. Further, itolizumab (EQ001) may not receive regulatory approval even if it is successful in clinical trials. If we do not receive regulatory approvals, our business, prospects, financial condition and results of operations will be adversely affected. Even if we obtain regulatory approval, we may never generate significant revenues from any commercial sales of itolizumab (EQ001). If itolizumab (EQ001) is approved and we fail to successfully commercialize it, we may be unable to generate sufficient revenues to sustain and grow our business, and our business, prospects, financial condition and results of operations will be adversely affected.

The positive preliminary data as reported by Biocon from its clinical trial of itolizumab in COVID-19 patients may be incomplete or inappropriately analyzed, and results of earlier studies may not be predictive of future clinical trial results.*

Our partner Biocon recently announced positive preliminary data from a clinical trial of itolizumab in patients hospitalized with COVID-19 in India. We own the rights to develop and commercialize itolizumab (EQ001) in the United States, Canada, Australia and New Zealand through an exclusive collaboration and license agreement with Biocon. We are still in the process of obtaining and reviewing data from the clinical trial conducted by Biocon. Data reported by Biocon may not be complete. Further, we do not control and are unable to validate study results reported by Biocon or third parties. Any errors or omissions in the data and public disclosures reported by Biocon or third parties could have a material adverse effect on our stock price and business plans. While we are currently planning to conduct a global randomized, controlled clinical trial of itolizumab (EQ001) in COVID-19 patients under a U.S. IND we plan to file, we may decide against initiating clinical development of itolizumab (EQ001) in COVID-19 patients in the United States or internationally after we complete our review and analysis of the Biocon data.

The results of Biocon's COVID-19 clinical trial may not be predictive of the results of subsequent clinical trials that we may undertake of itolizumab (EQ001) in patients with COVID-19. The design of any future clinical trials will be based on many assumptions, including, but not limited to, the expected effects of itolizumab (EQ001), and if those assumptions are incorrect, the trials may not produce results to support regulatory approval. Clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in early-stage clinical trials have nonetheless failed to replicate results in later-stage clinical trials and subsequently failed to obtain regulatory approval. Additionally, product candidates in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through nonclinical studies and earlier clinical trials. It is also possible that patients enrolled in clinical trials will experience adverse events or unpleasant side effects that are not currently part of the product candidate's profile.

We have not yet commenced development of itolizumab (EQ001) for COVID-19 patients. We may be unable to successfully develop and obtain regulatory approval of itolizumab (EQ001) for COVID-19 patients in a timely manner, if at all.*

Based on the initial topline data from the Biocon study and the subsequent restricted emergency use approval of itolizumab granted by the Drugs Controller General of India for the treatment of CRS in COVID-19 patients with moderate to severe ARDS in India, we are planning to conduct our own clinical trial of itolizumab (EQ001) in COVID-19 patients. Because we have not yet commenced development of itolizumab (EQ001) as a potential treatment for COVID-19 patients, such development will likely require extensive pre-clinical and clinical testing. In addition, we will need to submit an IND for acceptance by the FDA prior to initiating any clinical trials in the United States for COVID-19 patients. The FDA may require us to conduct additional preclinical studies for itolizumab (EQ001) before it allows us to initiate clinical trials, which would be costly and time consuming, and could delay, or even prevent, our development plans. We may be unable to successfully develop and obtain regulatory approval of itolizumab (EQ001) for COVID-19 patients and establish a competitive market share for our treatment before a competitor or before the COVID-19 outbreak is effectively contained, a vaccine or other effective competitive therapies are successfully developed, or the risk of coronavirus infection is significantly diminished, any of which could materially and adversely impact the commercial potential of itolizumab (EQ001) as a treatment for COVID-19 patients.

A large number of companies, academic institutions and other organizations currently have programs to develop COVID-19 vaccines and therapeutic candidates. Many of our competitors pursuing vaccines and treatments for COVID-19 have significantly greater financial, product development, manufacturing and marketing resources than we have. Larger pharmaceutical and biotechnology companies have extensive experience in clinical testing and obtaining regulatory approval for their products, and may have the resources to heavily invest to accelerate discovery and development of their products. Our business could be materially and adversely affected if competitors develop and commercialize one or more COVID-19 vaccines or treatments before we can complete development and obtain approval of itolizumab (EQ001) for COVID-19 patients, or if they develop and commercialize one or more COVID-19 vaccines or treatments that are safer, more effective, have fewer or less severe side effects, have broader market acceptance, are more convenient or are less expensive than itolizumab (EQ001).

We will need significant funding to support the development and commercialization of itolizumab (EQ001) for COVID-19 patients. Various government entities and private foundations are offering incentives, grants and contracts to encourage additional investment by commercial organizations into preventative and therapeutic agents against COVID-19, but such grants may have the effect of increasing the number of competitors and/or providing advantages to competitors working on COVID-19 vaccines and treatments. Accordingly, there can be no assurance that we will be able to successfully obtain the necessary funding to support our development and potential commercialization efforts.

Biocon's grant of restricted emergency use approval of itolizumab in India by the Drugs Controller General of India does not mean that we will be successful in obtaining regulatory approval of itolizumab (EQ001) from other regulatory authorities, including the FDA.*

Although Biocon was granted restricted emergency use approval of itolizumab by the Drugs Controller General of India for the treatment of CRS in COVID-19 patients with moderate to severe ARDS in India, that does not guarantee that we will be able to obtain regulatory approval for itolizumab (EQ001) for COVID-19 patients in any other jurisdiction, including in the United States from the FDA. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in other jurisdictions, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. The FDA and comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. We may not be able to submit for marketing approvals and may not receive necessary approvals to commercialize itolizumab (EQ001) for COVID-19 in any market.

If we fail to comply with U.S. export control and economic sanctions, our business, financial condition and prospects may be materially and adversely affected.*

Our business and our products are subject to U.S. export control laws and regulations, including the U.S. Export Administration Regulations and economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control, or OFAC. Our company must comply with these laws and regulations. The antibody sequence for both itolizumab (EQ001) and ALZUMAb is derived from Cuban-origin intellectual property and thus we believe this to be a pharmaceutical of Cuban origin, which would make the import, development and commercialization of itolizumab (EQ001) subject to these laws, sanctions and regulations. We currently rely on a general license issued by OFAC under the Cuban Assets Control Regulations, or CACR, relating to Cuban-origin pharmaceuticals to import and conduct clinical trials relating to itolizumab (EQ001). In the absence of the OFAC general license, all of our development and potential commercialization activities for itolizumab (EQ001) would be prohibited under the CACR, and we would be required to request a specific license from OFAC authorizing such activities, which OFAC could deny.

We submitted to OFAC, and subsequently amended and supplemented, a request for interpretive guidance confirming the applicability of the general license to itolizumab (EQ001), or in its absence, a specific license authorization from OFAC authorizing activities relating to the commercialization of itolizumab (EQ001), or the Submission. We simultaneously requested that OFAC treat the Submission as a voluntary disclosure if OFAC concluded that our determination that the general license applies to itolizumab (EQ001) was in error.

In November 2019, OFAC notified us that after careful consideration, which included consultation with the FDA, OFAC determined that itolizumab (EQ001) falls within the definition of "Cuban-origin pharmaceutical" and, as such, the general licenses at section 515.547(b) and (c) of the CACR authorize the conduct of clinical trials for itolizumab (EQ001) for the purpose of seeking approval for the drug from the FDA. Thus, no further authorization is required from OFAC at this time for our ongoing and future clinical trials of itolizumab (EQ001).

Even though OFAC has concluded that the general license for Cuban-origin pharmaceuticals applies to itolizumab (EQ001), there can be no assurance that the general license will not be revoked or modified by OFAC in the future, or that we will remain in compliance with the general license or other export laws and regulations. If OFAC revokes or modifies the general license, or otherwise determines that the general license does not apply to itolizumab (EQ001), and OFAC then denies our request for a specific license or delays issuance of a specific license, we will be unable to deal in, or otherwise commercialize, itolizumab (EQ001). In that case, we would be required to cease operations related to itolizumab (EQ001), which would materially and adversely affect our financial condition and business prospects. In addition, in the absence of the general or specific license, the transfer, sale and/or purchase of our securities could be prohibited, and the ownership or possession of our securities could be subject to an affirmative OFAC reporting requirement relating to blocked property. Any violations of the CACR or other applicable export control and sanctions laws could subject us and certain of our employees to substantial civil or criminal penalties.

Itolizumab (EQ001) is a monoclonal antibody that selectively targets CD6, a target for which there are no FDA-approved therapies. This makes it difficult to predict the timing and costs of clinical development for itolizumab (EQ001). We do not know whether our approach in targeting CD6 will allow us to develop any products of commercial value.

We have concentrated our research and development approach on targeting CD6, and our future success depends on the successful development of this therapeutic approach to the diseases we are targeting for treatment. To date, there are no FDA-approved drugs that target CD6, and while there are a number of independent studies clinically validating CD6 as a target, other than our partner Biocon, CD6 has not traditionally been a pathway targeted by other biopharmaceutical companies. The regulatory approval process for novel product candidates such as itolizumab (EQ001) can be more expensive and take longer than for other, better known or extensively studied therapeutic approaches. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring itolizumab (EQ001) to market could decrease our ability to generate sufficient revenue to maintain our business.

Additionally, companion diagnostic tests may be developed for use with itolizumab (EQ001). We, or our collaborators, will be required to obtain FDA clearance or approval for these tests, as well as coverage and reimbursement separate and apart from the approval and coverage and reimbursement we seek for our itolizumab (EQ001). Our inability to collaborate with a companion diagnostics developer could have a material and adverse effect on our business, financial condition, results of operations and prospects.

We will require substantial additional funding to complete the development and any commercialization of itolizumab (EQ001). If we are unable to raise this capital when needed, we may be forced to delay, reduce or eliminate our research and development programs or other operations.*

We expect our expenses to increase substantially during the next few years. The development of biotechnology product candidates is capital intensive. As itolizumab (EQ001) enters and advances through preclinical studies and clinical trials, we will need substantial additional funds to expand our clinical, regulatory and quality capabilities. In addition, if we obtain marketing approval for itolizumab (EQ001), we expect to incur significant commercialization expenses for marketing, sales, manufacturing and distribution.

As of June 30, 2020, we had $42.6 million in cash, cash equivalents and short-term investments. Based on our current operating plan, we believe that our existing cash, cash equivalents and short-term investments as of June 30, 2020, together with capital raised subsequent to June 30, 2020, will enable us to fund our operations for at least the next 12 months. However, changing circumstances or inaccurate estimates by us may cause us to use capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. For example, our ongoing and future clinical trials for itolizumab (EQ001) may encounter technical, enrollment or other issues that could cause our development costs to increase more than we expect. We do not have sufficient funds to complete the clinical development of itolizumab (EQ001) through regulatory approval, and we will need to raise substantial additional capital to complete the development and commercialization of itolizumab (EQ001).

Future capital requirements will depend on many factors, including:

- the initiation, progress, timing, costs and results of our ongoing and future clinical trials for itolizumab (EQ001), including as such activities may be adversely impacted by the COVID-19 pandemic;
- the number and scope of indications we decide to pursue for itolizumab (EQ001) development;
- the cost, timing and outcome of regulatory review of any BLA we may submit for itolizumab (EQ001);
- the costs and timing of manufacturing for itolizumab (EQ001), if approved;

- 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, including personnel to support the development of itolizumab (EQ001);
- the costs associated with being a public company;
- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements;
- the extent to which we acquire or in-license other product candidates and technologies; and
- the cost associated with commercializing itolizumab (EQ001), if approved for commercial sale.

In September 2019, we entered into a loan and security agreement, or Loan Agreement, with Oxford Finance LLC and Silicon Valley Bank, or together the Lenders, providing for up to $20.0 million in term loans. We borrowed $10.0 million upon execution of the Loan Agreement. We may borrow the remaining $10.0 million upon the achievement of certain aforementioned time-bounded clinical milestones. Missing those milestones either due to unsuccessful trial results and/or delays in our clinical trials, including as a result of the COVID-19 pandemic, would result in us being unable to advance those remaining amounts of the debt facility, which could adversely impact our financial position and business operations.

In November 2019, we entered into an ATM facility with Jefferies, or the 2019 ATM Facility, under which we may offer and sell shares of our common stock having an aggregate offering price of up to $8.45 million from time to time through Jefferies acting as our sales agent. As of June 30, 2020, we sold an aggregate of 192,899 shares of our common stock under the 2019 ATM Facility for gross proceeds of $0.9 million. In July 2020, we entered into a new ATM facility with Jefferies, or the 2020 ATM Facility, under which we may offer and sell shares of our common stock having an aggregate offering price of up to $150 million from time to time through Jefferies acting as our sales agent. Subsequent to June 30, 2020 and through the date of the filing of this Quarterly Report on Form 10-Q, we sold an aggregate of 1,539,525 shares of our common stock, which includes shares sold pursuant to the 2020 ATM Facility, but not yet delivered to Jefferies, for total gross proceeds of approximately $17.9 million under those ATM offerings.

In March 2020, we entered into the Purchase Agreement, with Lincoln Park which provides that, upon the terms and subject to the conditions and limitations set forth therein, we may sell to Lincoln Park up to $15.0 million of shares of our common stock from time to time over the 36-month term of the Purchase Agreement. Upon execution of the Purchase Agreement, we issued 65,374 shares of our common stock to Lincoln Park as commitment shares in accordance with the closing conditions contained within the Purchase Agreement. As of June 30, 2020 and through the date of the filing of this Quarterly Report on Form 10-Q, we have not sold any shares of our common stock to Lincoln Park under the Purchase Agreement.

Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for sale for at least the next several years, if ever. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, the COVID-19 pandemic continues to rapidly evolve and has already resulted in a significant disruption of global financial markets. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the COVID-19 pandemic. If the disruption persists and deepens, we could experience an inability to access additional capital. Subject to limited exceptions, our Loan Agreement also prohibits us from incurring indebtedness without the prior written consent of the lenders. 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 would be forced to delay, reduce or eliminate our research and development programs or other operations.

We are very early in our development efforts. We only recently initiated our initial clinical trials of itolizumab (EQ001), and as a company, we have limited experience in these areas.*

We initiated our first clinical trial of itolizumab (EQ001) for the treatment of aGVHD in the first quarter of 2019, our second clinical trial of itolizumab (EQ001) for the treatment of uncontrolled moderate to severe asthma in the second quarter of 2019 and our third clinical trial of itolizumab (EQ001) for the treatment of lupus nephritis in the third quarter of 2019. In March 2020, as a result of impacts and risks associated with the COVID-19 pandemic, we decided to pause enrollment in our Phase 1b clinical trials of itolizumab (EQ001) in uncontrolled asthma and lupus nephritis. In July 2020, we announced that patient enrollment in both of these trials had resumed. We have two active INDs with the FDA for the use of itolizumab (EQ001) in the treatment of aGVHD and lupus nephritis and we have not yet filed an IND with the FDA for the use of itolizumab (EQ001) for the treatment of uncontrolled moderate to severe asthma or for treatment of COVID-19 patients. Because of our limited interaction with the FDA, we may not learn of certain information or data that the FDA may request until future interactions. In part because of our limited infrastructure, experience conducting clinical trials as a company and regulatory interactions, we also cannot be certain that our ongoing and future clinical trials will be completed on time, if at all, that our

planned clinical trials will be initiated on time, if at all, or that our planned development programs would be acceptable to the FDA.

Adverse safety and toxicology findings may emerge as we conduct clinical trials. In addition, success in early clinical trials does not mean that later clinical trials will be successful, because later-stage clinical trials may be conducted in broader patient populations and involve different study designs. For example, although itolizumab (EQ001) and ALZUMAb share the same primary monoclonal antibody sequence, they are manufactured in different cell lines and thus could be considered different biopharmaceutical products. Therefore, results seen in clinical trials of ALZUMAb conducted by Biocon may not be predictive of the results of our clinical trials of itolizumab (EQ001). Furthermore, our future clinical trials will need to demonstrate sufficient safety and efficacy in larger patient populations for approval by the FDA. Companies frequently suffer significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results, and we cannot be certain that we will not face similar setbacks. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. In addition, only a small percentage of biologics under development result in the submission of a BLA to the FDA and even fewer are approved for commercialization.

Our ability to generate product revenues, which we do not expect will occur for at least the next several years, if ever, will depend heavily on our ability to successfully complete the above activities and any other activities required for the successful development and eventual commercialization of itolizumab (EQ001). The success of itolizumab (EQ001) will further depend on factors such as:

- completion of our ongoing and future clinical trials and preclinical studies with favorable results, including as such activities may be adversely impacted by the COVID-19 pandemic;
- acceptance of INDs by the FDA for our future clinical trials, as applicable;
- timely and successful enrollment in, and completion of, clinical trials with favorable results;
- demonstrating safety, efficacy and acceptable risk-benefit profile of itolizumab (EQ001) to the satisfaction of the FDA;
- receipt of marketing approvals from the FDA;
- maintaining arrangements with Biocon, our third-party manufacturer, for cell lines and drug product clinical supply and, if and when approved, for commercial supply of itolizumab (EQ001);
- establishing sales, marketing and distribution capabilities and launching commercial sale of itolizumab (EQ001), if and when approved in one or more indications;
- acceptance of itolizumab (EQ001), if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for itolizumab (EQ001); and
- maintaining a continued acceptable safety profile of itolizumab (EQ001), following approval.

If we do not achieve one or more of these factors in a timely manner, we could experience significant delays or an inability to successfully obtain marketing approval and commercialize itolizumab (EQ001), which would materially harm our business.

We have licensed itolizumab from Biocon pursuant to an exclusive license agreement, which license is conditioned upon us meeting certain diligence obligations with respect to the development, regulatory approval and commercialization of itolizumab, and making significant milestone payments in connection with regulatory approval and commercial milestones as well as royalty payments.*

We are party to an exclusive license agreement with Biocon, pursuant to which we initially acquired an exclusive license to develop, make, have made, use, sell, have sold, offer for sale, import and otherwise exploit itolizumab and any pharmaceutical composition or preparation containing or comprising itolizumab in the United States and Canada and which was later amended to grant us the same exclusive license in Australia and New Zealand as well, or, collectively, the Equillium Territory. We are obligated, under this agreement, to achieve certain development milestones within specified

timeframes in order to retain all of the licensed rights. Certain of such milestones are largely outside of our control. We are also obligated to use commercially reasonable efforts to develop and seek regulatory approval for, and if regulatory approval is obtained, to commercialize, itolizumab in the Equillium Territory and to secure funding for the development of itolizumab in two or more indications. Further, we are obligated to make certain cash milestone payments to Biocon upon completion of certain regulatory approval and commercial milestones and are required to pay royalties to Biocon on net sales of itolizumab, if approved. Though we believe that the royalty rates and milestone payments are reasonable in light of our business plan, we will require large amounts of capital to satisfy these obligations. We may become obligated to make a milestone payment when we do not have the cash on hand to make such payment, which could require us to delay our clinical trials, curtail our operations, scale back our commercialization and marketing efforts or seek funds to meet these obligations on terms unfavorable to us. In addition, if we are unable to make any payment when due or, if we fail to achieve the development milestones within the timeframes required by the license agreement, or to satisfy our general diligence obligation to use commercially reasonable efforts to develop, register and commercialize itolizumab and to secure funding for the development of itolizumab in two or more indications, Biocon may have the right to limit the scope of our license or terminate the agreement and all of our rights to develop and commercialize itolizumab.

We have licensed the rights to itolizumab in the United States, Canada, Australia, and New Zealand. Any adverse developments that occur during any clinical trials conducted by Biocon or third parties in other jurisdictions may affect our ability to obtain regulatory approval or commercialize itolizumab.*

Biocon, its Cuban partner, CIMAB, S.A., and their licensees, over which we have no control, have the rights to develop itolizumab worldwide and commercialize itolizumab in geographies outside of the Equillium Territory. Itolizumab is approved in India for the treatment of moderate to severe plaque psoriasis, and is marketed by Biocon as ALZUMAb. Biocon was also granted restricted emergency use approval of itolizumab by the Drugs Controller General of India for the treatment of CRS in COVID-19 patients with moderate to severe ARDS in India. We are also aware of ALZUMAb being utilized in India on a compassionate use basis for the treatment of aGVHD. In addition, regulatory approval of itolizumab in Cuba was granted to Centro de Immunologia Molecular for itolizumab to be used in patients with rheumatoid arthritis and psoriasis as well as emergency use approval in patients with COVID-19. We are unaware of any ongoing trials of itolizumab in Cuba.

Although information related to those uses of itolizumab and results observed is currently incomplete and would need to be critically examined before drawing conclusions, results could impact our development plans for itolizumab (EQ001). Further, we do not control and are unable to validate study results reported by Biocon or third parties. Any errors or omissions in the data and public disclosures reported by Biocon or third parties could have a material adverse effect on our stock price and business plans.

If serious adverse events occur with patients using ALZUMAb or during any clinical trials or exploratory studies of itolizumab conducted by Biocon or third parties, regulatory authorities, including the FDA, may delay, limit or deny approval of itolizumab (EQ001) or require us to conduct additional clinical trials as a condition to marketing approval, which would increase our costs. If we receive regulatory approval for itolizumab (EQ001) and a new and serious safety issue is identified in connection with use of ALZUMAb or in clinical trials or exploratory studies of itolizumab conducted by Biocon or third parties, regulatory authorities may withdraw their approval of the product or otherwise restrict our ability to market and sell itolizumab. In addition, treating physicians may be less willing to administer our product due to concerns over such adverse events, which would limit our ability to commercialize itolizumab (EQ001).

The development and commercialization of biopharmaceutical products are subject to extensive regulation, and we may not obtain regulatory approvals for itolizumab (EQ001) in any of the indications for which we plan to develop it, or any future product candidates, on a timely basis or at all.

The clinical development, manufacturing, labeling, packaging, storage, recordkeeping, advertising, promotion, export, import, marketing, distribution, adverse event reporting, including the submission of safety and other post-marketing information and reports, and other possible activities relating to itolizumab (EQ001), currently our only product candidate, as well as any other product candidate that we may develop in the future, are subject to extensive regulation. Marketing approval of biologics in the United States requires the submission of a BLA to the FDA and we are not permitted to market any product candidate in the United States until we obtain approval from the FDA of the BLA for that product. A BLA must be supported by extensive clinical and preclinical data, as well as extensive information regarding pharmacology, chemistry, manufacturing and controls.

FDA approval of a BLA is not guaranteed, and the review and approval process is an expensive and uncertain process that may take several years. The FDA also has substantial discretion in the approval process. The number and types of preclinical studies and clinical trials that will be required for BLA approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to treat and the regulations applicable to any particular product candidate. Despite the time and expense associated with preclinical studies and clinical trials, failure can occur at any stage. The results of preclinical and early clinical trials of itolizumab (EQ001) or any future product candidates may not be predictive of the results of our later-stage clinical trials.

Clinical trial failure may result from a multitude of factors including flaws in trial design, dose selection, placebo effect, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits, and failure in clinical trials can occur at any stage. Companies in the biopharmaceutical industry frequently suffer setbacks in the advancement of clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Based upon negative or inconclusive results, we may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. In addition, data obtained from clinical trials are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may further delay, limit or prevent marketing approval.

The FDA could delay, limit or deny approval of a product candidate for many reasons, including because they:

- may not deem our product candidate to be adequately safe and effective;
- may not agree that the data collected from clinical trials are acceptable or sufficient to support the submission of a BLA or other submission or to obtain regulatory approval, and may impose requirements for additional preclinical studies or clinical trials;
- may determine that adverse events experienced by participants in our clinical trials represents an unacceptable level of risk;
- may determine that population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- may not accept clinical data from trials, which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States;
- may disagree regarding the formulation, labeling and/or the specifications;
- may not approve the manufacturing processes or facilities associated with our product candidate;
- may change approval policies or adopt new regulations; or
- may not accept a submission due to, among other reasons, the content or formatting of the submission.

Generally, public concern regarding the safety of biopharmaceutical products could delay or limit our ability to obtain regulatory approval, result in the inclusion of unfavorable information in our labeling, or require us to undertake other activities that may entail additional costs. We have not obtained FDA approval for any product. This lack of experience may impede our ability to obtain FDA approval in a timely manner, if at all, for itolizumab.

If we experience delays in obtaining approval or if we fail to obtain approval of itolizumab, our commercial prospects will be harmed and our ability to generate revenues will be materially impaired which would adversely affect our business, prospects, financial condition and results of operations.

Any delays in the commencement or completion, or termination or suspension, of our ongoing, planned or future clinical trials could result in increased costs to us, delay or limit our ability to raise capital or generate revenue and adversely affect our commercial prospects.*

Any delays in the commencement or completion, or termination or suspension, of our ongoing, planned or future clinical trials could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects. Before we can initiate clinical trials of itolizumab (EQ001) in any distinct indication, we must submit the results of preclinical studies to the FDA along with other information, including information about itolizumab (EQ001) chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND or similar regulatory filing.

Before obtaining marketing approval from the FDA for the sale of itolizumab (EQ001) in any indication, we must conduct extensive clinical studies to demonstrate the safety and efficacy of itolizumab (EQ001). Clinical testing is expensive, time consuming and uncertain as to outcome. In addition, we expect to rely in part on preclinical, clinical and quality data generated by our partner, Biocon, as well as contract research organizations, or CROs, and other third parties for regulatory submissions for itolizumab (EQ001). While we have or will have agreements governing these third parties' services, we have limited influence over their actual performance. If these third parties do not make data available to us, or, if applicable, make regulatory submissions in a timely manner, in each case pursuant to our agreements with them, our development programs may be significantly delayed and we may need to conduct additional studies or collect additional data independently. In either case, our development costs would increase. To date, we have only submitted INDs for clinical trials of itolizumab (EQ001) for the treatment of aGVHD and lupus nephritis, and we will need to submit an IND for acceptance by the FDA prior to initiating any clinical trials in the United States in other indications, including for the treatment of COVID-19 patients.

The FDA may require us to conduct additional preclinical studies for itolizumab (EQ001) or any future product candidate before it allows us to initiate clinical trials under any IND, which may lead to additional delays and increase the costs of our preclinical development programs. Any such delays in the commencement or completion of our ongoing, planned or future clinical trials could significantly affect our product development costs. We do not know whether our ongoing and future trials will be completed on schedule, if at all, or whether our trials will begin on time, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including delays related to:

- impacts and risks associated with global health epidemics such as those related to COVID-19 (for example, in March 2020, as a result of impacts and risks associated with the COVID-19 pandemic, we decided to pause enrollment in our Phase 1b clinical trials of itolizumab (EQ001) in uncontrolled asthma and lupus nephritis), which enrollment was resumed in July 2020;
- the FDA disagreeing as to the design or implementation of our clinical studies;
- obtaining FDA authorizations to commence a trial or reaching a consensus with the FDA on trial design;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval from one or more institutional review boards, or IRBs;
- additional nonclinical pharmacology and toxicology studies to support Phase 2 and 3 trials;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- changes to clinical trial protocol;
- clinical sites deviating from trial protocol or dropping out of a trial;
- manufacturing sufficient quantities of product candidate or obtaining sufficient quantities of combination therapies for use in clinical trials;
- subjects failing to enroll or remain in our trial at the rate we expect, or failing to return for post-treatment follow-up;
- subjects choosing an alternative treatment, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected drug-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies;
- selection of clinical end points that require prolonged periods of clinical observation or analysis of the resulting data;
- a facility manufacturing our product candidates or any of their components being ordered by the FDA (or its own regulatory authorities if such facility is located outside the United States) to temporarily or permanently shut down or cease export of such materials due to violations of current good manufacturing practice, or cGMP, regulations or other applicable requirements, changes in export restrictions and controls, or infections or cross-contaminations during the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices, or GCP, or other regulatory requirements;
- us, or our third-party contractors not performing data collection or analysis in a timely or accurate manner or improperly disclosing data prematurely or otherwise in violation of a clinical trial protocol; or
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or by other regulatory agencies or health authorities that have jurisdiction in countries in which the trial is being conducted. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory agencies resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a pharmaceutical, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Certain of our scientific advisors or consultants who receive compensation from us are likely to be investigators for our future clinical trials. Under certain circumstances, we may be required to report some of these relationships to the FDA or other regulatory agencies. The FDA or other regulatory agencies may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or other regulatory agencies and may ultimately lead to the denial of marketing approval of itolizumab (EQ001) in one or more indications. If we experience delays in the completion of, or termination of, any clinical trial of itolizumab (EQ001), the commercial prospects of itolizumab (EQ001) will be harmed, and our ability to generate product revenues will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our development and approval process and jeopardize our ability to commence product sales and generate revenues which may harm our business, financial condition, results of operations and prospects significantly.

If we experience delays or difficulties in enrolling patients in our ongoing or planned clinical trials, our receipt of necessary regulatory approval could be delayed or prevented.*

We may not be able to continue our ongoing or initiate our future clinical trials for itolizumab (EQ001) if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA. Multiple factors could contribute to such challenges of enrolling our clinical trials, including impacts related to the COVID-19 pandemic, which have already adversely impacted enrollment across all three of our current clinical trials. One of the indications that we are pursuing, aGVHD, is an acute and life-threatening condition which may make it difficult to enroll patients in clinical trials. Enrollment in the Phase 1b portion of our aGVHD clinical trial has been progressing slower than expected due to longer site activation timelines at academic centers, a smaller number of available severe aGVHD patients as defined by Grade III-IV aGVHD, which constitutes a smaller portion of the overall aGVHD population, and higher screen failure rates due to comorbid conditions in this severe aGVHD population. In addition, some of our competitors may have ongoing clinical trials for product candidates that would treat the same indications as itolizumab (EQ001), and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates. This is acutely relevant for our development of itolizumab (EQ001) for the treatment of patients with uncontrolled moderate to severe asthma and lupus nephritis, and for our future potential development of itolizumab (EQ001) for the treatment of patients with COVID-19, each diseases for which there is significant competition for clinical trial subjects. Patient enrollment is also affected by other factors, including:

- impacts and risks associated with global health epidemics such as those related to COVID-19;
- severity of the disease under investigation;
- our ability to recruit clinical trial investigators of appropriate competencies and experience;
- invasive procedures required to obtain evidence of the product candidate's performance during the clinical trial;
- availability and efficacy of approved medications for the disease under investigation;
- eligibility criteria defined in the protocol for the trial in question;
- the size of the patient population required for analysis of the trial's primary endpoints;
- perceived risks and benefits;
- efforts to facilitate timely enrollment in clinical trials;

- reluctance of physicians to encourage patient participation in clinical trials;
- the ability to monitor patients adequately during and after treatment;
- our ability to obtain and maintain patient consents; and
- proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll and retain a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs, which would cause the value of our company to decline and limit our ability to obtain additional financing.

Adverse side effects or other safety risks associated with itolizumab could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon further development, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.*

As is the case with pharmaceuticals generally, it is likely that there may be side effects and adverse events associated with itolizumab in our ongoing and future clinical trials. In the Phase 1 clinical trial of itolizumab (EQ001) conducted by Biocon in Australia in healthy subjects, there were no serious adverse events, dose limiting toxicities, or study drug discontinuations reported in stage 1 of this trial, where doses up to 3.2 mg/kg were administered subcutaneously. The trial also included a separate stage to compare the pharmacokinetics of the intravenous administration of itolizumab (EQ001) to ALZUMAb and determine the absolute bioavailability of subcutaneous itolizumab (EQ001), but this stage was terminated early due to the occurrence of an initial decrease in lymphocyte counts and the occurrence of transient lymphopenia in the healthy subjects. No serious adverse events were reported in either stage of the Phase 1 trial.

Biocon has completed four clinical studies of ALZUMAb in India in patients with rheumatoid arthritis, chronic plaque psoriasis, and for the treatment of SARS-COV-2 pneumonia at dose levels ranging from 0.2 mg/kg to 1.6 mg/kg. Additional patients have received itolizumab in clinical studies in subjects with rheumatoid arthritis, psoriasis, and Type I diabetes conducted in Cuba. In Biocon’s Phase 3 clinical trials, infusion-related reactions and infusion-related events were the main adverse events attributed to itolizumab. There were five serious adverse events reported including exfoliative dermatitis (widespread redness and peeling of the skin), erythrodermic (severe) psoriasis, infusion-related reaction, adjustment disorder with anxiety, and bacterial arthritis. Post-market safety surveillance of ALZUMAb has collected non- serious reports, primarily involving the dermatologic system organ class that have included rash, acne, urticaria, increased pruritus (itching) and increased psoriasis. Serious reports have included infusion reaction, type 1 hypersensitivity, diarrhea and urticaria (hives). Through the date of the filing of this Quarterly Report on Form 10-Q, there has been no change in the benefit risk profile of itolizumab, which remains favorable.

We are aware of clinical studies conducted and/or supported by Biocon in India and Cuba related to the testing of itolizumab in patients with COVID-19. The preliminary efficacy results from the Biocon trial conducted in India suggest a mortality benefit and improvement in clinical status in patients receiving itolizumab. Based on this trial, Biocon received approval from the Drugs Controller General of India to market ALZUMAb for emergency use in India for the treatment of CRS in moderate to severe ARDS patients due to COVID-19. The Cuban COVID-19 study with itolizumab was an uncontrolled study and so interpretation of the efficacy results are limited. The preliminary safety findings of both studies indicate that there has been no change in the benefit risk profile of itolizumab, which remains favorable. We are further aware that Biocon is supporting compassionate use of ALZUMAb in treatment refractory patients with aGVHD in India.

At this point, we are not aware of any safety findings or adverse events attributed to the use of ALZUMAb in patients with COVID-19 or in treatment refractory patients with aGVHD. Biocon may continue to support use of ALZUMAb in aGVHD or other indications over which we have no control. Although itolizumab (EQ001) and ALZUMAb share the same primary monoclonal antibody sequence, they are manufactured in different cell lines and thus could be considered different biopharmaceutical products. Therefore, clinical results seen with ALZUMAb may have no bearing on results, including adverse events, that may be seen with itolizumab (EQ001).

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. Undesirable side effects caused by itolizumab (EQ001) could result in the delay, suspension or termination of clinical trials by us or the FDA for a number of reasons. Additionally, a material percentage of patients in our ongoing aGVHD and planned COVID-19 clinical trials may die from those respective diseases, possibly as a result of itolizumab (EQ001), which could impact development of itolizumab (EQ001). If we elect or are required to delay, suspend or terminate any clinical trial, the commercial prospects of itolizumab (EQ001) will be harmed and our ability to generate product revenues from this product candidate will be delayed or eliminated. Serious adverse events observed in clinical trials could hinder or prevent market acceptance of itolizumab (EQ001). Any of these occurrences may harm our business, prospects, financial condition and results of operations significantly.

Moreover, if itolizumab (EQ001) is associated with undesirable side effects in clinical trials or has characteristics that are unexpected, we may elect to abandon or limit its development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for itolizumab (EQ001), if approved. We may also be required to modify our study plans based on findings in our clinical trials. Many biologics that initially showed promise in early stage testing have later been found to cause side effects that prevented further development. In addition, regulatory authorities may draw different conclusions or require additional testing to confirm these determinations.

It is possible that as we test itolizumab (EQ001) in larger, longer and more extensive clinical trials, including with different dosing regimens, or as the use of itolizumab (EQ001) becomes more widespread following any regulatory approval, illnesses, injuries, discomforts and other adverse events that were observed in earlier trials, as well as conditions that did not occur or went undetected in previous trials, will be reported by patients. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition, results of operations and prospects significantly.

In addition, if itolizumab (EQ001) receives marketing approval, and we or others later identify undesirable side effects caused by itolizumab (EQ001) or ALZUMAb, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approval of itolizumab (EQ001);
- we may be required to recall a product or change the way itolizumab (EQ001) is administered to patients;
- regulatory authorities may require additional warnings on the label, such as a “black box” warning or a contraindication, or issue safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- we may be required to implement a Risk Evaluation and Mitigation Strategy, or REMS, or create a medication guide outlining the risks of such side effects for distribution to patients;
- additional restrictions may be imposed on the marketing or promotion of the particular product or the manufacturing processes for the product or any component thereof;
- we could be sued and held liable for harm caused to patients;
- itolizumab (EQ001) could become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of itolizumab (EQ001), if approved, and could significantly harm our business, financial condition, results of operations and prospects.

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

From time to time, we may publicly disclose preliminary or topline data from our clinical studies, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical studies. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses, or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is the material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular biopharmaceutical product, biopharmaceutical product candidate or our business. If the topline data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, itolizumab (EQ001) or any future product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

A Phase 1 single ascending dose clinical trial of itolizumab (EQ001) in normally healthy volunteers was conducted by Biocon in Australia, we have initiated a Phase 1b proof-of-concept clinical trial of itolizumab (EQ001) in uncontrolled moderate to severe asthma patients in Australia and New Zealand, and we may conduct additional clinical trials of itolizumab (EQ001) outside of the United States. However, the FDA may not accept data from such trials conducted outside the United States, in which case our development plans will be delayed, which could materially harm our business.*

In the fourth quarter of 2017, Biocon completed a Phase 1 clinical trial of itolizumab (EQ001) in healthy subjects in Australia to assess the safety and tolerability of the subcutaneous version of itolizumab (EQ001). The trial also included a separate stage to compare the pharmacokinetics of the intravenous administration of itolizumab (EQ001) to ALZUMAb and determine the absolute bioavailability of subcutaneous itolizumab (EQ001), but this stage was terminated early due to the occurrence of an initial decrease in lymphocyte counts and the occurrence of transient lymphopenia in the healthy subjects. We submitted this data to the FDA as part of our IND submissions for the conduct of clinical trials for the treatment of aGVHD and lupus nephritis. However, it is possible that the FDA will not authorize us to proceed with clinical studies in connection with any future IND submissions in other indications that have different patient populations, including for the treatment of COVID-19 patients, and we may be required to conduct additional Phase 1 clinical trials, which would be costly and time consuming, and delay aspects of our development plan, which could harm our business.

In June 2019, we initiated a Phase 1b, multiple ascending dose escalation, proof-of-concept clinical trial of itolizumab (EQ001) in uncontrolled moderate to severe asthma in Australia and have initiated sites in Australia and New Zealand. In March 2020, as a result of impacts and risks associated with the COVID-19 pandemic, we decided to pause enrollment in our Phase 1b clinical trials of itolizumab (EQ001) in uncontrolled asthma and lupus nephritis. In July 2020, we announced that patient enrollment in both of those trials had resumed. Although the FDA may accept data from clinical trials conducted entirely outside the United States and not under an IND, acceptance of such study data is generally subject to certain conditions. For example, the FDA requires the clinical trial to have been conducted in accordance with GCPs, and the FDA must be able to validate the data from the clinical trial through an onsite inspection if it deems such inspection necessary. In addition, when studies are conducted only at sites outside of the United States, the FDA generally does not provide advance comment on the clinical protocols for the studies, and therefore there is an additional potential risk that the FDA could determine that the study design or protocol for a non-U.S. clinical trial was inadequate, which would likely require us to conduct additional clinical trials. Conducting clinical trials outside the United States also exposes us to additional risks, including risks associated with:

- additional foreign regulatory requirements;
- foreign exchange fluctuations;
- compliance with foreign manufacturing, customs, shipment and storage requirements;
- cultural differences in medical practice and clinical research; and
- diminished protection of intellectual property in some countries.

We conduct significant operations through our Australian wholly-owned subsidiary. If we lose our ability to operate in Australia, or if our subsidiary is unable to receive the research and development tax credit allowed by Australian regulations, our business and results of operations will suffer.

In January 2019, we formed a wholly-owned Australian subsidiary, Equillium Australia Pty Ltd, to conduct the clinical development of itolizumab (EQ001) for the treatment of uncontrolled asthma in Australia and New Zealand. Due to the geographical distance and lack of employees currently in Australia, as well as our lack of experience operating in Australia, we may not be able to efficiently or successfully monitor, develop or commercialize itolizumab (EQ001) in Australia and New Zealand, including conducting clinical trials. Furthermore, we have no assurance that the results of any clinical trials that we conduct for our product candidate in Australia and New Zealand will be accepted by the FDA or other foreign regulatory authorities for development and commercialization approvals.

In addition, current Australian tax regulations provide for a refundable research and development tax credit. If we lose our ability to operate Equillium Australia Pty Ltd in Australia, or if we are ineligible or unable to receive the research and development tax credit, or the Australian government significantly reduces or eliminates the tax credit, our business and results of operations would be adversely affected.

We may not be successful in our efforts to expand our pipeline by identifying additional indications for which to test itolizumab (EQ001) in the future. We may expend our limited resources to pursue a particular indication for itolizumab (EQ001), for example in COVID-19 patients, and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.*

Our translational biology program may initially show promise in identifying additional indications for which itolizumab (EQ001) may have therapeutic benefit, yet this may fail to yield additional clinical development opportunities for itolizumab (EQ001) for a number of reasons, including, itolizumab (EQ001) may, on further study, be shown to have harmful side effects, limited to no efficacy or other characteristics that indicate that it is unlikely to receive marketing approval and achieve market acceptance in such additional indications. Research programs to identify additional indications for itolizumab (EQ001) require substantial technical, financial and human resources.

Because we have limited financial and managerial resources, we must prioritize our research programs and will need to focus itolizumab (EQ001) development on the potential treatment of certain indications. As a result, we may forego or delay pursuit of opportunities with other indications or for any future 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 itolizumab (EQ001) for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for itolizumab (EQ001) or any future product candidate, we may also 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.

Even if we receive regulatory approval for itolizumab (EQ001) or any future product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, itolizumab (EQ001) and any future product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

Any regulatory approvals that we receive for itolizumab (EQ001) or any future product candidates may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA approves any product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and record keeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMPs and GCPs, for any clinical trials that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, undesirable side effects caused by the product, problems encountered by our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, either before or after product approval, may result in, among other things:

- restrictions on the marketing or manufacturing of the product;
- requirements to include additional warnings on the label;
- requirements to create a medication guide outlining the risks to patients;
- withdrawal of the product from the market;

- voluntary or mandatory product recalls;
- requirements to change the way the product is administered or for us to conduct additional clinical trials;
- fines, warning letters or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us or our strategic partners, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- harm to our reputation.

Additionally, if any product candidate receives marketing approval, the FDA could require us to adopt a REMS to ensure that the benefits of the therapy outweigh its risks, which may include, among other things, a medication guide outlining the risks for distribution to patients and a communication plan to health care practitioners. Any of these events could prevent us from achieving or maintaining market acceptance of the product or the particular product candidate at issue and could significantly harm our business, prospects, financial condition and results of operations.

In addition, if we have any product candidate approved, our product labeling, advertising and promotion will be subject to regulatory requirements and continuing regulatory review. The FDA strictly regulates the promotional claims that may be made about biopharmaceutical products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. However, companies may share truthful and not misleading information that is otherwise consistent with a product's FDA approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of itolizumab (EQ001) or any future 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, which would adversely affect our business, prospects, financial condition and results of operations.

Even if itolizumab (EQ001) receives marketing approval in any indication, it may fail to achieve the degree of market acceptance by physicians, patients, hospitals, cancer treatment centers, healthcare payors and others in the medical community necessary for commercial success.

If itolizumab (EQ001) receives marketing approval in any one or more indication, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If itolizumab (EQ001) does 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 itolizumab (EQ001), if approved for commercial sale in any indication, will depend on a number of factors, including:

- efficacy and potential advantages compared to alternative treatments;
- our ability to offer itolizumab (EQ001) for sale at competitive prices;
- 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 strength of marketing and distribution support;

- potential product liability claims;
- the timing of market introduction of itolizumab (EQ001) as well as competitive biopharmaceutical products;
- the effectiveness of our or any of our potential future sales and marketing strategies;
- unfavorable publicity relating to itolizumab (EQ001);
- sufficient third-party payor coverage and adequate reimbursement;
- the willingness of patients to pay all, or a portion of, out-of-pocket costs associated with our products in the absence of sufficient third-party coverage and adequate reimbursement; and
- the prevalence and severity of any side effects.

We currently have no marketing and sales organization and have no experience as a company in commercializing products, and we may have to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell itolizumab (EQ001), we may not be able to generate product revenue.

We have no internal sales, marketing or distribution capabilities, nor have we commercialized a product. If itolizumab (EQ001) ultimately receives regulatory approval, we may not be able to effectively market and distribute it. We may have to seek collaborators or invest significant amounts of financial and management resources to develop internal sales, distribution and marketing capabilities, some of which will be committed prior to any confirmation that itolizumab (EQ001) will be approved, if at all. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenues and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute itolizumab (EQ001) ourselves. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market itolizumab (EQ001) effectively. Even if we determine to perform sales, marketing and distribution functions ourselves, we could face a number of additional related risks, including:

- we may not be able to attract and build an effective marketing department or sales force;
- the cost of establishing a marketing department or sales force may exceed our available financial resources and the revenue generated by itolizumab (EQ001); and
- our direct sales and marketing efforts may not be successful.

We face substantial competition, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us. If their product candidates are shown to be safer or more effective than ours, then our commercial opportunity will be reduced or eliminated.

The development and commercialization of new products is highly competitive. We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop drugs and biologics for the treatment of immuno-inflammatory diseases. 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, or that would render any products that we may develop obsolete or non-competitive. Our competitors also may obtain 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.

Other products in the same class as itolizumab have already been approved or are further along in development. We are aware of both private and public companies with development programs in aGVHD, including Alpine Immune Sciences, Inc., Bristol-Myers Squibb Company, CSL Behring LLC, Fate Therapeutics, Inc., Incyte Corporation, Takeda Pharmaceutical Company Limited, Jazz Pharmaceuticals plc, Kalytera Therapeutics, Inc., Kamada Ltd., Mesoblast Limited, and Xenikos B.V. Major, currently marketed asthma therapies include several biologic therapies that specifically target IgE or T_h 2-mediated cytokines including products developed by AstraZeneca plc, GlaxoSmithKline plc, Sanofi-Genzyme, Novartis AG, Regeneron Pharmaceuticals, Inc., Roche Holding AG and Teva Pharmaceutical Industries Limited. In addition, Regeneron Pharmaceuticals, Inc. and Sanofi-Aventis U.S. LLC have received approval for dupilimab, an anti-IL-4 receptor antibody, as an add-on maintenance treatment in patients with moderate to severe asthma aged 12 years and older with an eosinophilic phenotype or with oral corticosteroid dependent asthma. We are aware of several companies with

development programs in moderate to severe asthma, including Amgen Inc., AnaptysBio, Inc., AstraZeneca plc, Boehringer Ingelheim GmbH, GlaxoSmithKline plc, Gossamer Bio, Inc., Regeneron Pharmaceuticals, Inc., Roche Holding AG, Sanofi-Aventis U.S. LLC. and Theravance Biopharma, Inc. We are also aware of several companies with development programs targeting lupus nephritis including Alexion Pharmaceuticals, Inc, Apellis Pharmaceuticals, Inc., AstraZeneca plc, Aurinia Pharmaceuticals Inc., Boehringer Ingelheim GmbH, Genentech Inc., Novartis AG, GlaxoSmithKline plc, Kezar Life Sciences, Inc., and Omeros Corporation.

Many of our competitors, such as large pharmaceutical and biotechnology companies like Amgen Inc. and Bristol-Myers Squibb Company have longer operating histories and significantly greater financial resources and expertise in research and development, manufacturing, preclinical studies, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. In addition, these larger companies may be able to use their greater market power to obtain more favorable distribution and sales-related agreements with third parties, which could give them a competitive advantage over us.

Further, as more product candidates within a particular class of biopharmaceutical products proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. Consequently, the results of our clinical trials for product candidates in those classes will likely need to show a risk benefit profile that is competitive with or more favorable than those products and product candidates in order to obtain marketing approval or, if approved, a product label that is favorable for commercialization. If the risk benefit profile is not competitive with those products or product candidates, we may have developed a product that is not commercially viable, that we are not able to sell profitably or that is unable to achieve favorable pricing or reimbursement. In such circumstances, our future product revenues and financial condition would be materially and adversely affected.

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 other 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 subject enrollment for clinical trials, as well as in acquiring technologies complementary to, or necessary for, itolizumab (EQ001) or any future programs.

The key competitive factors affecting the success of itolizumab (EQ001) are likely to be its efficacy, safety, convenience and availability of reimbursement. If we are not successful in developing, commercializing and achieving higher levels of reimbursement than our competitors, we will not be able to compete against them and our business would be materially harmed.

Itolizumab (EQ001) and any future product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively Affordable Care Act, signed into law on March 23, 2010, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor’s own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. 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 biological products.

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. 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 products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. Moreover, the extent to which a biosimilar, 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.

If the U.S. market opportunities for itolizumab (EQ001) are smaller than we believe they are, our revenue may be adversely affected and our business may suffer.*

We only have the rights to itolizumab (EQ001) for the Equillium Territory, and we are focused on the development of itolizumab (EQ001) for immuno-inflammatory diseases, with an initial intention to develop it for the treatment of patients with uncontrolled moderate to severe asthma, aGVHD, lupus nephritis, and COVID-19. Our projections of addressable patient populations in the Equillium Territory that have the potential to benefit from treatment with itolizumab (EQ001) are based on estimates and may prove to be incorrect. If any of our estimates are inaccurate, the market opportunities for itolizumab (EQ001) could be significantly diminished and have an adverse material impact on our business.

We may not ultimately realize the potential benefits of orphan drug designation for itolizumab (EQ001).

We received orphan drug designations for itolizumab (EQ001) for both the prevention and treatment of aGVHD. The FDA grants orphan designation to drugs that are intended to treat rare diseases with fewer than 200,000 patients in the United States or that affect more than 200,000 persons but are not expected to recover the costs of developing and marketing a treatment drug. Orphan drugs do not require prescription drug user fees with a marketing application, may qualify the drug development sponsor for certain tax credits, and may be eligible for a market exclusivity period of seven years (with certain exceptions). However, orphan drug designation neither shortens the development time nor regulatory review time of a product candidate nor gives the candidate any advantage in the regulatory review or approval process. Even if we are awarded marketing exclusivity, the FDA can still approve another drug containing the same active ingredient and used for the same orphan indication if it determines that a subsequent drug is safer, more effective or makes a major contribution to patient care, and orphan exclusivity can be lost if the orphan drug manufacturer is unable to assure that a sufficient quantity of the orphan drug is available to meet the needs of patients with the rare disease or condition. Orphan drug exclusivity may also be lost if the FDA later determines that the initial request for designation was materially defective. In addition, orphan drug exclusivity does not prevent the FDA from approving competing drugs for the same or similar indication containing a different active ingredient. If orphan drug exclusivity is lost and we were unable to successfully enforce any remaining patents covering our eligible product candidates, we could be subject to biosimilar competition earlier than we anticipate. In addition, if a subsequent drug is approved for marketing for the same or a similar indication as itolizumab (EQ001), we may face increased competition and lose market share regardless of orphan drug exclusivity.

Fast track designation by the FDA may not actually lead to a faster development or regulatory review or approval process.

We have received fast track designation for itolizumab (EQ001) for the treatment of aGVHD and lupus nephritis. If a product is intended for the treatment of a serious or life-threatening condition and the product demonstrates the potential to address unmet medical needs for this condition, the product sponsor may apply for FDA fast track designation. Even with 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.

Risks Related to Manufacturing and Our Reliance on Third Parties

The manufacture of biologics is complex and Biocon, our third-party manufacturer, may encounter difficulties in production, distribution and delivery of such biologics. If Biocon encounters such difficulties, our ability to provide supply of itolizumab (EQ001) for clinical trials, our ability to obtain marketing approval, or our ability to obtain commercial supply of our products, if approved, could be delayed or stopped.*

We have no experience in biologic manufacturing and do not own or operate, and we do not expect to own or operate, facilities for product manufacturing, storage and distribution, or testing. We are completely dependent on Biocon to fulfill our clinical and commercial supply of itolizumab (EQ001). In May 2017, we entered into an exclusive clinical supply agreement with Biocon and have agreed to enter into an exclusive commercial supply agreement with Biocon in the future. Biocon manufactures itolizumab (EQ001) at its FDA regulated facility in Bangalore, India. However, the process of manufacturing biologics is complex, highly-regulated and subject to multiple risks. Manufacturing biologics is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects and other supply disruptions and higher costs. If microbial, viral or other contaminations are discovered at the facilities of our manufacturer, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials, result in higher costs of drug product and adversely harm our business. In addition, if the facilities of our manufacturer are located outside of the United States, as is the case for itolizumab (EQ001), the production, distribution and delivery of biologics is also subject to the laws and regulations of the country. Any changes in the laws and regulations of another country could delay clinical trials, result in higher costs of drug product and adversely harm our business. Moreover, if the FDA determines that our manufacturer is not in compliance with FDA laws and regulations, including those governing cGMPs, the FDA may deny BLA approval until the deficiencies are corrected or we replace the manufacturer in our BLA with a manufacturer that is in compliance.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with cGMPs, lot consistency and timely availability and delivery of raw materials. Even if we obtain regulatory approval for itolizumab (EQ001) or any future product candidates, there is no assurance that Biocon or other potential manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product or to meet potential future demand. Further, our third-party manufacturers may experience manufacturing or shipping difficulties due to resource constraints or as a result of natural disasters, labor disputes, unstable political environments, or public health epidemics such as the recent COVID-19 outbreak. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

Scaling up a biologic manufacturing process is a difficult and uncertain task, and Biocon may not have the necessary capabilities to complete the implementation and development process of further scaling up production, transferring production to other sites, or managing its production capacity to timely deliver our supplies of itolizumab (EQ001) (or other biologics) or meet product demand. For example, in March 2020, due to the spread of the coronavirus, the Indian government restricted the export of 26 active pharmaceutical ingredients and the medicines made from them. These export restrictions are indefinite and may be expanded. If the export restrictions are expanded to include itolizumab (EQ001), our supply of itolizumab (EQ001) may be disrupted, delayed or stopped indefinitely and our ability to continue development of itolizumab (EQ001), including our ongoing clinical trials, may be significantly impacted and may result in higher costs of drug product and adversely harm our business. If Biocon is unable to meet our manufacturing requirements (due to export restrictions or otherwise), it has the discretion to outsource manufacturing to a third party and the joint steering committee may determine to shift manufacturing to a third party. However, transfer of the manufacturing of biologic products to a new contract manufacturer can be lengthy and involve significant additional costs. Even if we are able to adequately validate and scale-up the manufacturing process for itolizumab (EQ001) with a contract manufacturer, we will still need to negotiate with such contract manufacturer an agreement for commercial supply and it is not certain we will be able to come to agreement on terms acceptable to us, if at all. In addition, Biocon has certain rights to reacquire exclusive manufacturing rights for itolizumab (EQ001), even after a third party has been engaged following shortfalls by Biocon, which will may make it difficult and expensive to engage any third party manufacturer for itolizumab (EQ001) other than Biocon.

We rely, and intend to continue to rely, on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties, fail to comply with applicable regulatory requirements or meet expected deadlines, our development programs may be delayed or subject to increased costs or we may be unable to obtain regulatory approval, each of which may have an adverse effect on our business, financial condition, results of operations and prospects.*

We do not have the ability to independently conduct all aspects of our preclinical testing or clinical trials ourselves. As a result, we are and will be dependent on third parties to conduct our ongoing and future clinical trials of itolizumab (EQ001) and preclinical studies, and any future preclinical studies and clinical trials of any other product candidates. The timing of the initiation and completion of these trials will therefore be partially controlled by such third parties and may result in delays to our development programs. Specifically, we expect CROs, clinical investigators and consultants to play a significant role in the conduct of these trials and the subsequent collection and analysis of data. However, we will not be able to control all aspects of their activities. Nevertheless, we are responsible for ensuring that each clinical trial is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on the CROs and other third parties does not relieve us of our regulatory responsibilities. We and our CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, for product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, clinical trial investigators and clinical trial sites. If we or any of our CROs or clinical trial sites fail to comply with applicable GCP requirements, the data generated in our clinical trials may be deemed unreliable, and the FDA may require us to perform additional clinical trials before approving our marketing applications. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to stop and/or repeat clinical trials, which would delay the marketing approval process.

There is no guarantee that any such CROs, clinical trial investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise performs in a substandard manner, or terminates its engagement with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If our clinical trial site terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trial unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible. In addition, clinical trial investigators for our clinical trial may serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any marketing application we submit by the FDA. Any such delay or rejection could prevent us from commercializing itolizumab (EQ001) or any future product candidates.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors for whom they may also be conducting clinical trials or other biopharmaceutical product development activities that could harm our competitive position. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for itolizumab (EQ001) or any future product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our products.

Even if we receive marketing approval, we may not be able to successfully commercialize itolizumab (EQ001) due to unfavorable pricing regulations or third-party coverage and reimbursement policies, which could make it difficult for us to sell itolizumab (EQ001) or any future product candidates profitably.*

Obtaining coverage and adequate reimbursement approval for a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost effectiveness data for the use of itolizumab (EQ001) or other future products to the payor. There may be significant delays in obtaining such coverage and reimbursement for newly approved products, and coverage may be more limited than the purposes for which the product is approved by the FDA. Moreover, eligibility for coverage and reimbursement does not imply that a product will be paid for in all cases or at a rate that covers our costs, including research, development, intellectual property, manufacture, sale and distribution expenses. Interim reimbursement levels for new products, 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 product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors, by any future laws limiting pharmaceutical prices and by any future relaxation of laws that presently restrict imports of product from countries where they may be sold at lower prices than in the United States.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting reimbursement policies, but also have their own methods and approval process apart from Medicare coverage and reimbursement determinations. Decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop will be made on a payor-by-payor basis. One third-party payor's determination to provide coverage for a drug does not assure that other payors will also provide coverage and adequate reimbursement for the drug. Additionally, a third-party payor's decision to provide coverage for a therapy does not imply that an adequate reimbursement rate will be approved. Third-party payors are increasingly challenging the price, examining the medical necessity and reviewing the cost-effectiveness of medical products, therapies and services, in addition to questioning their safety and efficacy.

Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;

- cost-effective; and
- neither experimental nor investigational.

We cannot be sure that coverage or reimbursement will be available for any product that we commercialize and, if coverage and reimbursement are available, what the level of reimbursement will be. Obtaining adequate reimbursement for our products may be particularly difficult because of the higher prices often associated with branded therapeutics and therapeutics administered under the supervision of a physician. Similarly, because our product candidates are physician-administered injectables, separate reimbursement for the product itself may or may not be available. Instead, the administering physician may be reimbursed for providing the treatment or procedure in which our product is used. Our inability to promptly obtain coverage and adequate reimbursement 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.

Reimbursement may impact the demand for, and the price of, any product for which we obtain marketing approval. Assuming we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Each third-party payor determines whether or not it will provide coverage for a therapy, what amount it will pay the manufacturer for the therapy and on what tier of its list of covered drugs, or formulary, it will be placed. The position on a third-party payor's formulary, generally determines the co-payment that a patient will need to make to obtain the therapy and can strongly influence the adoption of such therapy by patients and physicians. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to reimburse all or part of the costs associated with those medications. Patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement is critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Additionally, if we or our collaborators develop companion diagnostic tests for use with itolizumab (EQ001), such tests will be subject to the coverage and reimbursement process separate and apart from the coverage and reimbursement we seek for our itolizumab (EQ001).

We expect to experience pricing pressures in connection with the sale of itolizumab (EQ001) or any future product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription medicines, medical devices and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the successful commercialization of new products. Further, the adoption and implementation of any future governmental cost containment or other health reform initiative may result in additional downward pressure on the price that we may receive for any approved product.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to research and develop and to manufacture itolizumab (EQ001), we must share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's independent discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with will likely expect to be granted rights to publish data arising out of such collaboration and any joint research and development programs may require us to share trade secrets under the terms of our research and development or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

We may wish to acquire rights to future assets through in-licensing or may attempt to form collaborations in the future with respect to future product candidates, but may not be able to do so, which may cause us to alter or delay our development and commercialization plans.

The development and potential commercialization of itolizumab (EQ001) and any future product candidates will require substantial additional capital to fund expenses. We may, in the future, decide to collaborate with biotechnology companies for the development and potential commercialization of product candidates. We will face significant competition in seeking appropriate collaborators. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for any product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view such product candidates as having the requisite potential to demonstrate safety and efficacy. If and when we collaborate with a third party for development and commercialization of a product candidate, we can expect to relinquish some or all of the control over the future success of that product candidate to the third party. Our ability to 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 following:

- the design or results of clinical trials;
- the likelihood of approval by the FDA or comparable foreign regulatory authorities;
- the potential market for the product candidate;
- the costs and complexities of manufacturing and delivering such product candidate to patients;
- the potential of competing products;
- the existence of uncertainty with respect to our ownership of technology or other rights, which can exist if there is a challenge to such ownership without regard to the merits of the challenge; and
- industry and market conditions generally.

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. We may also be restricted under any license agreements from entering into agreements on certain terms or at all 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 and changes to the strategies of the combined company. As a result, 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 such product candidate, reduce or delay one or more of our other development programs, delay the potential commercialization or reduce the scope of any planned sales or marketing activities for such product candidate, or increase our expenditures and undertake development, manufacturing or commercialization activities at our own expense. If we elect to increase our expenditures to fund development, manufacturing 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 future product candidates or bring them to market and generate product revenue. Even if we are successful in our efforts to establish such collaborations, the terms that we agree upon may not be favorable to us, and we may not be able to maintain such collaborations if, for example, development approval of a product candidate is delayed, the safety of a product candidate is questioned or sales of an approved product candidate are unsatisfactory.

Risks Related to Intellectual Property

If we are unable to obtain or protect intellectual property rights covering our product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and we may not be able to compete effectively in our market.

Our success depends in significant part on our and Biocon's ability to establish, maintain and protect patents and other intellectual property rights with respect to our proprietary technologies, research programs, and product candidates, including itolizumab, and operate without infringing the intellectual property rights of others. The patent prosecution process is expensive and time-consuming, and we and our current or future licensors, licensees or partners may not be able to prepare, file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we or our current and future licensors, licensees or partners will fail to identify patentable aspects of our research or inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Although we enter into confidentiality agreements with parties who have access to patentable aspects of our research and development programs, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, independent contractors, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection on technology relating to our research programs. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license from or license to third parties and are reliant on our licensors, licensees or partners. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. If our current or future licensors, licensees or partners fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our licensors, licensees or partners are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. There may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns.

The patent position of biotechnology companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation, resulting in court decisions, including Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States, allowing foreign competitors a better opportunity to create, develop and market competing product candidates, or vice versa. We cannot be certain that the claims in our pending patent applications directed to our product candidates such as itolizumab and others, as well as technologies relating to our research programs, will be considered patentable by the United States Patent and Trademark Office, or USPTO, or by patent offices in foreign countries. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. As a result, the issuance, scope, validity, enforceability and commercial value of our and our current or future licensors', licensees' or partners' patent rights are highly uncertain. Our and our licensors', licensees' or partners' pending and future patent applications may not result in patents being issued, which protect our technology or products, in whole or in part, or their intended uses, methods of manufacture or formulations, or which effectively prevent others from commercializing competitive technologies and products. The patent examination process may require us or our licensors, licensees or partners to narrow the scope of the claims of our or our licensors', licensees' or partners' pending and future patent applications, which may limit the scope of patent protection that may be obtained. In the past, we have not always been able to obtain the full scope of patent protection we have initially sought in our patent applications, and as described above and as is typical for most biotechnology patent prosecution, we have been required to narrow or eliminate patent claims as part of the patent prosecution process. In addition, some patent applications that we or our licensors have filed have not resulted in issued patents because we or our licensors have abandoned those patent applications as changes in business and/or legal strategies dictated.

We cannot assure you that all of the potentially relevant prior art—information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention—relating to our patents and patent applications has been found. If such prior art exists, it can invalidate a patent or prevent a patent from issuing from a pending patent application, and we may be subject to a third party pre-issuance submission of prior art to the USPTO. Even if patents do successfully issue and even if such patents cover our product candidates, third parties may initiate litigation or opposition, interference, re-examination, post-grant review, inter partes review, nullification or derivation action in court or before patent offices, or similar proceedings challenging the validity, enforceability or scope of such patents, which may result in the patent claims being narrowed or invalidated, may allow third parties to commercialize our product candidates and compete directly with us, without payment to us, or limit the duration of the patent protection of our technology and products. The legal

threshold for initiating such proceedings may be low, so that even proceedings with a low probability of success might be initiated. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Our and our licensors', licensees' or partners' patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications, and then only to the extent the issued claims cover the technology.

Because patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we or our licensors were the first to file any patent application related to our research programs and product candidates such as itolizumab. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing our invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license. In addition, patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from competitive medications, including biosimilar or generic medications.

If we are not able to obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of our marketing exclusivity for itolizumab or any other product candidates that we may identify, our business may be materially harmed.

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. We expect to seek extensions of patent terms where these are available in any countries where we are prosecuting patents. This includes in the United States under the Drug Price Competition and Patent Term Restoration Act of 1984, or Hatch-Waxman Act, which permits a patent term extension of up to five years beyond the expiration of the patent. The Hatch-Waxman Act allows a maximum of one patent to be extended per FDA-approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates. However, the applicable authorities, including the FDA and USPTO, in the United States, and any equivalent foreign regulatory authority, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

The degree of future protection for our proprietary rights is uncertain, and we cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will provide protection against competitors;
- whether any of the patents we own or license will be found to ultimately be valid and enforceable;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether the patents of others will not have an adverse effect on our business;
- whether we will develop additional proprietary technologies or products that are separately patentable;

- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose; and/or
- whether the patent applications that we own or in-license will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries.

We depend on intellectual property licensed from Biocon and termination of our license could result in the loss of significant rights, which would harm our business.

We currently in-license certain intellectual property that is important to our business from Biocon and, in the future, we may enter into additional agreements that provide us with licenses to valuable intellectual property or technology. We rely to some extent on Biocon to file patent applications and to otherwise protect the intellectual property we license from them. We have limited control over these activities or any other intellectual property that may be related to our in-licensed intellectual property. For example, we cannot be certain that such activities by Biocon have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents and other intellectual property rights. We have limited control over the manner in which Biocon initiates an infringement proceeding against a third-party infringer of the intellectual property rights, or defend certain of the intellectual property that is licensed to us. It is possible that our licensor's infringement proceeding or defense activities may be less vigorous than had we conducted them ourselves.

Furthermore, in-licensed patents may be subject to a reservation of rights by one or more third parties. Further, our existing license with Biocon imposes, and future agreements may also impose, various diligence, milestone payment, royalty, insurance and other obligations on us. If we fail to comply with these obligations, we may be required to pay damages and our licensor may have the right to terminate the license, in which event we would not be able to develop or market the products covered by such licensed intellectual property and our competitors or other third parties might be able to gain access to technologies and products that are identical to ours. Our business would suffer if any current or future licenses terminate, if the licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Furthermore, if any current or future licenses terminate, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties may gain the freedom to seek regulatory approval of, and to market, products identical to ours. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights. Disputes may also arise between us and our licensor regarding intellectual property subject to a license agreement, including those relating to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the license agreement;
- our right to sublicense patent and other rights to third parties under collaborative development relationships;
- whether we are complying with our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates; and
- the allocation of ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and by us and our partners.

In addition, intellectual property or technology license agreements, including our existing agreements, are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. If disputes over intellectual property 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. We are generally also subject to all of the same risks with respect to protection of intellectual property that we license as we are for intellectual property that we own, which are described below. If we or our licensor fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

Because our programs may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license or use these proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

In the future, we may need to obtain additional licenses of third-party technology that may not be available to us or are available only on commercially unreasonable terms, and which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.

From time to time we may be required to license technologies relating to our therapeutic research programs from additional third parties to further develop or commercialize our product candidates such as itolizumab and/or others. Should we be required to obtain licenses to any third-party technology, including any such patents required to manufacture, use or sell our product candidates, such licenses may not be available to us on commercially reasonable terms, or at all. The inability to obtain any third-party license required to develop or commercialize any of our product candidates could cause us to abandon any related efforts, which could seriously harm our business and operations.

Any collaboration arrangements that we may enter into in the future may not be successful, which could adversely affect our ability to develop and commercialize our products.

Any future collaborations 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. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our products or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our current or future products or that results in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future products;

- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third party patent, which might adversely affect our ability to develop and market our products.

We cannot assure you that our operations do not, or will not in the future, infringe existing or future patents. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third party patent and pending application in the United States and abroad that is relevant to our therapeutic research programs or necessary for the commercialization of our product candidates such as itolizumab and/or others in any jurisdiction.

Numerous U.S. and foreign patents and pending patent applications exist in our market that are owned by third parties, and there may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of itolizumab that we may identify. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our products. We do not always conduct independent reviews of pending patent applications of and patents issued to third parties. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain U.S. applications that will not be filed outside the United States can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our products or the use of our products. As such, there may be applications of others now pending or recently revived patents of which we are unaware, potentially relating to our research programs and product candidates such as itolizumab and others, or their intended uses. These applications may later result in issued patents, or the revival of previously abandoned patents, that will prevent, limit or otherwise interfere with our ability to make, use or sell our products.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our product candidates. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

We cannot provide any assurances that third party patents do not exist which might be enforced against our current technology, including our research programs, product candidates, which include itolizumab and others, their respective methods of use, manufacture and formulations thereof, and could result in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell itolizumab and other potential future product candidates without infringing the intellectual property and other proprietary rights of third parties. Third parties may allege that we have infringed or misappropriated their intellectual property. Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and, even if resolved in our favor, is likely to divert significant resources from our core business, including distracting 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 market 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. 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 cannot assure you that our operations do not, or will not in the future, infringe existing or future patents.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our product candidates. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates. Third parties may assert infringement claims against us based on existing or future intellectual property rights. The pharmaceutical and biotechnology industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on our business and operations. In addition, we may not have sufficient resources to bring these actions to a successful conclusion. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure.

If we are found to infringe a third party’s intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. 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. 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, and could divert the time and attention of our technical personnel and management, cause development delays, and/or require us to develop non-infringing technology, which may not be possible on a cost-effective basis, 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.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents, trademarks, copyrights or other intellectual property that relate to our current and future product candidates, including itolizumab and others, their respective methods of use, manufacture and formulations thereof. To counter infringement or unauthorized use, we or our licensor may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we or our licensor assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and the outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent that we own or have licensed is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent’s claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. For example, an unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference or derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring itolizumab or other product candidates that we may identify to market. Any of these occurrences could adversely affect our competitive business position, results of operations business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. 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 litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, we cannot assure you that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent relating to our research programs and product candidates, any patents that may be issued as a result of our pending or future patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who previously worked with other companies, including our competitors or potential competitors. We could in the future be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of current or former employers or competitors. Although we try to ensure that our employees, consultants and independent contractors do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may become subject to claims that we caused an individual to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a current or former employer or competitor.

While we may litigate to defend ourselves against these claims, even if we are successful, litigation could result in substantial costs and could be a distraction to management and other employees. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to our product candidates, including itolizumab, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the current or former employers. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition.

Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents relating to our research programs and product candidates. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States or USPTO rules and regulations could increase the uncertainties and costs. Recent patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or the Leahy-Smith Act, signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. 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, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications, our ability to obtain future patents, and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO 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.

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

Filing, prosecuting and defending all current and future patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the United States. These products 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.

The legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights. For example, some foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. In addition, some countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submissions, 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, annuities fees and various other governmental fees on patents and/or patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent and/or patent application. The USPTO and various foreign governmental patent agencies also require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance 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. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering our research programs and product candidates such as itolizumab and others as well as their respective methods of use, manufacture and formulations thereof, our competitive position would be adversely affected, as, for example, competitors might be able to enter the market earlier than would otherwise have been the case.

We may rely on trade secret and proprietary know-how which can be difficult to trace and enforce and, 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 may also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position with respect to our research programs and product candidates. Elements of our product candidates, including processes for their preparation and manufacture, may involve proprietary know-how, information, or technology that is not covered by patents, and thus for these aspects we may consider trade secrets and know-how to be our primary intellectual property. Any disclosure, either intentional or unintentional, by our employees, the employees of third parties with whom we share our facilities or third party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

Trade secrets and know-how can be difficult to protect. We require our employees to enter into written employment agreements containing provisions of confidentiality and obligations to assign to us any inventions generated in the course of their employment. We and any third parties with whom we share facilities enter into written agreements that include confidentiality and intellectual property obligations to protect each party’s property, potential trade secrets, proprietary know-how, and information. We further seek to protect our potential trade secrets, proprietary know-how, and information in part, by entering into non-disclosure and confidentiality agreements with parties who are given access to them, such as our corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. With our consultants, contractors, and outside scientific collaborators, these agreements typically include invention assignment obligations. However, we cannot be certain that such agreements have been entered into with all relevant parties, and we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Moreover, despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. 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.

Trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. Trade secrets will over time be disseminated within the industry through independent development, the publication of journal articles and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors and consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. Because from time to time we expect to rely on third parties in the development, manufacture, and distribution of our products and provision of our services, we must, at times, share trade secrets with them. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be harmed.

We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We or our licensor may be subject to claims that former employees, consultants, independent contractors, collaborators or other third parties have an interest in our patents or other intellectual property as an owner, co-owner, inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship and/or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

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

Patent rights are of limited duration. In the United States, the natural expiration of a patent is generally 20 years after its first effective non-provisional filing date. 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 product candidates are commercialized. Even if patents covering our product candidates are obtained, once the patent life has expired for a product, we may be open to competition from biosimilar or generic products. A patent term extension based on regulatory delay may be available in the United States. However, only a single patent can be extended for each marketing approval, and any patent can be extended only once, for a single product. Moreover, the scope of protection during the period of the patent term extension does not extend to the full scope of the claim, but instead only to the scope of the product as approved. Laws governing analogous patent term extensions in foreign jurisdictions vary widely, as do laws governing the ability to obtain multiple patents from a single patent family. Additionally, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially.

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

We currently have two U.S. trademark registrations for EQUILLIUM respectively covering Classes 5 and 42, and one Canadian trademark registration for EQUILLIUM covering both Classes 5 and 42. Our current or future trademarks or trade names may be challenged, infringed, circumvented or declared generic or descriptive determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively, and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example:

- others may be able to make product candidates that are similar to ours but that are not covered by the claims of the patents that we own or have exclusively licensed;

- we or our licensors or future collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed;
- we or our licensors or future collaborators might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business, financial condition, results of operations and prospects.

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

We are highly dependent on the services of our key personnel.

We are highly dependent on the services of our key personnel, Bruce D. Steel, who serves as our President and Chief Executive Officer, Stephen Connelly, Ph.D., who serves as our Chief Scientific Officer, and Krishna R. Polu, M.D., who serves as our Executive Vice President Research & Development and Chief Medical Officer. Although we have entered into agreements with them regarding their employment, they are not for a specific term and each of them may terminate their employment with us at any time, though we are not aware of any present intention of any of these individuals to leave us.

We expect to expand our development, regulatory and operational capabilities and, as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.*

As of June 30, 2020, we had 22 full-time employees. As we advance itolizumab (EQ001) in clinical development, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development, quality, regulatory affairs and, if itolizumab (EQ001) or any future product candidates receive marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must:

- identify, recruit integrate, maintain and motivate additional qualified personnel;
- identify and lease additional facilities;
- manage our development efforts effectively, including the initiation and conduct of clinical trials for itolizumab (EQ001) and any future product candidates; and
- improve our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to develop, manufacture and commercialize itolizumab (EQ001) and any future product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert financial and other resources, and a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time, to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain third party contract organizations, advisors and consultants to provide certain services, including assuming substantial responsibilities for the conduct of our ongoing and future clinical trials and the manufacture of itolizumab (EQ001) and any future product candidates. We cannot assure you that the services of such third party contract organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are

unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by our vendors or consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of our product candidates or otherwise advance our business. We cannot assure you that we will be able to properly manage our existing vendors or consultants or find other competent outside vendors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by leasing additional facilities, hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize itolizumab (EQ001) and any future product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel.

Our industry has experienced a high rate of turnover in recent years. Our ability to compete in the highly competitive biopharmaceuticals industry depends upon our ability to attract, retain and motivate highly skilled and experienced personnel with scientific, medical, regulatory, manufacturing and management skills and experience. We conduct our operations in the Greater San Diego Area and the San Francisco Bay Area regions that are home to many other biopharmaceutical companies as well as many academic and research institutions, resulting in fierce competition for qualified personnel. We may not be able to attract or retain qualified personnel in the future due to the intense competition for a limited number of qualified personnel among biopharmaceutical companies. Many of the other biopharmaceutical companies against which we compete have greater financial and other resources, different risk profiles and a longer history in the industry than we do. Our competitors may provide higher compensation, more diverse opportunities and/or better opportunities for career advancement. Any or all of these competing factors may limit our ability to continue to attract and retain high quality personnel, which could negatively affect our ability to successfully develop and commercialize itolizumab (EQ001) or any future product candidates and to grow our business and operations as currently contemplated.

Our employees, clinical trial investigators, CROs, consultants, vendors and any potential commercial partners 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 of fraud or other misconduct by our employees, clinical trial investigators, CROs, consultants, vendors and any potential commercial partners. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) FDA laws and regulations or those of comparable foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information, (ii) manufacturing standards, (iii) federal and state health and data privacy, security, fraud and abuse, government price reporting, transparency reporting requirements, and other healthcare laws and regulations in the United States and abroad, (iv) sexual harassment and other workplace misconduct, or (v) laws that require the true, complete and accurate reporting of financial information or data. Such misconduct could also involve the improper use of information obtained in the course of 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, as well as a disclosure program and other applicable policies and procedures, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, additional integrity reporting and oversight obligations, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Our internal information technology systems, or those of our third-party CROs or other contractors or consultants, may fail or suffer security breaches, loss or leakage of data and other disruptions, which could result in a material disruption of our development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.*

We are increasingly dependent upon information technology systems, infrastructure and data to operate our business. As a result of the social distancing and remote working requirements related to the COVID-19 pandemic, we now have an even greater reliance on information technology and the effective functioning of our communication systems. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary business information and personal information). It is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. We also have outsourced elements of our operations to third parties, and as a result we manage a number of third party contractors who have access to our confidential information.

Despite the implementation of security measures, given their size and complexity and the increasing amounts of confidential information that they maintain, our internal information technology systems and those of our third-party CROs and other contractors and consultants are potentially vulnerable to breakdown or other damage or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure or lead to data leakage. Changes in how our employees work and access our systems during the COVID-19 pandemic could lead to additional opportunities for bad actors to launch cyber-attacks or for employees to cause inadvertent security risks or incidents. To the extent that any accidental or intentional 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 liability and reputational damage and the further development and commercialization of itolizumab (EQ001) or any future product candidates could be delayed. The effects of a disruption or security breach could be further amplified during the current COVID-19 pandemic.

While we have not experienced any such system failure, accident or security breach to date, we cannot assure you that our data protection efforts and our investment in information technology will prevent significant breakdowns, data leakages, breaches in our systems or other cyber incidents that could have a material adverse effect upon our reputation, business, operations or financial condition. For example, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our programs and the development of itolizumab (EQ001) or any future product candidates could be delayed. In addition, the loss of clinical trial data for itolizumab (EQ001) or any future product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of our internal information technology systems or security breaches could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure of, or the prevention of access to, confidential information (including trade secrets or other intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. For example, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

Failure to comply with health and data protection laws and regulations could lead to government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business.

We and any potential collaborators may be subject to federal, state, and foreign data protection laws and regulations (i.e., laws and regulations that address privacy and data security). In the United States, numerous federal and state laws and regulations, including federal health information privacy laws, state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), that govern the collection, use, disclosure, and protection of health-related and other personal information could apply to our operations or the operations of our collaborators. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH. Depending on the facts and circumstances, we could be subject to criminal penalties if we knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA-covered entity in a manner that is not authorized or permitted by HIPAA.

As of May 25, 2018, the General Data Protection Regulation, or GDPR, has replaced the Data Protection Directive with respect to the processing of personal data in the European Union. The GDPR imposes several stringent requirements for controllers and processors of personal data, including, for example, higher standards for obtaining consent from individuals to process their personal data, more robust disclosures to individuals and a strengthened individual data rights regime, shortened timelines for data breach notifications, limitations on retention and secondary use of information, increased requirements pertaining to health data and pseudonymised (i.e., key-coded) data and additional obligations when we contract third party processors in connection with the processing of the personal data. The GDPR provides that European Union member states may make their own further laws and regulations limiting the processing of genetic, biometric or health data, which could limit our ability to use and share personal data or could cause our costs could increase, and harm our business and financial condition. Failure to comply with the requirements of GDPR and the applicable national data protection laws of the European Union member states may result in fines of up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties. To comply with the new data protection rules imposed by GDPR we may be required to put in place additional mechanisms ensuring compliance. This may be onerous and adversely affect our business, financial condition, results of operations and prospects.

European data protection law also imposes strict rules on the transfer of personal data out of the European Union, including to the United States. These obligations may be interpreted and applied in a manner that is inconsistent from one jurisdiction to another and may conflict with other requirements or our practices. In addition, these rules are constantly under scrutiny. For example, following a decision of the Court of Justice of the European Union in October 2015, transferring personal data to U.S. companies that had certified as members of the U.S. Safe Harbor Scheme was declared invalid. In July 2016 the European Commission adopted the U.S.-EU Privacy Shield Framework which replaces the Safe Harbor Scheme. However, this Framework is under review and there is currently litigation challenging other European Union mechanisms for adequate data transfers (i.e., the standard contractual clauses). It is uncertain whether the Privacy Shield Framework and/or the standard contractual clauses will be similarly invalidated by the European courts. We rely on a mixture of mechanisms to transfer personal data from our European Union business to the United States, and could be impacted by changes in law as a result of a future review of these transfer mechanisms by European regulators under the GDPR, as well as current challenges to these mechanisms in the European courts.

Further, the United Kingdom's withdrawal from the European Union, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear whether the United Kingdom will enact data protection legislation equivalent to the GDPR and how data transfers to and from the United Kingdom will be regulated.

Additionally, California recently enacted legislation that has been dubbed the first "GDPR-like" law in the United States. Known as the California Consumer Privacy Act, or CCPA, it creates new individual privacy rights for consumers (as that word is broadly defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA, which went into effect on January 1, 2020, requires covered companies to provide new disclosures to California consumers, and provides such consumers new ways to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability. Some observers have noted that the CCPA could mark the beginning of a trend toward more stringent privacy legislation in the United States, which could increase our potential liability and adversely affect our business.

Compliance with U.S and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

We or the third parties upon whom we depend may be adversely affected by earthquakes, fires, other natural disasters, or other sudden, unforeseen and severe adverse events, including public health events, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.*

Our headquarters and main research facility are located in the Greater San Diego Area, which in the past has experienced severe earthquakes and fires. If these earthquakes, fires, other natural disasters, terrorism and similar unforeseen events beyond our control prevented us from using all or a significant portion of our headquarters or research facility, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. We do not have a disaster recovery or business continuity plan in place and may incur substantial expenses as a result of the absence or limited nature of our internal or third party service provider disaster recovery and business continuity plans, which, particularly when taken together with our lack of earthquake insurance, could have a material adverse effect on our business. Furthermore, integral parties in our supply chain are operating from single sites, increasing their vulnerability to natural disasters or other sudden, unforeseen and severe adverse events, including public health events such as the COVID-19 pandemic that could impact our business. If such an event were to affect our supply chain, it could have a material adverse effect on our ability to conduct our clinical trials, our development plans and business. For example, in March 2020, due to the spread of the coronavirus, the Indian government restricted the export of 26 active pharmaceutical ingredients and the medicines made from them. These export restrictions are indefinite and may be expanded. If the export restrictions are expanded to include itolizumab (EQ001), our supply of itolizumab (EQ001) may be disrupted, delayed or stopped indefinitely and our ability to continue development of itolizumab (EQ001), including our ongoing clinical trials, may be significantly impacted and may result in higher costs of drug product and adversely harm our business.

Changes in tax laws or regulations that are applied adversely to us or our customers may have a material adverse effect on our business, cash flow, financial condition or results of operations.*

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could affect the tax treatment of our domestic and foreign earnings. Any new taxes could adversely affect our domestic and international business operations, and our business and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, on December 22, 2017, U.S. federal income tax legislation was signed into law (H.R. 1, “An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018”), informally titled the Tax Cuts and Jobs Act, that significantly revised the Internal Revenue Code of 1986, as amended, or the Code. Future guidance from the Internal Revenue Service and other tax authorities with respect to the Tax Cuts and Jobs Act may affect us, and certain aspects of the Tax Cuts and Jobs Act could be repealed or modified in future legislation. For example, legislation enacted on March 27, 2020, entitled the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, modified certain provisions of the Tax Cuts and Jobs Act. In addition, it is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act, the CARES Act or any newly enacted federal tax legislation. We do not expect the Tax Cuts and Jobs Act or the CARES Act to have a material impact on our current projection of minimal cash taxes for the near future. However, we continue to examine the impact that the Tax Cuts and Jobs Act and the CARES Act may have on our business in the longer term. We urge prospective investors to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

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

As of December 31, 2019, we had aggregate U.S. federal net operating loss, or NOL, carryforwards of approximately $28.3 million. Our U.S. federal NOLs generated in taxable years ending prior to 2018 could expire unused. Under the Tax Cuts and Jobs Act, as modified by the CARES Act, U.S. federal NOLs incurred in taxable years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such U.S. federal NOLs in tax years beginning after December 31, 2017 is generally limited to 80% of taxable income. It is uncertain if and to what extent various states will conform to the Tax Cuts and Jobs Act or the CARES Act.

In addition, under Sections 382 and 383 of the Code and corresponding provisions of state law, if a corporation undergoes an “ownership change,” which is generally defined as a greater than 50% change (by value) in its equity ownership over a three-year period, the corporation’s ability to use its pre-change NOL carryforwards and other pre-change tax attributes (such as research tax credits) to offset its post-change income may be limited. It is possible that we have experienced one or more ownership changes in the past. In addition, we may also experience ownership changes in the future as a result of subsequent shifts in our stock ownership some of which may be outside of our control. As a result, if we earn net taxable income, our ability to use our pre-ownership change NOL carryforwards to offset U.S. federal taxable income may be subject to limitations, which 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.

The terms of our Loan Agreement place restrictions on our operating and financial flexibility.

In September 2019, we entered into the Loan Agreement with Oxford Finance LLC and Silicon Valley Bank providing for up to $20.0 million in term loans, which is secured by a first priority perfected security interest in substantially all of our current and future assets, other than our intellectual property (except rights to payment from the sale, licensing or disposition of such intellectual property). We borrowed $10.0 million upon execution of the Loan Agreement.

The Loan Agreement includes affirmative and restrictive covenants, including covenants regarding delivery of financial statements, maintenance of inventory, payment of taxes, maintenance of insurance, protection of intellectual property rights, dispositions of property, business combinations or acquisitions, incurrence of additional indebtedness or liens, investments and transactions with affiliates, among other customary covenants. We are also restricted from paying dividends or making other distributions or payments on our capital stock, subject to limited exceptions.

The Loan Agreement also includes events of default, the occurrence and continuation of which provide Oxford Finance LLC, as collateral agent, with the right to exercise remedies against us and the collateral securing the loans under the Loan Agreement, including foreclosure against our properties securing the Loan Agreement, including our cash, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. These events of default include, among other things, our failure to satisfy our payment obligations under the Loan Agreement, the breach of certain of our other covenants under the Loan Agreement, or the occurrence of a material adverse change, cross defaults to other indebtedness or material agreements, judgment defaults and defaults related to failure to maintain governmental approvals failure of which to maintain could result in a material adverse effect. Further, if we are liquidated, the lenders' right to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. The lenders could declare a default upon the occurrence of any event that they interpret as a material adverse change as defined under the Loan Agreement, thereby requiring us to repay the loan immediately or to attempt to reverse the declaration of default through negotiation or litigation. Any declaration by the lenders of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline.

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

We face an inherent risk of product liability exposure related to the testing of itolizumab (EQ001) and any future product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that itolizumab (EQ001) or any future product candidates or products caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- delay or termination of clinical trials;
- 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 subjects;
- initiation of investigations by regulators;
- significant costs to defend the related litigation and diversion of management's time and our resources;
- substantial monetary awards to study subjects or patients;
- product recalls, withdrawals or labeling, or marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize any products that we may develop.

We currently have product liability insurance. However, the amount of insurance may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage as itolizumab (EQ001) and any future product candidates advance through clinical trials and if we successfully commercialize any products. Insurance coverage is increasingly expensive. 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.

Changes in healthcare law and implementing regulations, as well as changes in healthcare policy, may impact our business in ways that we cannot currently predict and may have a significant adverse effect on our business and results of operations.*

There have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Among policy makers and payors in the United States there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access and the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives.

The Affordable Care Act substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The Affordable Care Act, among other things: (i) introduced a new average manufacturer price definition for drugs and biologics that are inhaled, infused, instilled, implanted or injected and not generally dispensed through retail community pharmacies; (ii) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and expanded rebate liability from fee-for-service Medicaid utilization to include the utilization of Medicaid managed care organizations as well; (iii) established a branded prescription drug fee that pharmaceutical manufacturers of branded prescription drugs must pay to the federal government; (iv) expanded the list of covered entities eligible to participate in the 340B drug pricing program by adding new entities to the program; (v) established a new Medicare Part D coverage gap discount program, in which manufacturers must now agree to offer 70 % point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; (vi) extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; (vii) expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals, including individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liability; (viii) created a licensure framework for follow-on biologic products; and (ix) established a Center for Medicare & Medicaid Innovation at the Centers for Medicare & Medicaid Services to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

There remain judicial and Congressional challenges to certain aspects of the Affordable Care Act, as well as efforts by the Trump administration to repeal or replace certain aspects of the Affordable Care Act. For example, the Tax Cuts and Jobs Act included a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Since the enactment of the Tax Cuts and Jobs Act, there have been additional amendments to certain provisions of the Affordable Care Act, and we expect the current Trump administration and Congress will likely continue to seek to modify, repeal or otherwise invalidate all, or certain provisions of, the Affordable Care Act. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments, which are expected to occur in the fall of 2020. It is unclear how such litigation and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act and our business. We continue to evaluate the effect that the Affordable Care Act and its possible repeal and replacement has on our business. It is uncertain the extent to which any such changes may impact our business or financial condition.

Other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011 and subsequent laws, which began in 2013 and will remain in effect through 2030, unless additional Congressional action is taken. The CARES Act, which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. New laws may result in additional reductions in Medicare and other healthcare funding, which may materially adversely affect customer demand and affordability for our products and, accordingly, the results of our financial operations.

Also, there has been heightened governmental scrutiny recently over the manner in which pharmaceutical companies set prices for their marketed products, which have resulted in several Congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to product pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. At the federal level, the Trump administration's budget proposal for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and to increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the administration sent "principles" for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Further, the Trump administration previously released a "Blueprint," or plan, to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and has implemented others under its existing authority. On July 24, 2020, the Trump administration announced four executive orders related to prescription drug pricing that attempt to implement several of the administration's proposals, including a policy that would tie Medicare Part B drug prices to international drug prices; one that directs HHS to finalize the Canadian drug importation proposed rule previously issued by HHS and makes other changes allowing for personal importation of drugs from Canada; one that directs HHS to finalize the rulemaking process on modifying the anti-kickback law safe harbors for discounts for plans, pharmacies, and pharmaceutical benefit managers; and one that reduces costs of insulin and epipens to patients of federally qualified health centers. While some of the existing measures and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, individual states in the United States have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded 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 drugs, once marketing approval is obtained. It is also possible that additional governmental action is taken to address the COVID-19 pandemic.

We may be subject to applicable foreign, federal and state fraud and abuse, transparency, government price reporting, and other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of any future product candidates for which we obtain marketing approval. Our arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may affect the business or financial arrangements and relationships through which we conduct research and would market, sell and distribute our products. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, any person or entity from knowingly and willfully soliciting, receiving, offering or paying any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of an item or service reimbursable, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value. The federal Anti-Kickback Statute has also been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other the other hand. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. Additionally, the intent standard under the federal Anti-Kickback Statute was amended by the Affordable Care Act such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act, or FCA;

- federal civil and criminal false claims laws, such as the FCA which can be enforced by private citizens, on behalf of the government, through civil qui tam actions, and civil monetary penalty laws prohibits individuals or entities from, among other things, knowingly presenting, or causing to be presented, false, fictitious or fraudulent claims for payment or approval by the federal government, including federal health care programs, such as Medicare and Medicaid, and knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim, or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. In addition, a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. Criminal prosecution is also possible for making or presenting a false, fictitious or fraudulent claim to the federal government. Government enforcement agencies and private whistleblowers have investigated pharmaceutical companies for or asserted liability under the FCA for a variety of alleged promotional and marketing activities, such as providing free product to customers with the expectation that the customers would bill federal programs for the product, providing consulting fees and other benefits to physicians to induce them to prescribe products, engaging in promotion for "off-label" uses, and submitting inflated best price information to the Medicaid Rebate Program;
- HIPAA, among other things, imposes criminal and civil liability for executing or attempting to execute a scheme to defraud any healthcare benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation, in connection with the delivery of or payment for healthcare benefits, items or services. Like the federal Anti-Kickback Statute, the Affordable Care Act amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by HITECH and their implementing regulations, which imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon entities subject to the law, such as health plans, healthcare clearinghouses and certain healthcare providers, known as covered entities, and their respective business associates that perform services for them that involve individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in U.S. federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- the U.S. federal Food, Drug and Cosmetic Act, which prohibits, among other things, the adulteration or misbranding of drugs, biologics and medical devices;
- the Public Health Service Act, which prohibits, among other things, the introduction of a biological product into interstate commerce without an approved BLA;
- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the federal transparency requirements under the Physician Payments Sunshine Act, created under the Affordable Care Act, which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children's Health Insurance Program to annually report to CMS information related to payments and other transfers of value provided to physicians, as defined by such law, and teaching hospitals and physician ownership and investment interests, including such ownership and investment interests held by a physician's immediate family members;
- state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws, that may impose similar or more prohibitive restrictions, and may apply to items or services reimbursed by any non-governmental third-party payors, including private insurers; and

- state and foreign laws that require pharmaceutical companies to implement compliance programs and comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; track and report gifts, compensation and other remuneration provided to physicians, other health care providers, and certain health care entities; report information related to drug pricing; and/or ensure the registration and compliance of sales personnel. In addition, we may be subject to federal, state and foreign laws that govern the privacy and security of health information or personally identifiable information in certain circumstances, including state health information privacy and data breach notification laws which govern the collection, use, disclosure, and protection of health-related and other personal information, many of which differ from each other in significant ways and often are not pre-empted by HIPAA, thus complicating compliance efforts.

We have entered into consulting and scientific advisory board arrangements with physicians and other healthcare providers, including some who could influence the use of itolizumab (EQ001) and any future product candidates, if approved. Because of the complex and far-reaching nature of these laws, regulatory agencies may view these transactions as prohibited arrangements that must be restructured, or discontinued, or for which we could be subject to other significant penalties. We could be adversely affected if regulatory agencies interpret our financial relationships with providers who may influence the ordering of and use of itolizumab (EQ001) or any future product candidates, if approved, to be in violation of applicable laws.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies, healthcare providers and other third parties, including charitable foundations, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities may conclude that our business practices, including our consulting arrangements with physicians, some of whom receive stock options as compensation for services provided, do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. Responding to investigations can be time and resource-consuming and can divert management's attention from the business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

Ensuring that our business arrangements with third parties comply with applicable healthcare laws and regulations will likely be costly. If our operations are found to be in violation of any of these laws or any other current or future governmental laws and regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, contractual damages, reputational harm, diminished profits and future earnings, additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could substantially disrupt 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 significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

We are subject to certain U.S. and certain foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations. We can face serious consequences for violations.

U.S. and foreign anti-corruption, anti-money laundering, export control, sanctions, and other trade laws and regulations, or collectively Trade Laws, prohibit, among other things, companies and their employees, agents, CROs, legal counsel, accountants, consultants, contractors, and other partners from authorizing, promising, offering, providing, soliciting, or receiving, directly or indirectly, corrupt or improper payments or anything else of value to or from recipients in the public or private sector. Violations of Trade Laws can result in substantial criminal fines and civil penalties, imprisonment, the loss of trade privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities, and other organizations. We also expect our non-U.S. activities to increase over time. We expect to rely on third parties for research, preclinical studies, and clinical trials and/or to obtain necessary permits, licenses, patent registrations, and other marketing approvals. We can be held liable for the corrupt or other illegal activities of our personnel, agents, or partners, even if we do not explicitly authorize or have prior knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Requirements associated with being a public company will increase our costs significantly, as well as divert significant company resources and management attention.

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or the other rules and regulations of the SEC, or any securities exchange relating to public companies. The Sarbanes-Oxley Act of 2002, as amended, or Sarbanes-Oxley, as well as rules subsequently adopted by the SEC, and The Nasdaq Global Market to implement provisions of Sarbanes-Oxley, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory “say on pay” voting requirements that will apply to us when we cease to be an emerging growth company. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Compliance with the various reporting and other requirements applicable to public companies requires considerable time and attention of management. We cannot assure you that we will satisfy our obligations as a public company on a timely basis.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition and results of operations. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services. In addition, as a public company, it may be more difficult or more costly for us to obtain certain types of insurance, including directors’ and officers’ liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified personnel to serve on our board of directors, our board committees or as executive officers.

If any of our services providers are characterized as employees, we would be subject to employment and tax withholding liabilities and other additional costs.

We rely on independent third parties to provide certain services to us. We structure our relationships with these outside services providers in a manner that we believe results in an independent contractor relationship, not an employee relationship. Tax or other regulatory authorities may challenge our characterization of services providers as independent contractors both under existing laws and regulations and under laws and regulations adopted in the future. We are aware of a number of judicial decisions and legislative proposals that could bring about major changes in the way workers are classified, including the California legislature’s recent passage of California Assembly Bill 5, which California Governor Gavin Newsom signed into law in September 2019, or AB 5. AB 5 purports to codify the holding of the California Supreme Court’s unanimous decision in Dynamex Operations West, Inc. v. Superior Court of Los Angeles, which introduced a new test for determining worker classification that is widely viewed as expanding the scope of employee relationships and narrowing the scope of independent contractor relationships. While AB 5 exempts certain licensed health care professionals, including physicians and psychologists, not all of our independent contractors work in exempt occupations. Given AB 5’s recent passage, there is no guidance from the regulatory authorities charged with its enforcement and there is a significant degree of uncertainty regarding its application. In addition, AB 5 has been the subject of widespread national discussion and it is possible that other jurisdictions might enact similar laws. As a result, there is significant uncertainty regarding what the state, federal and foreign worker classification regulatory landscape will look like in future years. The current economic climate indicates that the debate over worker classification will continue for the foreseeable future. If such regulatory authorities or state, federal or foreign courts were to determine that our services providers are employees and not independent contractors, we would, among other things, be required to withhold income taxes, to withhold and pay Social Security, Medicare and similar taxes, to pay unemployment and other related payroll taxes, and to provide certain employee benefits. We could also be liable for unpaid past taxes and other costs and subject to penalties. As a result, any determination that the service providers we characterize as independent contractors should be classified as employees could adversely impact our business, financial condition and results of operations.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We, and the third parties with whom we share our facilities, 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. Each of our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Each of our operations 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. We could be held liable for any resulting damages in the event of contamination or injury resulting from the use of hazardous materials by us or the third parties with whom we share our facilities, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties.

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 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 research and development. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Risks Related to our Common Stock

The stock price of our common stock may be volatile or may decline regardless of our operating performance, and you could lose all or part of your investment.*

The market price of our common stock may fluctuate significantly in response to numerous factors, many of which are beyond our control, including:

- our operating performance and the performance of other similar companies;
- delays or other adverse impacts to our clinical trials from global health epidemics, such as those related to COVID-19;
- our ability to enroll and retain subjects in our ongoing and future clinical trials;
- results from our ongoing and future clinical trials and future clinical trials with our current and future product candidates, of our competitors, or of Biocon;
- the timing of topline data from ongoing trials, including our ongoing and planned clinical trials of itolizumab;
- changes in our projected operating results that we provide to the public, our failure to meet these projections or changes in recommendations by securities analysts that elect to follow our common stock;
- regulatory or legal developments in the United States and other countries of ours, our competitors', or Biocon's;
- the level of expenses related to future product candidates or clinical development programs;
- changes in the structure of healthcare payment systems;
- our ability to achieve product development goals in the timeframe we announce;
- announcements of clinical trial results, regulatory developments, acquisitions, strategic alliances or significant agreements by us, by our competitors, or by Biocon;
- the success or failure of our efforts to acquire, license or develop additional product candidates;
- recruitment or departure of key personnel;
- the economy as a whole and market conditions in our industry;

- trading activity by a limited number of stockholders who together beneficially own a majority of our outstanding common stock;
- the size of our market float; and
- any other factors discussed in this report.

In addition, the stock markets have experienced extreme price and volume fluctuations, including as a result of the COVID-19 pandemic, that have affected and continue to affect the market prices of equity securities of many life sciences companies. Stock prices of many biopharmaceutical companies have fluctuated in a manner unrelated or disproportionate to the operating performance of those companies. In the past, stockholders have filed securities class action litigation following periods of market volatility. If we were to become involved in securities litigation, it could subject us to substantial costs, divert resources and the attention of management from our business and adversely affect our business.

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 equity offerings, debt financings, collaboration and license agreements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. In November 2019, we entered into the 2019 ATM Facility with Jefferies under which we may offer and sell shares of our common stock having an aggregate offering price of up to $8.45 million from time to time through Jefferies acting as our sales agent. As of June 30, 2020, we have sold an aggregate of 192,899 shares of our common stock under the 2019 ATM facility for gross proceeds of $0.9 million.

On July 14, 2020, we entered into the 2020 ATM Facility with Jefferies, under which we may offer and sell shares of our common stock having an aggregate offering price of up to $150 million from time to time through Jefferies acting as our sales agent. Subsequent to June 30, 2020 and through the date of our filing, we sold an aggregate of 1,539,525 shares of our common stock under both of our ATM facilities, which includes shares sold pursuant to the 2020 ATM Facility, but not yet delivered to Jefferies, for gross proceeds of $17.9 million.

In March 2020, we entered into the Purchase Agreement with Lincoln Park which provides that, upon the terms and subject to the conditions and limitations set forth therein, we may sell to Lincoln Park up to $15.0 million of shares of our common stock, from time to time over the 36-month term of the Purchase Agreement, and we issued an additional 65,374 shares of our common stock to Lincoln Park as commitment shares under the Purchase Agreement. As of the date of the filing of this Quarterly Report on Form 10-Q, we have not sold any shares of our common stock to Lincoln Park under the Purchase Agreement.

Debt 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. Subject to limited exceptions, our Loan Agreement also prohibits us from incurring indebtedness without the prior written consent of the lenders.

If we raise funds through collaboration and license agreements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings 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 product candidates that we would otherwise prefer to develop and market ourselves.

If there are substantial sales of shares of our common stock, the price of our common stock could decline.*

The price of our common stock could decline if there are substantial sales of our common stock, particularly sales by our directors, executive officers and significant stockholders, or if there is a large number of shares of our common stock available for sale and the market perceives that sales will occur. As of August 11, 2020, we had 19,263,375 shares of our common stock outstanding. Shares held by directors, executive officers and other affiliates will be subject to volume limitations under Rule 144 under the Securities Act and various vesting agreements. We have registered shares of common stock that we have issued and may issue under our employee equity incentive plans, which shares may be sold freely in the public market upon issuance. Sales of our common stock by current stockholders may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate, and make it more difficult for other stockholders to sell shares of our common stock.

The market price of the shares of our common stock could decline as a result of the sale of a substantial number of our shares of common stock in the public market or the perception in the market that the holders of a large number of shares intend to sell their shares. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

We will have broad discretion in the use of working capital and may not use it effectively or in ways that increase the value of our share price.

We cannot specify with any certainty the particular uses of working capital, but we currently expect such uses will include funding research and development of itolizumab (EQ001) and general corporate purposes as well as potentially acquiring additional products. We will have broad discretion in the application of working capital, and you and other stockholders may disagree with how we spend or invest the working capital. The failure by our management to apply our working capital effectively could adversely affect our business and financial condition. Pending their use, we may invest working capital in a manner that does not produce income or that loses value. These investments may not yield a favorable return to our investors.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research 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. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, our common stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause our common stock price and trading volume to decline.

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

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC.

We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. In addition, we do not have a risk management program or processes or procedures for identifying and addressing risks to our business in other areas.

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

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or JOBS Act, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- 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

- not being required to hold a non-binding advisory vote on executive compensation or obtain stockholder approval of any golden parachute payments not previously approved.

In addition, as an "emerging growth company" the JOBS Act allows us to delay adoption of new or revised accounting pronouncements applicable to public companies until such pronouncements are made applicable to private companies. We have elected to use this extended transition period under the JOBS Act.

We cannot predict if investors will find our common stock less attractive because we will 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. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of our initial public offering (i.e. December 31, 2023), (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th and (2) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We do not intend to pay dividends for the foreseeable future.

We have never declared nor paid cash dividends on our capital stock. We currently intend to retain any future earnings to finance the operation and expansion of our business, and we do not expect to declare or pay any dividends in the foreseeable future, including due to limitations that are currently imposed by our Loan Agreement. In addition, the terms of any future debt agreements may preclude us from paying dividends. Consequently, stockholders must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investment.

The concentration of our stock ownership will likely limit your ability to influence corporate matters, including the ability to influence the outcome of director elections and other matters requiring stockholder approval.

Our executive officers, directors and the holders of more than 5% of our outstanding common stock, in the aggregate, beneficially own a significant percentage of our common stock. As a result, these stockholders, acting together, will have significant influence over all matters that require approval by our stockholders, including the election of directors and approval of significant corporate transactions. Corporate actions might be taken even if other stockholders oppose them. This concentration of ownership might also have the effect of delaying or preventing a change of control of our company that other stockholders may view as beneficial.

Delaware law and provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make a merger, tender offer or proxy contest difficult, thereby depressing the trading price of our common stock.*

Provisions of our amended and restated certificate of incorporation and amended and restated bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our amended and restated certificate of incorporation and amended and restated bylaws:

- permit our board of directors to issue up to 10,000,000 shares of preferred stock, with any rights, preferences and privileges as they may designate (including the right to approve an acquisition or other change in our control);
- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that the board of directors or any individual director may only be removed with cause and the affirmative vote of the holders of at least 66-2/3% of the voting power of all of our then outstanding common stock;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide our board of directors into three classes;
- require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent;

- provide that stockholders seeking to present proposals before a meeting of stockholders or to nominate candidates for election as directors at a meeting of stockholders must provide notice in writing in a timely manner and also specify requirements as to the form and content of a stockholder's notice;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provide that special meetings of our stockholders may be called only by the chairman of the board, our Chief Executive Officer or by the board of directors pursuant to a resolution adopted by a majority of the total number of authorized directors; and
- provide that the Court of Chancery of the State of Delaware will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law; (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors or officers to us or our stockholders, (iii) any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law or our certificate of incorporation or bylaws, or (iv) any action asserting a claim against us governed by the internal affairs doctrine. These provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims.

The amendment of any of these provisions, with the exception of the ability of our board of directors to issue shares of preferred stock and designate any rights, preferences and privileges thereto, would require approval by the holders of at least 66-2/3% of our then-outstanding common stock.

In addition, as a Delaware corporation, we are subject to Section 203 of the Delaware General Corporation Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us for a certain period of time. A Delaware corporation may opt out of this provision by express provision in its original certificate of incorporation or by amendment to its certificate of incorporation or bylaws approved by its stockholders. However, we have not opted out of this provision.

These and other provisions in our amended and restated certificate of incorporation, amended and restated bylaws and Delaware law could make it more difficult for stockholders or potential acquirors to obtain control of our board of directors or initiate actions that are opposed by our then-current board of directors, including delay or impede a merger, tender offer or proxy contest involving our company. The existence of these provisions could negatively affect the price of our common stock and limit opportunities for you to realize value in a corporate transaction.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums 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.*

Our amended and restated certificate of incorporation provides that, to the fullest extent permitted by law, the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a breach of fiduciary duty, (iii) any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or amended and restated bylaws or (iv) any action asserting a claim against us that is governed by the internal affairs doctrine. These provisions would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation also provides that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in these other jurisdictions.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

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

Use of Proceeds

On October 11, 2018, our Registration Statement on Form S-1 (file No. 333-227387) was declared effective by the SEC for our initial public offering of common stock. On October 16, 2018, we sold an aggregate of 4,670,000 shares of common stock and on November 2, 2018, we sold an additional 445,097 shares of common stock pursuant to the underwriters' partial exercise of their option to purchase additional shares, each at an offering price of $14.00 per share, for aggregate gross proceeds of approximately $71.6 million. After deducting underwriting discounts, commissions and offering costs incurred by us of approximately $7.1 million, the net proceeds from the offering were approximately $64.5 million. The joint book-running managers for the offering were Jefferies LLC, Leerink Partners LLC and Stifel, Nicolaus & Company, Incorporated. No offering costs were paid or are payable, directly or indirectly, to our directors or officers, to persons owning 10% or more of any class of our equity securities, or to any of our affiliates.

There has been no material change in the expected use of the net proceeds from our IPO as described in our final prospectus filed with the SEC on October 12, 2018. Upon receipt, the net proceeds from our IPO were held in cash, cash equivalents and short-term investments. As of June 30, 2020, we have used $32.4 million of the net proceeds from the IPO. Pending such uses, we plan to continue investing the unused proceeds from the IPO in fixed, non-speculative income instruments and money market funds.

Item 6. Exhibits

The following exhibits are filed as part of this Quarterly Report on Form 10-Q.

Exhibit Number	Description of Exhibit
3.1	Amended and Restated Certificate of Incorporation of the Registrant, incorporated by reference to Exhibit 3.1 of the Registrant's Current Report on Form 8-K filed on October 16, 2018.
3.2	Amended and Restated Bylaws of the Registrant, incorporated by reference to Exhibit 3.2 of the Registrant's Current Report on Form 8-K filed on October 16, 2018.
4.1	Form of Common Stock Certificate of the Registrant, incorporated by reference to Exhibit 4.1 of the Registrant's Registration Statement on Form S-1 (File No. 333-227387), as amended, originally filed with the Securities and Exchange Commission on September 17, 2018.
4.2	Warrant to Purchase Common Stock, dated September 30, 2019, issued to Oxford Finance LLC, incorporated by reference to Exhibit 4.2 of the Registrant's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on November 12, 2019.
4.3	Warrant to Purchase Common Stock, dated September 30, 2019, issued to Silicon Valley Bank, incorporated by reference to Exhibit 4.3 of the Registrant's Quarterly Report on Form 10-Q, filed with the Securities and Exchange Commission on November 12, 2019.
4.4	Registration Rights Agreement, dated as of March 27, 2020, by and between the Registrant and Lincoln Park Capital Fund, LLC, incorporated by reference to Exhibit 4.1 of the Registrant's Current Report on Form 8-K filed on March 30, 2020.
10.1*+	Equillium, Inc. Non-Employee Director Compensation Policy, as amended.
31.1*	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act, as amended.
31.2*	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) of the Securities Exchange Act, as amended.
32.1**	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rules 13a-14(b) or 15d-14(b) of the Securities Exchange Act, as amended, and 18 U.S.C. Section 1350.
101.INS*	XBRL Instance Document.
101.SCH*	XBRL Taxonomy Extension Schema Document.
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.

* Filed herewith.

** Furnished herewith.

+ Indicates management contract or compensatory plan.

SIGNATURES

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

Date: August 12, 2020	**EQUILLIUM, INC.**	
	By:	/s/ Bruce D. Steel
		Bruce D. Steel President and Chief Executive Officer (Principal Executive Officer)
	By:	/s/ Jason A. Keyes
		Jason A. Keyes Chief Financial Officer (Principal Financial Officer)

EXHIBIT 10.1

EQUILLIUM, INC.

NON-EMPLOYEE DIRECTOR COMPENSATION POLICY
(amended and restated, effective as of May 19, 2020)

Each member of the Board of Directors (the "***Board***") who is not also serving as an employee of or consultant to Equillium, Inc. (the "***Company***") or any of its subsidiaries (each such member, an "***Eligible Director***") will receive the compensation described in this Non-Employee Director Compensation Policy for his or her Board service. An Eligible Director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date cash may be paid or equity awards are to be granted, as the case may be. This policy may be amended at any time in the sole discretion of the Board or the Compensation Committee of the Board.

Annual Cash Compensation

The annual cash compensation amount set forth below is payable to Eligible Directors in equal quarterly installments, payable in arrears on the last day of each fiscal quarter in which the service occurred. If an Eligible Director joins the Board or a committee of the Board at a time other than effective as of the first day of a fiscal quarter, each annual retainer set forth below will be pro-rated based on days served in the applicable fiscal year, with the pro-rated amount paid for the first fiscal quarter in which the Eligible Director provides the service and regular full quarterly payments thereafter. All annual cash fees are vested upon payment.

1. Annual Board Service Retainer:
    a. All Eligible Directors: $40,000
    b. Chairman of the Board Service Retainer (in addition to Eligible Director Service Retainer): $20,000

2. Annual Committee Chair Service Retainer:
    a. Chairman of the Audit Committee: $15,000
    b. Chairman of the Compensation Committee: $10,000
    c. Chairman of the Nominating and Corporate Governance Committee: $8,000

3. Annual Committee Member Service Retainer (not applicable to Committee Chairs):
    a. Member of the Audit Committee: $7,500
    b. Member of the Compensation Committee: $5,000
    c. Member of the Nominating and Corporate Governance Committee: $4,000

Equity Compensation

The equity compensation set forth below will be granted under the Company’s 2018 Equity Incentive Plan (the “***Plan***”). All stock options granted under this policy will be nonstatutory stock options, with an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the underlying common stock of the Company (the “***Common Stock***”) on the date of grant, and a term of ten years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan, provided that upon a termination of service other than for death, disability or cause, the post-termination exercise period will be 12 months from the date of termination).

1. Initial Grant: For each Eligible Director who is first elected or appointed to the Board, on the date of such Eligible Director’s initial election or appointment to the Board (or, if such date is not a market trading day, the first market trading day thereafter), the Eligible Director will be granted a stock option to purchase 24,000 shares of Common Stock (the “***Initial Grant***”). The shares subject to each Initial Grant will vest in equal monthly installments over a three year period such that the option is fully vested on the third anniversary of the date of grant, subject to the Eligible Director’s Continuous Service (as defined in the Plan) through each such vesting date and will vest in full upon a Change in Control (as defined in the Plan).

2. Annual Grant: On the date of each annual stockholder meeting of the Company, each Eligible Director who continues to serve as a non-employee member of the Board following such stockholder meeting will be granted a stock option to purchase 24,000 shares of Common Stock (the “***Annual Grant***”). The shares subject to the Annual Grant will vest in equal monthly installments over the 12 months following the date of grant, provided that the Annual Grant will in any case be fully vested on the date of Company’s next annual stockholder meeting, subject to the Eligible Director’s Continuous Service (as defined in the Plan) through such vesting date and will vest in full upon a Change in Control (as defined in the Plan).

Exhibit 31.1

CERTIFICATION

I, Bruce D. Steel, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Equillium, Inc., a Delaware corporation (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

   (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 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

/s/ Bruce D. Steel
Bruce D. Steel
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Jason A. Keyes, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Equillium, Inc., a Delaware corporation (the "registrant");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant’s other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

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

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

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

   (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 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

/s/ Jason A. Keyes

Jason A. Keyes
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

Certification Pursuant to 18 U.S.C. §1350, as Adopted
Pursuant to §906 of the Sarbanes-Oxley Act of 2002

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the “Exchange Act”) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), each of the undersigned hereby certifies in his capacity as an officer of Equillium, Inc. (the “Company”), that, to the best of his knowledge:

(1) the Company’s Quarterly Report on Form 10-Q for the quarterly period ended June 30, 2020, to which this Certification is attached as Exhibit 32.1 (the “Report”) fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and

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

/s/ Bruce D. Steel
Bruce D. Steel
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 12, 2020

/s/ Jason A. Keyes
Jason A. Keyes
Chief Financial Officer
(Principal Financial and Accounting Officer)

Date: August 12, 2020

This certification accompanies the Quarterly Report on Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Equillium, Inc. under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing. A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to Equillium, Inc. and will be retained by Equillium, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.