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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**FORM 10-Q**

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(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 001-39402

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**ANNEXON, INC.**

(Exact name of Registrant as specified in its Charter)

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**Delaware**  
(State or other jurisdiction  
of incorporation or organization)

27-5414423  
(I.R.S. Employer  
Identification No.)

180 Kimball Way, Suite 200  
South San Francisco, California 94080  
(Address of principal executive offices including zip code)

Registrant's telephone number, including area code: (650) 822-5500

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	ANNX	The Nasdaq Stock 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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

The number of shares of Registrant's Common Stock outstanding as of August 31, 2020 was 38,148,090.

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In this Quarterly Report on Form 10-Q, “we,” “our,” “us,” “Annexon” and the “Company” refer to Annexon, Inc. and its consolidated subsidiary. Annexon, Annexon, Inc., the Annexon logo and other trade names, trademarks or service marks of Annexon are the property of Annexon, Inc. This report contains references to our trademarks and to trademarks belonging to other entities. Trade names, trademarks and service marks of other companies appearing in this report are the property of their respective holders. We do not intend our use or display of other companies’ trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

**ANNEXON, INC.**  
**Condensed Consolidated Balance Sheets**  
**(in thousands, except share and per share amounts)**  
**(Unaudited)**

	<u>June 30,</u> <u>2020</u>	<u>December 31,</u> <u>2019</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 124,761	\$ 43,931
Prepaid expenses and other current assets	907	1,475
Total current assets	<u>125,668</u>	<u>45,406</u>
Property and equipment, less accumulated depreciation of \$1,566 and \$1,304 as of June 30, 2020 and December 2019, respectively	2,048	2,138
Other long-term assets	3,371	2,354
Total assets	<u>\$ 131,087</u>	<u>\$ 49,898</u>
<b>Liabilities, Redeemable Convertible Preferred Stock and Stockholders' Deficit</b>		
Current liabilities:		
Accounts payable	\$ 3,064	\$ 2,371
Accrued liabilities	9,218	2,194
Deferred rent, current	378	366
Total current liabilities	<u>12,660</u>	<u>4,931</u>
Deferred rent	<u>1,247</u>	<u>1,437</u>
Total liabilities	<u>13,907</u>	<u>6,368</u>
Commitments and contingencies (Note 6)		
Redeemable convertible preferred stock, \$0.001 par value, 183,467,924 and 119,155,472 shares authorized as of June 30, 2020 and December 31, 2019, respectively; 183,467,924 and 111,748,065 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively; liquidation preference of \$239,814 and \$137,814 as of June 30, 2020 and December 31, 2019, respectively	235,054	143,984
Stockholders' Deficit:		
Common stock, \$0.001 par value; 239,100,000 and 150,000,000 shares authorized as of June 30, 2020 and December 31, 2019, respectively; 433,749 shares issued and outstanding as of June 30, 2020 and December 31, 2019, respectively	4	4
Additional paid-in capital	9,365	2,202
Accumulated other comprehensive loss	(82)	(80)
Accumulated deficit	<u>(127,161)</u>	<u>(102,580)</u>
Total stockholders' deficit	<u>(117,874)</u>	<u>(100,454)</u>
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	<u>\$ 131,087</u>	<u>\$ 49,898</u>

See accompanying notes to unaudited condensed consolidated financial statements.

**ANNEXON, INC.**  
**Condensed Consolidated Statements of Operations**  
**(in thousands, except share and per share amounts)**  
**(Unaudited)**

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	\$ 9,287	\$ 5,987	\$ 19,504	\$ 10,640
General and administrative	2,950	2,230	5,189	3,679
Total operating expenses	<u>12,237</u>	<u>8,217</u>	<u>24,693</u>	<u>14,319</u>
Loss from operations	(12,237)	(8,217)	(24,693)	(14,319)
Loss on remeasurement of redeemable convertible preferred stock liability	—	(1,560)	—	(4,330)
Other income, net	1	376	116	597
Net loss before taxes	(12,236)	(9,401)	(24,577)	(18,052)
Provision for income taxes	4	—	4	1
Net loss	(12,240)	(9,401)	(24,581)	(18,053)
Accretion on redeemable convertible preferred stock	281	272	560	534
Net loss attributable to common stockholders	<u>\$ (12,521)</u>	<u>\$ (9,673)</u>	<u>\$ (25,141)</u>	<u>\$ (18,587)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (28.87)</u>	<u>\$ (22.30)</u>	<u>\$ (57.96)</u>	<u>\$ (42.90)</u>
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	<u>433,749</u>	<u>433,749</u>	<u>433,749</u>	<u>433,232</u>

See accompanying notes to unaudited condensed consolidated financial statements.

**ANNEXON, INC.**  
**Condensed Consolidated Statements of Comprehensive Loss**  
**(in thousands)**  
**(Unaudited)**

	<u>Three Months Ended</u> <u>June 30,</u>		<u>Six Months Ended</u> <u>June 30,</u>	
	<u>2020</u>	<u>2019</u>	<u>2020</u>	<u>2019</u>
Net loss	\$(12,240)	\$(9,401)	\$(24,581)	\$(18,053)
Other comprehensive gain (loss):				
Foreign currency translation adjustment	9	(4)	(2)	(10)
Comprehensive loss	<u>\$(12,231)</u>	<u>\$(9,405)</u>	<u>\$(24,583)</u>	<u>\$(18,063)</u>

See accompanying notes to unaudited condensed consolidated financial statements.

**ANNEXON, INC.**  
**Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit**  
(in thousands, except share amounts)  
(Unaudited)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Cost	Shares	Cost				
<b>Balances as of December 31, 2019</b>	111,748,065	\$ 143,984	433,749	\$ 4	\$ 2,202	\$ (80)	\$ (102,580)	\$ (100,454)
Accretion on redeemable convertible preferred stock	—	279	—	—	(279)	—	—	(279)
Stock-based compensation	—	—	—	—	663	—	—	663
Foreign currency translation adjustment	—	—	—	—	—	(11)	—	(11)
Net loss	—	—	—	—	—	—	(12,341)	(12,341)
<b>Balances as of March 31, 2020</b>	111,748,065	144,263	433,749	4	2,586	(91)	(114,921)	(112,422)
Issuance of Series D redeemable convertible preferred stock, net of issuance costs of \$5,193	71,719,859	96,807	—	—	—	—	—	—
Beneficial conversion feature on Series D redeemable convertible preferred stock	—	(6,297)	—	—	6,297	—	—	6,297
Accretion on redeemable convertible preferred stock	—	281	—	—	(281)	—	—	(281)
Stock-based compensation	—	—	—	—	763	—	—	763
Foreign currency translation adjustment	—	—	—	—	—	9	—	9
Net loss	—	—	—	—	—	—	(12,240)	(12,240)
<b>Balances as of June 30, 2020</b>	<u>183,467,924</u>	<u>\$ 235,054</u>	<u>433,749</u>	<u>\$ 4</u>	<u>\$ 9,365</u>	<u>\$ (82)</u>	<u>\$ (127,161)</u>	<u>\$ (117,874)</u>

See accompanying notes to unaudited condensed consolidated financial statements.

**ANNEXON, INC.**  
**Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit**  
(in thousands, except share amounts)  
(Unaudited)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Cost	Shares	Cost				
<b>Balances as of December 31, 2018</b>	89,525,848	\$102,082	432,309	\$ 4	\$ 1,257	\$ (66)	\$ (65,397)	\$ (64,202)
Accretion on redeemable convertible preferred stock	—	262	—	—	(262)	—	—	(262)
Stock option exercises	—	—	1,440	—	3	—	—	3
Stock-based compensation	—	—	—	—	466	—	—	466
Foreign currency translation adjustment	—	—	—	—	—	(6)	—	(6)
Net loss	—	—	—	—	—	—	(8,652)	(8,652)
<b>Balances as of March 31, 2019</b>	89,525,848	102,344	433,749	4	1,464	(72)	(74,049)	(72,653)
Accretion on redeemable convertible preferred stock	—	272	—	—	(272)	—	—	(272)
Stock-based compensation	—	—	—	—	437	—	—	437
Foreign currency translation adjustment	—	—	—	—	—	(4)	—	(4)
Net loss	—	—	—	—	—	—	(9,401)	(9,401)
<b>Balances as of June 30, 2019</b>	<u>89,525,848</u>	<u>\$102,616</u>	<u>433,749</u>	<u>\$ 4</u>	<u>\$ 1,629</u>	<u>\$ (76)</u>	<u>\$ (83,450)</u>	<u>\$ (81,893)</u>

See accompanying notes to unaudited condensed consolidated financial statements.



**ANNEXON, INC.**  
**Condensed Consolidated Statements of Cash Flows**  
**(in thousands)**  
**(Unaudited)**

	<b>Six Months Ended</b>	
	<b>June 30,</b>	
	<b>2020</b>	<b>2019</b>
<b>Operating activities:</b>		
Net loss	\$ (24,581)	\$(18,053)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	262	236
Stock-based compensation	1,426	903
Change in fair value of redeemable convertible preferred stock liability	—	4,330
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	568	(496)
Other long-term assets	44	—
Accounts payable	787	893
Accrued liabilities	1,425	(346)
Deferred rent	(178)	(166)
Net cash used in operating activities	<u>(20,247)</u>	<u>(12,699)</u>
<b>Investing activities:</b>		
Purchases of property and equipment	(16)	(18)
Net cash used in investing activities	<u>(16)</u>	<u>(18)</u>
<b>Financing activities:</b>		
Proceeds from the exercise common stock options	—	3
Proceeds from Paycheck Protection Program loan	500	—
Repayments of Paycheck Protection Program loan	(500)	—
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	101,985	—
Payment of deferred offering costs	(890)	—
Net cash provided by financing activities	<u>101,095</u>	<u>3</u>
Net increase (decrease) in cash and cash equivalents	80,832	(12,714)
Effect of exchange rate changes on cash and cash equivalents	(2)	(10)
Cash and cash equivalents at beginning of period	43,931	44,175
Cash and cash equivalents at end of period	<u>\$124,761</u>	<u>\$ 31,451</u>
<b>Non-cash investing and financing activities:</b>		
Accretion on redeemable convertible preferred stock	\$ 560	\$ 534
Deferred offering costs included in accounts payable and accrued liabilities	\$ 171	\$ —
Purchase of property and equipment included in accounts payable	\$ 156	\$ —
Beneficial conversion feature recognized upon issuance of redeemable convertible preferred stock	\$ 6,297	\$ —
Issuance costs of redeemable convertible preferred stock included in accounts payable and accrued liabilities	\$ 5,178	\$ —

See accompanying notes to unaudited condensed consolidated financial statements.

**ANNEXON, INC.**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

**1. Organization**

Annexon, Inc., or the Company, is a clinical-stage biopharmaceutical company targeting C1q and initiating molecules of the classical complement pathway to develop transformative therapies for autoimmune and neurodegenerative disorders of the body, brain and eye. The Company is located in South San Francisco, California and was incorporated in Delaware in March 2011.

The Company's wholly-owned subsidiary, Annexon Biosciences Australia Pty Ltd, or the Subsidiary, is a proprietary limited company incorporated in 2016 and domiciled in Australia. The Subsidiary is also engaged in research and development activities in support of its parent company.

***Initial Public Offering***

On July 23, 2020, the Company's registration statement on Form S-1 relating to its initial public offering, or the IPO, was declared effective by the Securities and Exchange Commission, or the SEC, and the shares of its common stock began trading on the Nasdaq Global Select Market on July 24, 2020. The IPO closed on July 28, 2020, pursuant to which the Company issued and sold 14,750,000 shares of its common stock at a public offering price of \$17.00 per share. On August 4, 2020, the Company issued 2,139,403 shares of our common stock to the underwriters of the IPO pursuant to the partial exercise of their option to purchase additional shares. The Company received net proceeds of approximately \$262.7 million from the IPO, after deducting underwriting discounts and commissions of \$20.1 million and offering costs of \$4.3 million, of which \$3.3 million was incurred as of June 30, 2020. Prior to the completion of the IPO, all shares of redeemable convertible preferred stock then outstanding were converted into 20,824,938 shares of common stock.

The condensed consolidated financial statements as of June 30, 2020, including share and per share amounts, do not give effect to the IPO as it closed subsequent to June 30, 2020.

***Liquidity***

Since inception, the Company has been involved primarily in performing research and development activities, conducting clinical trials, hiring personnel, and raising capital to support and expand these activities. The Company has experienced losses and negative cash flows from operations since its inception and, as of June 30, 2020, had an accumulated deficit of \$127.2 million and cash and cash equivalents of \$124.8 million.

The Company has historically funded its operations through the issuance of shares of its redeemable convertible preferred stock. Based on projected activities, management projects that cash on hand and the proceeds from the IPO are sufficient to support operations for at least the next 12 months following issuance of these condensed consolidated financial statements. Management expects to continue to incur losses and negative cash flows from operations for at least the next several years.

**2. Basis of Presentation and Significant Accounting Policies**

***Basis of Presentation***

The accompanying unaudited condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP, and applicable rules and regulations of the SEC regarding interim financial reporting.

The interim condensed consolidated balance sheet as of June 30, 2020, the interim condensed consolidated statements of operations, comprehensive loss, changes in redeemable convertible preferred stock and stockholders' deficit for the three and six months ended June 30, 2020 and 2019 and the condensed consolidated statements of cash flows for the six months ended June 30, 2020 and 2019 are unaudited. These unaudited condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, necessary to present fairly the Company's consolidated financial position as of June 30, 2020 and its results of operations and cash flows for the six months ended June 30, 2020 and 2019. The financial data and the other financial information contained in these notes to the condensed consolidated financial statements related to the three- and six-month periods are also unaudited. The results of operations for the three and six months ended June 30, 2020 are not necessarily indicative of the results to be expected for the year

**ANNEXON, INC.**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

ending December 31, 2020 or for any other future annual or interim period. The condensed consolidated balance sheet as of December 31, 2019 included herein was derived from the audited financial statements as of that date. These condensed consolidated financial statements should be read in conjunction with the Company's audited consolidated financial statements included in the prospectus dated July 23, 2020 that forms a part of the Company's Registration Statement on Form S-1 (File No. 333-239647), as filed with the SEC pursuant to Rule 424(b)(4) promulgated under the Securities Act of 1933, as amended.

***Use of Estimates***

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported expenses during the reporting period. On an ongoing basis, management evaluates its estimates, including but not limited to the fair value of common stock, redeemable convertible preferred stock, redeemable convertible preferred stock liability, stock options, income taxes and certain accruals. The Company evaluates its estimates and assumptions on an ongoing basis using historical experience and other factors and adjusts those estimates and assumptions when facts and circumstances dictate. Actual results could differ from those estimates.

***Principles of Consolidation***

The consolidated financial statements include the operations of Annexon, Inc. and its wholly-owned subsidiary and include the results of operations and cash flows of these entities. All intercompany balances and transactions have been eliminated in consolidation.

***Deferred Offering Costs***

Deferred offering costs, consisting of legal, accounting, audit and filing fees relating to an IPO, are capitalized. The deferred offering costs will be offset against offering proceeds upon the completion of the offering. In the event the offering is terminated or delayed, deferred offering costs will be expensed. As of June 30, 2020 and December 31, 2019, \$3.3 million and \$2.3 million, respectively, of deferred offering costs were capitalized, which are included in other long-term assets in the accompanying consolidated balance sheets.

In July 2020, upon the closing of the IPO, all deferred costs were offset against the Company's IPO proceeds.

***Redeemable Convertible Preferred Stock Liability***

The obligation to issue additional shares of the Company's Series C redeemable convertible preferred stock at a future date was determined to be a freestanding financial instrument that should be accounted for as a liability. At initial recognition, the Company recorded the redeemable convertible preferred stock liability on the balance sheet at its estimated fair value. The liability is subject to remeasurement at each balance sheet date, with changes in fair value recognized as gain (loss) on remeasurement of redeemable convertible preferred stock liability on the consolidated statement of operations. Upon settlement of the redeemable convertible preferred stock liability in August 2019, the Company remeasured the liability and reclassified the final value associated with the redeemable convertible preferred stock liability to the carrying value of the Series C redeemable convertible preferred stock.

***Foreign Currencies***

The Company's reporting currency is the U.S. dollar. The functional currency of the Company's subsidiary located in Australia is the Australian Dollar. Balance sheets prepared in the functional currencies are translated to the reporting currency at exchange rates in effect at the end of the accounting period, except for stockholders' equity accounts, which are translated at rates in effect when these balances were originally recorded. Revenue and expense accounts are translated using a weighted-average rate during the year. The resulting foreign currency translation adjustments are recorded as a separate component of accumulated other comprehensive loss in the accompanying consolidated balance sheets. Foreign exchange translation gain (loss) for the three and six months ended June 30, 2020 and 2019 were not material.

Gains and losses resulting from exchange rate changes on transactions denominated in a currency other than the local currency are included in earnings as incurred.

**ANNEXON, INC.**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

***Research and Development Expense***

Research and development expenses consist primarily of direct and indirect costs incurred for the development of the Company's product candidates.

Direct expenses include (i) preclinical and clinical outside service costs associated with discovery, preclinical and clinical testing of the Company's product candidates; (ii) professional services agreements with third-party contract organizations, investigative clinical trial sites and consultants that conduct research and development activities on the Company's behalf; (iii) contract manufacturing costs to produce clinical trial materials; and (iv) laboratory supplies and materials. Indirect expenses include (A) compensation and personnel-related expenses (including stock-based compensation), (B) allocated expenses for facilities and depreciation; and (C) other indirect costs.

Research and development costs are expensed as incurred. Payments made to third parties are under agreements that are generally cancelable by the Company. Advance payments for research and development activities are deferred as prepaid expenses. The prepaid amounts are expensed as the related services are performed.

The Company estimates preclinical studies and clinical trial expenses based on the services performed pursuant to contracts with research institutions and clinical research organizations that conduct and manage preclinical studies and clinical trials on the Company's behalf. In accruing service fees, the Company estimates the period over which services will be performed and the level of effort to be expended in each period. These estimates are based on the Company's communications with the third-party service providers and on information available at each balance sheet date. If the actual timing of the performance of services or the level of effort varies significantly from the estimate, the Company will adjust the accrual accordingly to reflect the best information available at the time of the financial statement issuance. The Company has not experienced any material differences between accrued costs and actual costs incurred since its inception.

***Stock-Based Compensation***

The Company accounts for stock-based compensation arrangements using a fair value method which requires the recognition of compensation expense for costs related to all stock-based payments, including stock options. The fair value method requires the Company to estimate the fair value of stock-based payment awards to employees on the date of grant using the Black-Scholes option pricing model.

The Company grants certain employees performance-based stock options. For awards that include performance conditions, no compensation cost is recognized until the performance goals are probable of being met, at which time the cumulative compensation expense from the service inception date would be recognized.

Stock-based compensation costs are based on the fair value of the underlying option calculated using the Black-Scholes option pricing model and recognized as expense on a straight-line basis (for all but performance based awards for which the accelerated method is used) over the requisite service period, which is the vesting period.

Determining the appropriate fair value model and related assumptions requires judgment, including estimating the fair value of the underlying common stock, expected term, expected stock price volatility, risk-free interest rate and dividend yield. The Company accounts for forfeitures as they occur.

***Net Loss Per Share Attributable to Common Stockholders***

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period, without consideration for potential dilutive shares of common stock. As the Company was in a loss position for all periods presented, basic net loss per share attributable to common stockholders is the same as diluted net loss per share attributable to common stockholders because the effects of potentially dilutive securities are antidilutive.

**ANNEXON, INC.**  
**Notes to Condensed Consolidated Financial Statements**  
**(Unaudited)**

***Recently Adopted Accounting Pronouncements***

In June 2018, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*. This standard simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. The Company adopted this standard on January 1, 2020 and the adoption of this standard did not have a material impact on its condensed consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, which eliminates certain disclosure requirements for fair value measurements for all entities, requires public entities to disclose certain new information and modifies some disclosure requirements. This standard is effective for all entities for fiscal years beginning after December 15, 2019, with early adoption permitted. The Company adopted this standard on January 1, 2020 and the adoption of this standard did not have a material impact on its condensed consolidated financial statements.

***Recently Issued Accounting Pronouncements***

In February 2016, the FASB issued ASU No. 2016-02, *Leases (Topic 842)*, which supersedes the guidance in former ASC 840, *Leases*. This standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less may be accounted for similar to existing guidance for operating leases today. In November 2019, the FASB issued ASU No. 2019-10, *Financial Instruments – Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842)*, delaying the effective implementation date for Topic 842 by one year for entities that have not yet adopted the standard. This standard is effective for annual reporting periods, and interim periods within those years, for public entities beginning after December 15, 2018 and for private entities beginning after December 15, 2020. In June 2020, the FASB issued ASU No. 2020-05 in response to the ongoing impacts to US businesses in response to the COVID-19 pandemic. ASU No. 2020-05, *Revenue from Contracts with Customers (Topic 606) and Leases (Topic 842)*, provides a limited deferral of the effective dates for implementing previously issued Topic 606 and Topic 842 to give some relief to businesses and the difficulties they are facing during the pandemic. The leasing standard's effective dates are fiscal year beginning after December 15, 2019 as originally issued (ASU 2016-02) and fiscal year beginning after December 15, 2020 as amended by ASU 2019-10. As amended by ASU No. 2020-05, the leasing standard's effective date is the fiscal year beginning after December 15, 2021. Originally, a modified retrospective transition approach was required for leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements. In July 2018, the FASB issued guidance to permit an alternative transition method for Topic 842, which allows transition to the new lease standard by recognizing a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. Entities may elect to apply either approach. There are also a number of optional practical expedients that entities may elect to apply. The Company plans to adopt Topic 842 on January 1, 2022, and is currently assessing the impact of this standard on its consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-15, *Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement that is a Service Contract*. The standard requires implementation costs incurred by customers in cloud computing arrangements to be deferred over the noncancelable term of the cloud computing arrangements plus any optional renewal periods (1) that are reasonably certain to be exercised by the customer or (2) for which exercise of the renewal option is controlled by the cloud service provider. The effective date of this pronouncement is for fiscal years beginning after December 15, 2020, and interim periods within annual periods beginning after December 15, 2021, and early adoption is permitted. The standard can be adopted either using the prospective or retrospective transition approach. The Company is currently evaluating the impact of this pronouncement on the Company's consolidated financial statements and disclosures.

**3. Fair Value Measurements**

The Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The Company determines fair value based on assumptions that market participants would use in pricing an asset or liability in the principal or most advantageous market. When considering market participant assumptions in fair value

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**Notes to Condensed Consolidated Financial Statements**  
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measurements, the following fair value hierarchy distinguishes between observable and unobservable inputs, which are categorized in one of the following levels:

- *Level 1 Inputs:* Unadjusted quoted prices in active markets for identical assets or liabilities accessible to the reporting entity at the measurement date.
- *Level 2 Inputs:* Other than quoted prices included in Level 1 inputs that are observable for the asset or liability, either directly or indirectly, for substantially the full term of the asset or liability.
- *Level 3 Inputs:* Unobservable inputs for the asset or liability used to measure fair value to the extent that observable inputs are not available, thereby allowing for situations in which there is little, if any, market activity for the asset or liability at measurement date.

On a recurring basis, the Company measures certain financial assets and liabilities at fair value. The following tables summarize the fair value of the Company's financial assets and liabilities measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	June 30, 2020			
	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
Money market funds	\$124,171	\$ —	\$ —	\$124,171
Total assets	\$124,171	\$ —	\$ —	\$124,171

	December 31, 2019			
	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
Money market funds	\$43,621	\$ —	\$ —	\$43,621
Total assets	\$43,621	\$ —	\$ —	\$43,621

The Company has an operating account invested in money market funds with maturities of less than three months and is classified as cash and cash equivalents on the Company's condensed consolidated balance sheet. The money market funds are valued using Level 1 inputs that are based on quoted prices in active markets for identical assets.

For the three months ended June 30, 2020 and 2019 and for the six months ended June 30, 2020 and 2019, the Company recognized no material realized gains or losses on financial instruments.

The Company's Level 3 liabilities include the redeemable convertible preferred stock liability which was settled in August 2019 upon the completion of the second closing of the Company's Series C redeemable convertible preferred stock financing. The liability was remeasured at June 30, 2019 using a probability-weighted expected return method, or PWERM, whereby the Company's total equity value was estimated under various exit scenarios and allocated to the Company's different classes of equity. The PWERM included two scenarios, IPO or staying private, that considered an estimate of the timing of each scenario and were weighted based on the Company's estimate of the probability of each event occurring. The equity value under the IPO scenario was based on recent IPO values of comparable companies and weighted 40%. The equity value under the staying private scenario was based on the recent Series C redeemable convertible preferred stock financing and was weighted 60%. The liability was remeasured to its fair value of \$9.5 million as of June 30, 2019. The Company recorded a loss of \$1.6 million and \$4.3 million in the condensed consolidated statements of operations for the three and six months ended June 30, 2019, respectively, for the change in the fair value of the liability.

The changes in the carrying value of the liability were as follows (in thousands):

Fair value as of December 31, 2018	\$5,140
Change in fair value	4,330
Fair value as of June 30, 2019	\$9,470

There were no transfers between Levels 1, 2 or 3 for the periods presented.

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**Notes to Condensed Consolidated Financial Statements**  
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**4. Balance Sheet Components*****Prepaid Expenses and Other Current Assets***

Prepaid expenses and other current assets consisted of the following (in thousands):

	<b>June 30, 2020</b>	<b>December 31, 2019</b>
Prepaid research and development costs	\$ 333	\$ 1,086
Prepaid expenses	574	310
Other receivables	—	79
Total prepaid expenses and other current assets	<u>\$ 907</u>	<u>\$ 1,475</u>

***Accrued Liabilities***

Accrued liabilities consisted of the following (in thousands):

	<b>June 30, 2020</b>	<b>December 31, 2019</b>
Accrued commission related to issuance of redeemable convertible preferred stock	\$ 5,055	\$ —
Accrued research and development expenses	1,610	459
Accrued professional services	1,002	733
Accrued compensation	904	926
Other accrued expenses	647	76
Total accrued liabilities	<u>\$ 9,218</u>	<u>\$ 2,194</u>

**5. Promissory Note**

Pursuant to the Coronavirus Aid, Relief, and Economic Security Act, the Company obtained a \$0.5 million promissory note from the U.S. Small Business Administration on April 21, 2020, which was repaid in full on May 1, 2020.

**6. Commitments and Contingencies*****Leases***

The Company leases its offices and laboratory in South San Francisco, California under a 7-year noncancelable lease agreement that ends in June 2024 with a 5-year renewal option. Rent expense is recognized on a straight-line basis over the non-cancelable term of the lease and, accordingly, the Company records the difference between cash rent payments and the recognition of rent expense as a deferred rent liability on the accompanying condensed consolidated balance sheet.

Rent expense for each of the three months ended June 30, 2020 and 2019 was \$88,000. Rent expense for each of the six months ended June 30, 2020 and 2019 was \$176,000.

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**License and Other Agreements**

In November 2011, the Company entered into an exclusive licensing agreement, or the Stanford Agreement, with The Board of Trustees of the Leland Stanford Junior University, or Stanford, whereby the Company was granted an exclusive, worldwide, royalty-bearing, sublicensable license, under certain patent rights, or the Licensed Patents, to make, use, offer for sale, sell, import and otherwise commercialize products covered by the Licensed Patents for human or animal diseases, disorders or conditions. Under the Stanford Agreement, the Company made an upfront payment and is obligated to pay Stanford annual license maintenance fees, potential future milestone payments totaling up to \$600,000, and royalty payments at a rate equal to a low single-digit percentage of worldwide net sales of licensed products.

In December 2016, the Company entered into a Sponsored Research Agreement with a not-for-profit entity to perform research on multiple sclerosis. The Sponsored Research Agreement was amended in March 2019. Under the terms of the Sponsored Research Agreement, the Company may receive up to \$651,000, which was amended from \$693,000, in funding. If within 15 years of the end of the Sponsored Research Agreement the Company files a marketing authorization application for a product treating multiple sclerosis, the Company will be obligated to pay milestone payments up to four times the amounts received under the Sponsored Research Agreement. The Company has received \$455,000 in funding to date.

The Company received \$190,000 representing the final amount received under the Sponsored Research Agreement, which was recorded as other income for the three and six months ended June 30, 2019. No funding was received for the three and six months ended June 30, 2020.

**Guarantees and Indemnifications**

In the normal course of business, the Company enters into agreements that contain a variety of representations and provide for general indemnification. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. As of June 30, 2020, the Company did not have any material indemnification claims that were probable or reasonably possible and consequently has not recorded related liabilities.

**7. Redeemable Convertible Preferred Stock and Stockholder's Deficit****Redeemable Convertible Preferred Stock**

As of June 30, 2020, redeemable convertible preferred stock consisted of the following:

	<u>Shares Authorized</u>	<u>Shares Outstanding</u>	<u>Net Carrying Value (in thousands)</u>	<u>Liquidation Preference (in thousands)</u>
Series A	1,015,434	1,015,434	\$ 1,000	\$ 1,000
Series A-1	16,398,995	16,398,995	17,149	17,219
Series B	38,778,090	38,778,090	44,518	44,595
Series C	55,555,546	55,555,546	81,877	75,000
Series D	71,719,859	71,719,859	90,510	102,000
Total	<u>183,467,924</u>	<u>183,467,924</u>	<u>\$ 235,054</u>	<u>\$ 239,814</u>



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**Notes to Condensed Consolidated Financial Statements**  
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As of December 31, 2019, redeemable convertible preferred stock consisted of the following:

	Shares Authorized	Shares Outstanding	Net Carrying Value (in thousands)	Liquidation Preference (in thousands)
Series A	1,015,434	1,015,434	\$ 1,000	\$ 1,000
Series A-1	16,398,995	16,398,995	17,144	17,219
Series B	38,778,091	38,778,090	44,505	44,595
Series C	62,962,952	55,555,546	81,335	75,000
Total	<u>119,155,472</u>	<u>111,748,065</u>	<u>\$ 143,984</u>	<u>\$ 137,814</u>

In June 2020, the Company completed its financing of Series D redeemable convertible preferred stock, which resulted in the Company issuing 71,719,859 shares of Series D redeemable convertible preferred stock, including 9,773,587 shares issued to related parties who were 10% or greater holders of the Company, at a price per share of \$1.4222 for aggregate proceeds of \$96.8 million, net of issuance costs of \$5.2 million. The shares of Series D redeemable convertible preferred stock are convertible at any time, at the holders' option, into shares of common stock.

In connection with the issuance and sale of the Series D redeemable convertible preferred stock, the Company recognized a beneficial conversion feature of approximately \$6.3 million. A beneficial conversion feature represents the intrinsic value of the conversion feature, as determined by comparing the effective conversion price at the commitment date with the estimated fair value of the Company's common stock. The beneficial conversion feature was recorded in additional paid-in capital as of June 30, 2020 resulting in a discount to the carrying value of the Series D redeemable convertible preferred stock.

The Company has presented all of its Series A, Series A-1, Series B, Series C and Series D redeemable convertible preferred stock as temporary equity in its condensed consolidated financial statements as the shares of stock contain redemption features that commence at any time on or after the fifth anniversary of the Series D financing date at the option of the holders. The Company adjusts the carrying amount of the Series A, Series A-1, Series B, Series C and Series D redeemable convertible preferred stock to its redemption value over the period from the date of issuance to the earliest redemption date using the effective interest method.

In July 2020, immediately prior to the completion of the IPO (see Note 1), all outstanding shares of redeemable convertible preferred stock were automatically converted into 20,824,938 shares of common stock.

**Common Stock**

The Company has reserved the following shares of common stock for issuance as follows:

	June 30, 2020	December 31, 2019
Redeemable convertible preferred stock outstanding on an as-converted basis	20,824,938	12,684,214
Options issued and outstanding	3,026,480	2,007,222
Options available for future grant	376,894	454,110
Total common stock reserved	<u>24,228,312</u>	<u>15,145,546</u>

**ANNEXON, INC.**  
**Notes to Condensed Consolidated Financial Statements**  
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### 8. Equity Incentive Plan

Stock option activity under the Plan was as follows:

	Shares Available for Grant	Number of Shares	Weighted- Average Exercise Price Per Share	Weighted- Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Balances as of December 31, 2019	454,110	2,007,222	\$ 4.91	8.26	\$ 21,623
Additional shares authorized	942,042	—			
Stock options granted	(1,021,898)	1,021,898	13.39		
Stock options cancelled	2,640	(2,640)	4.67		
Balances as of June 30, 2020	<u>376,894</u>	<u>3,026,480</u>	\$ 7.77	8.50	\$ 16,828
Exercisable as of June 30, 2020		<u>1,032,734</u>	\$ 3.39	6.87	\$ 10,236

No options were exercised during the six months ended June 30, 2020. The total intrinsic value of options exercised during each of the three and six months ended June 30, 2019 was \$8,000. The intrinsic value is the difference between the estimated fair value of the Company's common stock at the time of exercise, as determined by the Board of Directors, and the exercise price of the stock option.

#### *Stock-Based Compensation Expense*

The total stock-based compensation expense recognized for options granted was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Research and development	\$ 335	\$ 135	\$ 660	\$ 232
General and administrative	428	302	766	671
Total stock-based compensation expense	<u>\$ 763</u>	<u>\$ 437</u>	<u>\$ 1,426</u>	<u>\$ 903</u>

As of June 30, 2020, the total unrecognized stock-based compensation cost related to outstanding unvested stock options that are expected to vest was \$15.4 million, which the Company expects to recognize over an estimated weighted-average period of 3.2 years.

To determine the value of stock option awards for stock-based compensation purposes, the Company uses the Black-Scholes option pricing model and the assumptions discussed below. Each of these inputs is subjective and generally requires significant judgment.

*Expected Term*—The Company's expected term represents the period that the Company's stock-based awards are expected to be outstanding. The Company's historical share option exercise information is limited due to a lack of sufficient data points, and did not provide a reasonable basis upon which to estimate an expected term. The expected term for option grants is therefore determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term).

*Expected Volatility*—Because the Company is privately held and does not have any trading history for its common stock, the expected volatility was estimated based on the average volatility for comparable publicly traded life science companies over a period equal to the expected term of the stock option grants. The comparable companies were chosen based on the similar size, stage in the life cycle, or area of specialty. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

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*Risk-Free Interest Rate*—The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of the option.

*Dividend Yield*—The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.

*Fair Value of Common Stock*—The grant date fair market value of the shares of common stock underlying stock options has historically been determined by the Company’s Board of Directors. Because there has been no public market for the Company’s common stock, the Board of Directors exercises reasonable judgment and considers a number of objective and subjective factors to determine the best estimate of the fair market value, which include contemporaneous valuations performed by an independent third-party, important developments in the Company’s operations, sales of redeemable convertible preferred stock, the rights, preferences and privileges of the Company’s redeemable convertible preferred stock relative to those of its common stock, lack of marketability of its common stock, actual operating results, financial performance, the progress of clinical development, the likelihood of achieving a liquidity event for the Company’s security holders, the trends, development and conditions in the life sciences and biotechnology sectors, the economy in general, the stock price performance and volatility of comparable public companies.

The fair value of each award issued was estimated on the date of grant using the Black-Scholes option pricing model with the following assumptions:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Expected term (in years)	5.00 – 6.08	6.02 – 6.08	5.00 – 6.08	6.02 – 6.08
Expected volatility	85%	76%	85%	76% – 77%
Risk-free interest rate	0.33% – 0.45%	1.87% – 2.20%	0.33% – 1.45%	1.87% – 2.61%
Dividend yield	—	—	—	—

**9. Income Taxes**

For the six months ended June 30, 2019 and 2020, the Company incurred insignificant amounts for an income tax provision. The U.S. federal and California deferred tax assets generated from the Company’s net operating losses have been fully reserved, as the Company believes it is not more likely than not that the benefit will be realized.

**10. Net Loss Per Share Attributable to Common Stockholders**

The following outstanding potentially dilutive shares have been excluded from the calculation of diluted net loss per share due to their anti-dilutive effect:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2020	2019	2020	2019
Redeemable convertible preferred stock on an as-converted basis	20,824,938	10,161,828	20,824,938	10,161,828
Stock options to purchase common stock	3,026,480	2,109,906	3,026,480	2,109,906
Total	<u>23,851,418</u>	<u>12,271,734</u>	<u>23,851,418</u>	<u>12,271,734</u>

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**Notes to Condensed Consolidated Financial Statements**  
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**11. Subsequent Events**

***Reverse Stock Split***

In July 2020, the Company's board of directors approved an amendment to the Company's certificate of incorporation to effect a reverse split of shares of the Company's common stock on a one-for-8.81 basis, which was effected on July 17, 2020, or the Reverse Stock Split. The number of authorized shares and the par values of the common stock and redeemable convertible preferred stock were not adjusted as a result of the Reverse Stock Split. In connection with the Reverse Stock Split, the conversion ratio for the Company's outstanding redeemable convertible preferred stock was proportionately adjusted such that the common stock issuable upon conversion of such preferred stock was decreased in proportion to the Reverse Stock Split. All references to common stock and options to purchase common stock share data, per share data and related information contained in the consolidated financial statements have been retroactively adjusted to reflect the effect of the Reverse Stock Split for all periods presented.

***Initial Public Offering***

In July 2020, the Company completed an initial public offering of its common stock. As part of the IPO, the Company issued and sold 14,750,000 shares of its common stock at a public offering price of \$17.00 per share and 2,139,403 shares of its common stock to the underwriters of the IPO pursuant to the partial exercise of their option to purchase additional shares at a price of \$17.00 per share less the underwriting discounts and commissions. The Company received net proceeds of approximately \$262.7 million from the IPO, after deducting underwriting discounts and commissions of \$20.1 million and offering costs of \$4.3 million, of which \$3.3 million was incurred as of June 30, 2020. Prior to the completion of the IPO, all shares of redeemable convertible preferred stock then outstanding were converted into 20,824,938 shares of common stock. Upon conversion of the redeemable convertible preferred stock, the unamortized balance of \$6.2 million of the discount from the beneficial conversion feature was recorded as a deemed dividend to the preferred stockholders resulting in an increase to the carrying value of redeemable convertible preferred stock. Upon conversion into common stock, the carrying value of the redeemable convertible preferred stock of \$241.4 million was reclassified to equity. In July 2020, the Company adopted the 2020 Incentive Award Plan, or the 2020 Plan, and the Employee Stock Purchase Plan, or the ESPP, which became effective in connection with the IPO. The Company has reserved 3,600,868 shares of common stock for future issuance under the 2020 Plan and 360,086 shares under the ESPP, respectively.

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

*You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our condensed consolidated financial statements and the related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q and our final prospectus, dated July 23, 2020, filed with the Securities and Exchange Commission pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, or the Prospectus.*

*In addition to historical financial information, this discussion and other parts of this report contain forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, based upon current expectations that involve risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth in the section titled "Risk Factors" under Part II, Item 1A below. In some cases, you can identify forward-looking statements by terminology such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potentially," "predict," "should," "will" or the negative of these terms or other similar expressions. Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties that could cause actual results and events to differ from those anticipated. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements, like all statements in this report, speak only as of their date, and we undertake no obligation to update or revise these statements in light of future developments. These statements are inherently uncertain and investors are cautioned not to unduly rely upon these statements.*

### Overview

We are a clinical-stage biopharmaceutical company developing a pipeline of novel therapies for patients with classical complement-mediated disorders of the body, brain and eye. Our pipeline is based on our platform technology addressing well-researched classical complement-mediated autoimmune and neurodegenerative disease processes, both of which are triggered by aberrant activation of C1q, the initiating molecule of the classical complement pathway. Evidence suggests that potent and selective inhibition of C1q can prevent tissue damage triggered in antibody-mediated autoimmune disease and preserve loss of functioning synapses associated with cognitive and functional decline in complement-mediated neurodegeneration. Our upstream complement approach targeting C1q acts as an "on/off switch" designed to block all downstream components of the classical complement pathway that lead to excess inflammation, tissue damage and patient disability in a host of complement-mediated disorders, while preserving the normal immune function of the lectin and alternative complement pathways involved in the clearance of pathogens and damaged cells.

Our pipeline of product candidates is designed to block the activity of C1q and the entire classical complement pathway in a broad set of complement-mediated diseases. Our first product candidate, ANX005, is a full-length monoclonal antibody formulated for intravenous administration in autoimmune and neurodegenerative disorders. Our second product candidate, ANX007, is an antigen-binding fragment, or Fab, formulated for intravitreal administration for the treatment of neurodegenerative ophthalmic disorders. We are also developing ANX009, an investigational, subcutaneous formulation of a Fab designed for the treatment of systemic autoimmune diseases. We have completed Phase 1b safety and dose-ranging clinical trials for ANX005 and ANX007 in patients with Guillain-Barré Syndrome, or GBS, and glaucoma, respectively. Both ANX005 and ANX007 were well-tolerated and showed full inhibition of C1q and the classical complement pathway in the Phase 1b trials.

We intend to advance ANX005 into multiple Phase 2 trials in 2020 and 2021 including in patients with GBS, warm autoimmune hemolytic anemia, Huntington's disease and amyotrophic lateral sclerosis. We plan to advance ANX007 into a Phase 2 trial in patients with GA in 2021. Additionally, we are developing novel product candidates designed to inhibit C1q and other components of the early classical complement cascade with the goal of further broadening our portfolio. Finally, we are leveraging our disciplined development strategy in early clinical trials utilizing established biomarkers to enhance patient selection, measure target engagement and assess our product candidates' potential to meaningfully impact the disease process and improve the probability of technical success over shorter development timelines.

We hold worldwide development and commercialization rights, including through exclusive licenses, to all of our product candidates, which allows us to strategically maximize value from our product portfolio over time. Our patent portfolio includes patent protection for our upstream complement platform and each of our product candidates.

We were incorporated in March 2011 and commenced operations later that year. To date, we have focused primarily on performing research and development activities, hiring personnel and raising capital to support and expand these activities. We do not have any products approved for sale, and we have not generated any revenue from product sales. We have incurred net losses each year since our inception. Our net losses were \$12.2 million and \$9.4 million for the three months ended June 30, 2020 and 2019, respectively, and \$24.6 million and \$18.1 million for the six months ended June 30, 2020 and 2019, respectively. As of June 30, 2020, we had an accumulated deficit of \$127.2 million and cash and cash equivalents of \$124.8 million.

## **Recent Developments**

In July 2020, we completed an initial public offering of our common stock. As part of the IPO, we issued and sold 14,750,000 shares of our common stock at a public offering price of \$17.00 per share and 2,139,403 shares of our common stock to the underwriters of the IPO pursuant to the partial exercise of their option to purchase additional shares at a price of \$17.00 per share less underwriting discounts and commissions. We received net proceeds of approximately \$262.7 million from the IPO, after deducting underwriting discounts and commissions of \$20.1 million and offering costs of \$4.3 million.

The global COVID-19 pandemic continues to rapidly evolve, and its ultimate impact is highly uncertain and subject to change. We will continue to monitor the COVID-19 situation closely. The extent of the impact of COVID-19 on our business, operations and clinical development timelines and plans remains uncertain, and will depend on the duration and spread of the outbreak and its impact on our clinical trial enrollment, trial sites, contract research organizations, or CROs, third-party manufacturers, regulatory authorities and other third parties with whom we do business.

## **Components of Operating Results**

### ***Revenue***

Our product candidates are not approved for commercial sale. We have not generated any revenue from sales of our product candidates and do not expect to do so in the foreseeable future and until we complete clinical development, submit regulatory filings and receive approvals from applicable regulatory bodies for such product candidates, if ever.

### ***Operating Expenses***

#### ***Research and Development***

Research and development expenses account for a significant portion of our operating expenses. Research and development expenses consist primarily of direct and indirect costs incurred for the development of our product candidates.

Direct expenses include:

- preclinical and clinical outside service costs associated with discovery, preclinical and clinical testing of our product candidates;
- professional services agreements with third party contract organizations, investigative clinical trial sites and consultants that conduct research and development activities on our behalf;
- contract manufacturing costs to produce clinical trial materials; and
- laboratory supplies and materials.

Indirect expenses include:

- compensation and personnel-related expenses (including stock-based compensation);
- allocated expenses for facilities and depreciation; and
- other indirect costs.

We record research and development expenses as incurred. Payments made to other entities are under agreements that are generally cancelable by us. Advance payments for goods or services to be received in future periods for use in research and development activities are deferred as prepaid expenses. The prepaid amounts are then expensed as the related services are performed. At this time, we cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete the development of, and obtain regulatory approval for, any of our product candidates.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, particularly as they advance into later stages of development and as we conduct larger clinical trials, engage in other research and development activities and seek regulatory approvals for any product candidates that successfully complete clinical trials and as we incur expenses associated with hiring additional personnel to support our research and development efforts. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain.

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### **General and Administrative**

General and administrative expenses consist primarily of compensation and personnel-related expenses (including stock-based compensation) for our personnel in executive, finance and other administrative functions. General and administrative expenses also include professional fees paid for accounting, legal and tax services, allocated expenses for facilities and depreciation and other general and administrative costs.

We expect our general and administrative expenses to increase substantially for the foreseeable future as we continue to support our research and development activities, grow our business and, if any of our product candidates receive marketing approval, commercialization activities. We will also incur additional expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC, Sarbanes-Oxley Act and the Nasdaq Stock Market, additional insurance expenses, investor relations activities and other administrative and professional services. We also expect to increase the size of our administrative function to support the growth of our business.

### **Loss on Remeasurement of Redeemable Convertible Preferred Stock Liability**

Loss on remeasurement of redeemable convertible preferred stock liability consists of gains and losses from the remeasurement to fair value of the redeemable convertible preferred stock liability related to our Series C redeemable convertible preferred stock. We remeasured the liability each reporting period from the date of issuance (December 2018) until the second closing of our Series C redeemable convertible preferred stock which occurred in August 2019.

### **Other Income, Net**

Other income, net, primarily consists of non-recurring income from research grants and interest income earned on our cash equivalents.

## **Results of Operations**

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

The following tables summarize our results of operations for the periods presented.

	<b>Three Months Ended June 30,</b>		<b>Dollar Change</b>	<b>% Change</b>
	<b>2020</b>	<b>2019</b>		
	<b>(unaudited)</b>			
	<b>(in thousands)</b>			
Operating expenses:				
Research and development	\$ 9,287	\$ 5,987	\$ 3,300	55%
General and administrative	2,950	2,230	720	32%
Total operating expenses	12,237	8,217	4,020	49%
Loss from operations	(12,237)	(8,217)	(4,020)	49%
Loss on remeasurement of redeemable convertible preferred stock liability	—	(1,560)	1,560	(100)%
Other income, net	1	376	(375)	*
Net loss before taxes	(12,236)	(9,401)	(2,835)	30%
Provision for income taxes	4	—	4	*
Net loss	<u><u>\$ (12,240)</u></u>	<u><u>\$ (9,401)</u></u>	<u><u>\$ (2,839)</u></u>	30%

\* Not meaningful

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### **Research and Development Expenses**

	<b>Three Months Ended June 30,</b>		<b>Dollar Change</b>	<b>% Change</b>
	<b>2020</b>	<b>2019</b>		
	<b>(unaudited)</b>			
	<b>(in thousands)</b>			
Direct costs:				
Preclinical and clinical outside services	\$4,038	\$3,071	\$ 967	31%
Professional services	764	451	313	69%
Contract manufacturing	1,784	861	923	107%
Laboratory supplies and materials	216	199	17	9%
Indirect costs:				
Compensation and personnel-related (including stock-based compensation)	2,224	1,186	1,038	88%
Facilities and depreciation	228	211	17	8%
Other	33	8	25	*
Total research and development expenses	<u>\$9,287</u>	<u>\$5,987</u>	<u>\$3,300</u>	55%

\* Not meaningful

Research and development expenses increased by \$3.3 million, or 55%, for the three months ended June 30, 2020 compared to the same period in 2019. The increase was primarily due to an increase of \$1.0 million in direct clinical outside services related to our ongoing and planned clinical trials. Contract manufacturing expenses increased by \$0.9 million primarily due to the manufacturing of ANX005 to support the initiation of multiple clinical trials and pre-IND activities for our next generation pipeline. Direct professional services costs increased by \$0.3 million related to external research and development during the three months ended June 30, 2020. Compensation and personnel-related expenses increased by \$1.0 million due to an increase in headcount and related employee costs.

### **General and Administrative Expenses**

	<b>Three Months Ended June 30,</b>		<b>Dollar Change</b>	<b>% Change</b>
	<b>2020</b>	<b>2019</b>		
	<b>(unaudited)</b>			
	<b>(in thousands)</b>			
Professional services	\$1,735	\$1,333	\$ 402	30%
Compensation and personnel-related (including stock-based compensation)	998	751	247	33%
Facilities and depreciation	120	104	16	15%
Other	97	42	55	*
Total general and administrative expenses	<u>\$2,950</u>	<u>\$2,230</u>	<u>\$ 720</u>	32%

\* Not meaningful

General and administrative expenses increased by \$0.7 million, or 32%, for the three months ended June 30, 2020 compared to the same period in 2019. The increase was primarily due to an increase of \$0.4 million in professional services for public company readiness efforts including accounting, legal and audit fees, and an increase of \$0.2 million in compensation and personnel-related expenses due to an increase in headcount and related employee costs.

### **Loss on Remeasurement of Redeemable Convertible Preferred Stock Liability**

For the three months ended June 30, 2019, we recorded a \$1.5 million loss on remeasurement of redeemable convertible preferred stock liability related to the change in the fair value of the liability. The liability was recognized in connection with the initial closing of our Series C redeemable convertible preferred stock financing in December 2018 and was settled upon completion of the second closing in August 2019.



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### **Other Income, Net**

Other income, net, decreased by \$0.4 million for the three months ended June 30, 2020 compared to the same period in 2019. In the three months ended June 30, 2019, we received \$0.2 million under the Sponsored Research Agreement for a new therapeutic agent, ANX005, which was recorded as other income. In addition, the decrease in other income was primarily driven by lower interest income.

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

The following tables summarize our results of operations for the periods presented.

	Six Months Ended June 30,		Dollar Change	% Change
	2020	2019		
	(unaudited)			
	(in thousands)			
Operating expenses:				
Research and development	\$ 19,504	\$ 10,640	\$ 8,864	83%
General and administrative	5,189	3,679	1,510	41%
Total operating expenses	24,693	14,319	10,374	72%
Loss from operations	(24,693)	(14,319)	(10,374)	72%
Loss on remeasurement of redeemable convertible preferred stock liability	—	(4,330)	4,330	*
Other income, net	116	597	(481)	(81)%
Net loss before taxes	(24,577)	(18,052)	(6,525)	36%
Provision for income taxes	4	1	3	*
Net loss	<u>\$ (24,581)</u>	<u>\$ (18,053)</u>	<u>\$ (6,528)</u>	36%

\* Not meaningful

### **Research and Development Expenses**

	Six Months Ended June 30,		Dollar Change	% Change
	2020	2019		
	(unaudited)			
	(in thousands)			
Direct costs:				
Preclinical and clinical outside services	\$ 8,086	\$ 5,137	\$ 2,949	57%
Professional services	1,372	839	533	64%
Contract manufacturing	4,785	1,751	3,034	173%
Laboratory supplies and materials	273	282	(9)	(3)%
Indirect costs:				
Compensation and personnel-related (including stock-based compensation)	4,463	2,191	2,272	104%
Facilities and depreciation	444	412	32	8%
Other	81	28	53	*
Total research and development expenses	<u>\$ 19,504</u>	<u>\$ 10,640</u>	<u>\$ 8,864</u>	83%

\* Not meaningful

Research and development expenses increased by \$8.9 million, or 83%, for the six months ended June 30, 2020 compared to the same period in 2019. The increase was primarily due to \$3.0 million in the manufacturing of ANX005 to support the initiation of multiple clinical trials and pre-IND activities including cell line development for our next generation pipeline. Preclinical and clinical outside services increased by \$3.0 million primarily related to our GBS Phase 1b drug-drug interaction trial and planning activities for our GBS Phase 2/3 and HD Phase 2 clinical trials. In addition, preclinical expenses were higher due to toxicology studies to support ANX009. Compensation and personnel-related expenses increased by \$2.3 million due to growth in the number of research and development employees. In addition, professional services increased by \$0.5 million due to an increase in external research and development capabilities.

**General and Administrative Expenses**

	Six Months Ended June 30,		Dollar Change	% Change
	2020	2019		
	(unaudited) (in thousands)			
Professional services	\$2,806	\$1,906	\$ 900	47%
Compensation and personnel-related (including stock-based compensation)	1,935	1,512	423	28%
Facilities and depreciation	233	189	44	23%
Other	215	72	143	*
<b>Total general and administrative expenses</b>	<b>\$5,189</b>	<b>\$3,679</b>	<b>\$1,510</b>	<b>41%</b>

\* Not meaningful

General and administrative expenses increased by \$1.5 million, or 41%, for the six months ended June 30, 2020 compared to the same period in 2019. The increase was primarily due to \$0.9 million in professional services for public company readiness efforts including accounting, legal and audit fees. Compensation and personnel-related expenses increased by \$0.4 million primarily related to due to an increase in headcount and related employee costs.

**Loss on Remeasurement of Redeemable Convertible Preferred Stock Liability**

For the six months ended June 30, 2019, we recorded a \$4.3 million loss on remeasurement of redeemable convertible preferred stock liability related to the change in the fair value of the liability. The liability was recognized in connection with the initial closing of our Series C redeemable convertible preferred stock financing in December 2018 and was settled upon completion of the second closing in August 2019.

**Other Income, Net**

Other income, net, decreased by \$0.5 million, or 81%, for the six months ended June 30, 2020 compared to the same period in 2019. In the six months ended June 30, 2019, we had received \$0.2 million under the Sponsored Research Agreement for a new therapeutic agent, ANX005, which was recorded as other income. The remaining \$0.3 million decrease was primarily driven by lower interest income as a result of a lower cash balance and interest rates.

**Liquidity and Capital Resources**

**Sources of Liquidity**

Due to our significant research and development expenditures, we have generated operating losses since our inception. We have funded our operations primarily through the sale of equity securities. From our inception through June 30, 2020, we have raised net cash proceeds of \$233.9 million from the sale of our equity securities. As of June 30, 2020, we had available cash and cash equivalents of \$124.8 million and an accumulated deficit of \$127.2 million. In connection with our IPO, we issued and sold 16,889,403 shares of our common stock at a public offering price of \$17.00 per share for net proceeds of approximately \$262.7 million, after deducting underwriting discounts and commissions and offering costs.

**Historical Cash Flows**

	Six Months Ended June 30,	
	2020	2019
	(in thousands)	
Cash used in operating activities	\$ (20,247)	\$(12,699)
Cash used in investing activities	(16)	(18)
Cash provided by financing activities	101,095	3
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>\$ 80,832</b>	<b>\$(12,714)</b>

### ***Cash Flows from Operating Activities***

Cash used in operating activities for the six months ended June 30, 2020 was \$20.2 million, which consisted of a net loss of \$24.6 million, partially offset by \$1.7 million in non-cash charges and a net change of \$2.7 million in our net operating assets and liabilities. The non-cash charges consisted of stock-based compensation of \$1.4 million and depreciation and amortization of \$0.3 million.

Cash used in operating activities for the six months ended June 30, 2019 was \$12.7 million, which consisted of a net loss of \$18.1 million and a net change of \$0.1 million in our net operating assets and liabilities, partially offset by \$5.4 million in non-cash charges. The non-cash charges consisted of the loss on remeasurement of the redeemable convertible preferred stock liability of \$4.3 million, stock-based compensation of \$0.9 million and depreciation and amortization of \$0.2 million.

### ***Cash Flows from Investing Activities***

Cash used in investing activities for the six months ended June 30, 2020 and 2019 was \$16,000 and \$18,000, respectively, related to purchases of property and equipment.

### ***Cash Flows from Financing Activities***

Cash provided by financing activities for the six months ended June 30, 2020 was \$101.1 million, which consisted of gross proceeds received from sale and issuance of our Series D redeemable convertible preferred stock of approximately \$102.0 million and proceeds of \$0.5 million from Paycheck Protection Program loan, partially offset by payments for deferred offering costs of \$0.9 million and repayments of \$0.5 million of Paycheck Protection Program loan.

Cash provided by financing activities for the six months ended June 30, 2019 was \$3,000 related to proceeds from the exercise of stock options.

### ***Funding Requirements***

We use our cash to fund operations, primarily to fund our clinical trials, research and development expenditures and related personnel costs. We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to our product candidates, particularly as they advance into later stages of development and as we conduct larger clinical trials, engage in other research and development activities, seek regulatory approvals for any product candidates that successfully complete clinical trials and as we incur expenses associated with hiring additional personnel to support our research and development efforts. In addition, we expect our general and administrative expenses to increase substantially for the foreseeable future as we continue to support our research and development activities and to grow our business and as we expect to engage in commercialization activities, if any of our product candidates receive marketing approval. We will also incur additional expenses as a result of operating as a public company and also expect to increase the size of our administrative function to support the growth of our business. The timing and amount of our operating expenditures will depend on many factors, including:

- the scope, progress, results and costs of researching and developing our current product candidates or any other future product candidates we choose to pursue, and conducting preclinical studies and clinical trials, including our planned clinical trials of ANX005 and ANX007;
- the timing of, and the costs involved in, obtaining regulatory approvals for our lead product candidates or any future product candidates;
- the number and characteristics of any additional product candidates we develop or acquire;
- the timing and amount of any milestone, royalty and/or other payments we are required to make pursuant to our current or any future license or collaboration agreements;

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- the cost of manufacturing our lead product candidates or any future product candidates and any products we successfully commercialize;
- the cost of building a sales force in anticipation of product commercialization;
- the cost of commercialization activities of our product candidates, if approved for sale, including marketing, sales and distribution costs;
- our ability to establish strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract, hire and retain skilled personnel;
- the costs associated with operating as a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our intellectual property portfolio; and
- the timing, receipt and amount of sales of any future approved products.

Based upon our current operating plan, we believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements through 2023. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. We expect to continue to expend significant resources for the foreseeable future. Until such time, if ever, as we can generate substantial product revenue, we will be required to seek additional funding in the future and currently intend to do so through public or private equity offerings or debt financings, credit or loan facilities, collaborations or a combination of one or more of these funding sources. Additional funds may not be available to us on acceptable terms or at all. If we fail to obtain necessary capital when needed on acceptable terms, or at all, we could be forced to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations. If we raise additional funds by issuing equity securities, our stockholders will suffer dilution and the terms of any financing may adversely affect the rights of our stockholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Debt financing, if available, is likely to involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities received any distribution of our corporate assets.

### **Contractual Obligations and Other Commitments**

During the six months ended June 30, 2020, there have been no material changes outside the ordinary course of business to our contractual obligations from those disclosed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in the Prospectus.

### **Off-Balance Sheet Arrangements**

Since our inception, we have not engaged in any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

### ***Emerging Growth Company Status***

We are an “emerging growth company,” as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies.

We have elected to use this extended transition period to enable us to get comply with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

## **Critical Accounting Policies and Estimates**

Management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates and assumptions for the reported amounts of assets, liabilities, expenses and related disclosures. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions and any such differences may be material.

During the six months ended June 30, 2020, there were no material changes to our critical accounting policies or in the methodology used for estimates from those described in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in the Prospectus.

## **Recent Accounting Pronouncements Not Yet Adopted**

See Note 2—Basis of Presentation and Significant Accounting Policies to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q for information about recent accounting pronouncements, the timing of their adoption, and our assessment, to the extent we have made one yet, of their potential impact on our financial condition of results of operations.

## **Item 3. Quantitative and Qualitative Disclosures About Market Risk**

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities.

### ***Interest Rate Risk***

We held cash and cash equivalents of \$124.8 million and \$43.9 million as of June 30, 2020 and December 31, 2019, respectively. We generally hold our cash in interest-bearing money market accounts. We believe that historical fluctuations in interest rates have not had a material effect on our results of operations during the periods presented. Due to the low risk profile of our investments, an immediate 100 basis point change in interest rates would not have a material effect on the fair market value of our cash.

### ***Foreign Currency***

Our reporting currency is the U.S. dollar. The functional currency of the subsidiary located in Australia is the Australian Dollar. Balance sheets prepared in the functional currencies are translated to the reporting currency at exchange rates in effect at the end of the accounting period, except for stockholders' equity accounts, which are translated at rates in effect when these balances were originally recorded. Revenue and expense accounts are translated using a weighted-average rate during the year. The resulting foreign currency translation adjustments are recorded as a separate component of accumulated other comprehensive loss in the consolidated balance sheets. Foreign exchange translation gains (losses) for the three and six months ended June 30, 2020 and 2019 were not material. Gains and losses resulting from exchange-rate changes on transactions denominated in a currency other than the local currency are included in earnings as incurred.

### ***Effects of Inflation***

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

## **Item 4. Controls and Procedures**

### ***Evaluation of Disclosure Controls and Procedures***

Our management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, have evaluated 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, or the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures are effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC 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.

***Changes in Internal Control over Financial Reporting***

There were no changes in our internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) during the quarter ended June 30, 2020 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## PART II – OTHER INFORMATION

### Item 1. Legal Proceedings.

We are not party to any material legal proceedings at this time. From time to time, we may become involved in various legal proceedings that arise in the ordinary course of our business.

### Item 1A. Risk Factors.

#### RISK FACTORS

*Our business involves significant risks, some of which are described below. You should carefully consider the risks and uncertainties described below, together with all of the other information contained in this Quarterly Report on Form 10-Q, including “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and the financial statements and the related notes. If any of the following risks actually occur, it could harm our business, prospects, operating results and financial condition and future prospects. In such event, the market price of our common stock could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. This Quarterly Report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of factors that are described below and elsewhere in this Quarterly Report.*

#### **Risks Related to Our Limited Operating History, Financial Condition and Capital Requirements**

*We are a clinical-stage biopharmaceutical company with a limited operating history and no products approved for commercial sale. We have incurred significant losses since our inception, and we anticipate that we will continue to incur significant losses for the foreseeable future, which, together with our limited operating history, makes it difficult to assess our future viability.*

We are a clinical-stage biopharmaceutical company, and we have only a limited operating history upon which you can evaluate our business and prospects. Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We have no products approved for commercial sale and have not generated any revenue from sales of our product candidates and have incurred losses in each year since our inception in March 2011. We have only a limited operating history upon which you can evaluate our business and prospects. In addition, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the pharmaceutical, biopharmaceutical and biotechnology industry.

We have had significant operating losses since our inception. Our net loss for the three months ended June 30, 2020 and 2019 was approximately \$12.2 million and \$9.4 million, respectively, and \$24.6 million and \$18.1 million for the six months ended June 30, 2020 and 2019, respectively. As of June 30, 2020, we had an accumulated deficit of \$127.2 million. Substantially all of our losses have resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase as we continue to develop our product candidates, conduct clinical trials and pursue research and development activities. Even if we achieve profitability in the future, we may not be able to sustain profitability in subsequent periods. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders’ equity and working capital.

*We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development programs, commercialization efforts or other operations.*

Since our inception, we have invested a significant portion of our efforts and financial resources in research and development activities. Our product candidates will require additional clinical development, and we intend to conduct additional research and development activities to discover and develop new product candidates, including conducting preclinical studies and clinical trials, all of which will require substantial additional funds. We will continue to expend significant resources for the foreseeable future in connection with these activities. These expenditures will include costs associated with conducting preclinical studies and clinical trials, obtaining regulatory approvals and manufacturing and supply, as well as marketing and selling any products approved for sale. In addition, other unanticipated costs may arise. Because the outcome of any preclinical study or clinical trial is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of our product candidates or any future product candidates.

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As of June 30, 2020, we had capital resources consisting of cash and cash equivalents of approximately \$124.8 million. We expect our existing capital resources will fund our planned operating expenses through 2023. However, our operating plans may change as a result of many factors currently unknown to us, and we may need to seek additional funds sooner than planned through public or private equity offerings or debt financings or other sources, such as strategic collaborations. Such financing may result in dilution to our stockholders, imposition of burdensome debt covenants and repayment obligations, or other restrictions that may affect our business. 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.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing our current product candidates or any other future product candidates we choose to pursue, and conducting preclinical studies and clinical trials, including our planned clinical trials of ANX005 and ANX007 and any delays related to the COVID-19 pandemic;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates or any future product candidates;
- the number and characteristics of any additional product candidates we develop or acquire;
- the timing and amount of any milestone, royalty and/or other payments we are required to make pursuant to our current or any future license or collaboration agreements;
- the cost of manufacturing our product candidates or any future product candidates and any products we successfully commercialize;
- the cost of building a sales force in anticipation of product commercialization;
- the cost of commercialization activities of our product candidates, if approved for sale, including marketing, sales and distribution costs;
- our ability to establish strategic collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- any product liability or other lawsuits related to our products;
- the expenses needed to attract, hire and retain skilled personnel;
- the costs associated with being a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our intellectual property portfolio;
- the timing, receipt and amount of sales of any future approved products; and
- the impact of the COVID-19 pandemic, which may exacerbate the magnitude of the factors discussed above.

Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. 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 ongoing COVID-19 pandemic. If adequate funds are not available to us on a timely basis, we may be required to:

- delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for our product candidates or any future product candidate;
- delay, limit, reduce or terminate our research and development activities; or
- delay, limit, reduce or terminate our efforts to establish manufacturing and sales and marketing capabilities or other activities that may be necessary to commercialize our product candidates or any future product candidate, or reduce our flexibility in developing or maintaining our sales and marketing strategy.

We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies or product candidates that we would otherwise pursue on our own. We do not expect to realize revenue from sales of products or royalties from licensed products in the foreseeable future, if at all, and unless and until our product candidates are clinically tested, approved for commercialization and successfully marketed. To date, we have primarily financed our operations through the sale of equity securities. We will be required to seek additional funding in the future and currently intend to do so through



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public or private equity offerings or debt financings, credit or loan facilities, collaborations or a combination of one or more of these funding sources. Our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond our control. Additional funds may not be available to us on acceptable terms or at all. If we raise additional funds by issuing equity securities, our stockholders will suffer dilution and the terms of any financing may adversely affect the rights of our stockholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. Debt financing, if available, is likely to involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities received any distribution of our corporate assets.

***Due to the significant resources required for the development of our product candidates, we must prioritize development of certain product candidates and/or certain disease indications. We may expend our limited resources on candidates or indications that do not yield a successful product and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.***

We are currently focused on developing product candidates to address classical complement-mediated autoimmune and neurodegenerative diseases. We seek to maintain a process of prioritization and resource allocation among our programs to maintain a balance between aggressively advancing our two clinical-stage product candidates, ANX005 and ANX007, in identified indications and exploring additional indications or mechanisms as well as developing future product candidates. However, due to the significant resources required for the development of our product candidates, we must focus on specific diseases and disease pathways and decide which product candidates to pursue and the amount of resources to allocate to each such product candidate.

Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities. Similarly, any decision to delay, terminate or collaborate with third parties in respect of certain programs may subsequently also prove to be suboptimal and could cause us to miss valuable opportunities. If we make incorrect determinations regarding the viability or market potential of any of our programs or product candidates or misread trends in the autoimmune or neurodegenerative or pharmaceutical, biopharmaceutical or biotechnology industry, our business, financial condition and results of operations could be materially adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain development and commercialization rights.

***Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations.***

Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control and may be difficult to predict, including:

- the timing and cost of, and level of investment in, research, development and, if approved, commercialization activities relating to our product candidates, which may change from time to time;
- the timing and status of enrollment for our clinical trials;
- the cost of manufacturing our product candidates, as well as building out our supply chain, which may vary depending on the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we may incur to acquire, develop or commercialize additional product candidates and technologies;
- timing and amount of any milestone, royalty or other payments due under any collaboration or license agreement;
- future accounting pronouncements or changes in our accounting policies;
- the timing and success or failure of preclinical studies and clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners;
- the timing of receipt of approvals for our product candidates from regulatory authorities in the United States and internationally;
- coverage and reimbursement policies with respect to our product candidates, if approved, and potential future drugs that compete with our products; and
- the level of demand for our product candidates, if approved, which may vary significantly over time.

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The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance.

This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if any forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide.

### **Risks Related to Our Business**

***Our business is heavily dependent on the successful development, regulatory approval and commercialization of our two clinical-stage product candidates, ANX005 and ANX007, each of which is in early stages of clinical development.***

We have no products approved for sale, and our two clinical-stage product candidates are in early stages of clinical development. The success of our business, including our ability to finance our company and generate revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of our product candidates and, in particular, the advancement of our current clinical-stage product candidates, ANX005 and ANX007. However, given our stage of development, it may be many years, if we succeed at all, before we have demonstrated the safety and efficacy of a product candidate sufficient to warrant approval for commercialization. We cannot be certain that our product candidates will receive regulatory approval or be successfully commercialized even if we receive regulatory approval.

While inhibition of the complement pathway has been validated as a therapeutic approach, C1q inhibition is a novel therapeutic approach, which exposes us to certain risks. For example, we may discover unforeseen safety events or that our product candidates do not possess certain properties required for therapeutic effectiveness, or that even if found to be effective in one type of disease, a product candidate, or the therapeutic approach, is not effective in other diseases. In addition, given the novel nature of this therapeutic approach, designing preclinical studies and clinical trials to demonstrate the effect of the product candidates is complex and exposes us to risks, including that our biomarker-driven approach may not translate into therapeutic effectiveness.

In the future, we may also become dependent on other product candidates that we may develop or acquire. The clinical and commercial success of our product candidates and future product candidates will depend on a number of factors, including the following:

- the COVID-19 pandemic, which may result in clinical site closures, delays to patient enrollment, patients discontinuing their treatment or follow up visits or changes to trial protocols;
- our ability to raise any additional required capital on acceptable terms, or at all;
- our ability to complete an investigational new drug application, or IND, enabling studies and successfully submit INDs or comparable applications;
- timely completion of our preclinical studies and clinical trials, which may be significantly slower or cost more than we currently anticipate and will depend substantially upon the performance of third-party contractors;
- whether we are required by the U.S. Food and Drug Administration, or FDA, or similar foreign regulatory agencies to conduct additional clinical trials or other studies beyond those planned to support the approval and commercialization of our product candidates or any future product candidates;
- acceptance of our proposed indications and primary endpoint assessments relating to the proposed indications of our product candidates by the FDA and similar foreign regulatory authorities;
- our ability to demonstrate to the satisfaction of the FDA and similar foreign regulatory authorities the safety, efficacy and acceptable risk to benefit profile of our product candidates or any future product candidates;
- the prevalence, duration and severity of potential side effects or other safety issues experienced with our product candidates or future approved products, if any;
- the timely receipt of necessary marketing approvals from the FDA and similar foreign regulatory authorities;
- achieving and maintaining, and, where applicable, ensuring that our third-party contractors achieve and maintain compliance with our contractual obligations and with all regulatory requirements applicable to our product candidates or any future product candidates or approved products, if any;

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- the ability of third parties with whom we contract to manufacture adequate clinical trial and commercial supplies of our product candidates or any future product candidates remain in good standing with regulatory agencies and develop, validate and maintain commercially viable manufacturing processes that are compliant with current good manufacturing practices, or cGMPs;
- our ability to successfully develop a commercial strategy and thereafter commercialize our product candidates or any future product candidates in the United States and internationally, if approved for marketing, reimbursement, sale and distribution in such countries and territories, whether alone or in collaboration with others;
- our ability to achieve sufficient market acceptance, coverage and adequate reimbursement from third-party payors and adequate market share and revenue for any approved products;
- the convenience of our treatment or dosing regimen;
- acceptance by physicians, payors and patients of the benefits, safety and efficacy of our product candidates or any future product candidates, if approved, including relative to alternative and competing treatments;
- the willingness of physicians, operators of clinics and patients to utilize or adopt any of our product candidates or any future product candidates, if approved;
- patients' willingness to enroll or continue to participate in a clinical trial during the COVID-19 pandemic;
- patient demand for our product candidates, if approved, including patients' willingness to pay out-of-pocket for any approved products in the absence of coverage and/or adequate reimbursement from third-party payors;
- our ability to establish and enforce intellectual property rights in and to our product candidates or any future product candidates; and
- our ability to avoid third-party patent interference, intellectual property challenges or intellectual property infringement claims.

These factors, many of which are beyond our control, could cause us to experience significant delays or an inability to obtain regulatory approvals or commercialize our product candidates. Even if regulatory approvals are obtained, we may never be able to successfully commercialize any of our product candidates. Accordingly, we cannot provide assurances that we will be able to generate sufficient revenue through the sale of our product candidates or any future product candidates to continue our business or achieve profitability.

### ***Public health crises such as pandemics or similar outbreaks could materially and adversely affect our preclinical and clinical trials, business, financial condition and results of operations.***

In March 2020, the World Health Organization declared COVID-19 a global pandemic and the United States declared a national emergency with respect to COVID-19. In response to the COVID-19 pandemic, "shelter in place" orders and other public health guidance measures have been implemented across much of the United States and Europe, including in the locations of our offices, clinical trial sites, key vendors and partners. We expect that our clinical development program timelines will be negatively affected by COVID-19, which could materially and adversely affect our business, financial condition and results of operations. Further, due to "shelter in place" orders and other public health guidance measures, we have implemented a work-from-home policy for all staff members excluding those necessary to maintain minimum basic operations. Our increased reliance on personnel working from home may negatively impact productivity, or disrupt, delay or otherwise adversely impact our business. For example, with our personnel working from home, some of our research activities that require our personnel to be in our laboratories will be delayed.

As a result of the COVID-19 pandemic, or similar pandemics, and related "shelter in place" orders and other public health guidance measures, we have and may in the future experience disruptions that could materially and adversely impact our clinical trials, business, financial condition and results of operations. Potential disruptions include but are not limited to:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in initiating or expanding clinical trials, including delays or difficulties with clinical site initiation and recruiting clinical site investigators and clinical site staff;
- increased rates of patients withdrawing from our clinical trials following enrollment as a result of contracting COVID-19 or other health conditions or being forced to quarantine;
- interruption of key clinical trial activities, such as clinical trial site data monitoring and efficacy, safety and translational data collection, processing and analyses, due to limitations on travel imposed or recommended by federal, state or local governments, employers and others or interruption of clinical trial subject visits, which may impact the collection and integrity of subject data and clinical study endpoints;

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- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- delays or disruptions in preclinical experiments and IND-enabling studies due to restrictions of on-site staff and unforeseen circumstances at contract research organizations, or CROs, and vendors;
- interruption or delays in the operations of the FDA and comparable foreign regulatory agencies;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- limitations on employee or other resources that would otherwise be focused on the conduct of our clinical trials and pre-clinical work, including because of sickness of employees or their families, the desire of employees to avoid travel or contact with large groups of people, an increased reliance on working from home, school closures or mass transit disruptions;
- changes in regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue such clinical trials altogether;
- delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government or contractor personnel; and
- refusal of the FDA to accept data from clinical trials in affected geographies outside the United States.

These and other factors arising from the COVID-19 global pandemic could worsen in countries that are already afflicted with COVID-19, could continue to spread to additional countries or could return to countries where the pandemic has been partially contained, each of which could further adversely impact our ability to conduct clinical trials and our business generally, and could materially and adversely affect our business, financial condition and results of operations.

The COVID-19 global pandemic continues to rapidly evolve. The extent to which the outbreak may affect our clinical trials, business, financial condition and results of operations will depend on future developments, which are highly uncertain and cannot be predicted at this time, such as the ultimate geographic spread of the disease, the duration of the outbreak, travel restrictions and actions to contain the outbreak or treat its impact, such as social distancing and quarantines or lock-downs in the United States and other countries, business closures or business disruptions and the effectiveness of actions taken in the United States and other countries to contain and treat the disease. Future developments in these and other areas present material uncertainty and risk with respect to our clinical trials, business, financial condition and results of operations.

***Research and development of biopharmaceutical products is inherently risky. We cannot give any assurance that any of our product candidates will receive regulatory approval, which is necessary before they can be commercialized.***

We are at an early stage of clinical development of our product candidates. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for and then successfully commercialize our product candidates, and we may fail to do so for many reasons, including the following:

- our product candidates may not successfully complete preclinical studies or clinical trials;
- a product candidate may on further study be shown to have harmful side effects or other characteristics that indicate it does not meet applicable regulatory criteria;
- our competitors may develop therapeutics that render our product candidates obsolete or less attractive;
- the market for a product candidate may change so that the continued development of that product candidate is no longer reasonable or commercially attractive;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all;
- if a product candidate obtains regulatory approval, we may be unable to establish sales and marketing capabilities, or successfully market such approved product candidate; and
- a product candidate may not be accepted as safe and effective by patients, the medical community or third-party payors.

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If any of these events occur, we may be forced to abandon our development efforts for a product candidate or candidates, which would have a material adverse effect on our business and could potentially cause us to cease operations. Failure of a product candidate may occur at any stage of preclinical or clinical development, and we may never succeed in developing marketable products or generating product revenue.

We may not be successful in our efforts to further develop our current and future product candidates. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. Each of our product candidates will require significant additional clinical development, management of preclinical, clinical and manufacturing activities, regulatory approval, adequate manufacturing supply, a commercial organization and significant marketing efforts before we generate any revenue from product sales, if at all. Any clinical studies that we may conduct may not demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates. If the results of our ongoing or future clinical studies are inconclusive with respect to the efficacy of our product candidates, if we do not meet the clinical endpoints with statistical significance or if there are safety concerns or adverse events associated with our product candidates, we may be prevented or delayed in obtaining marketing approval for our product candidates.

The FDA or other regulatory agencies may not agree with our clinical development plan and require that we conduct additional clinical trials to support our regulatory submissions. We have not yet conducted an end of Phase 2 meeting with the FDA to discuss the registration pathway for ANX005, and our current clinical development plans for ANX005 in Guillain-Barre Syndrome, or GBS, may change as a result of future interactions with the FDA. For example, the FDA may require that we conduct more than one pivotal trial in order to gain approval in GBS. Furthermore, any approval of ANX005 for GBS may be limited to ANX005 in combination with the existing standard of care. While not approved for use in GBS in the United States due to differing levels of efficacy in GBS patients, IVIg has developed as the standard of care in the Western world and parts of Asia for patients with GBS and has been shown to be a reasonably effective treatment in some GBS patients.

If any of our product candidates successfully completes clinical trials, we plan to seek regulatory approval to market our product candidates in the United States, the European Union and in additional foreign countries where we believe there is a viable commercial opportunity. We have never commenced, compiled or submitted an application seeking regulatory approval to market any product candidate. We may never receive regulatory approval to market any product candidates even if such product candidates successfully complete clinical trials, which would adversely affect our viability. To obtain regulatory approval in countries outside the United States, we must comply with numerous and varying regulatory requirements of such other countries regarding safety, efficacy, chemistry, manufacturing and controls, clinical trials, commercial sales, pricing and distribution of our product candidates. We may also rely on collaborators or partners to conduct the required activities to support an application for regulatory approval and to seek approval for one or more of our product candidates. We cannot be sure that any such collaborators or partners will conduct these activities successfully or do so within the timeframe we desire. Even if we or any future collaborators or partners are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdictions. If we are unable to obtain approval for our product candidates in multiple jurisdictions, our revenue and results of operations could be negatively affected.

Even if we receive regulatory approval to market any of our product candidates, we cannot assure you that any such product candidate will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. Any approval we may obtain could be for indications or patient populations that are not as broad as intended or desired or may require labeling that includes significant use or distribution restrictions or safety warnings. We may also be required to perform additional or unanticipated clinical trials to obtain approval or be subject to additional post-marketing testing requirements to maintain approval. In addition, regulatory authorities may withdraw their approval of a product or impose restrictions on its distribution, such as in the form of a Risk Evaluation and Mitigation Strategy, or REMS. The failure to obtain timely regulatory approval of product candidates, any product marketing limitations or a product withdrawal would negatively impact our business, results of operations and financial condition.

***We may encounter substantial delays in our clinical trials or may not be able to conduct or complete our clinical trials on the timelines we expect, if at all.***

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. We cannot be sure that submission of an IND or a clinical trial application, or CTA, will result in the FDA or other regulatory authority, as applicable, allowing clinical trials to begin in a timely manner, if at all. For example, prior to the authorization of our IND for HD, the FDA placed the Phase 2a trial on clinical hold in order to obtain additional information on our preclinical data package; we provided the required information and the clinical hold was lifted in March 2020. Moreover, even if these trials begin, issues may arise that could suspend or terminate such clinical trials. A failure

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of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful. Clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

- the COVID-19 pandemic, which may result in clinical site closures, delays to patient enrollment, patients discontinuing their treatment or follow up visits or changes to trial protocols;
- inability to generate sufficient preclinical, toxicology or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- delays in obtaining regulatory authorization to commence a trial;
- reaching agreement on acceptable terms with prospective 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;
- identifying, recruiting and training suitable clinical investigators;
- obtaining institutional review board, or IRB, approval at each trial site;
- imposition of a temporary or permanent clinical hold by regulatory agencies for a number of reasons, including after review of an IND or amendment, or equivalent foreign application or amendment;
- new safety findings that present unreasonable risk to clinical trial participants;
- a negative finding from an inspection of our clinical trial operations or study sites;
- recruiting an adequate number of suitable patients to participate in a trial;
- having subjects complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocol or dropping out of a trial;
- addressing subject safety concerns that arise during the course of a trial;
- adding a sufficient number of clinical trial sites; or
- obtaining sufficient product supply of product candidates for use in preclinical studies or clinical trials from third-party suppliers.

We may experience numerous adverse or unforeseen events during, or as a result of, preclinical studies and clinical trials which could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials or require that we submit additional data or information before allowing a clinical trial to be initiated;
- clinical studies of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements, fail to maintain adequate quality controls or be unable to provide us with sufficient product supply to conduct and complete preclinical studies or clinical trials of our product candidates in a timely manner, or at all;
- we or our investigators might have to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the quality of our product candidates or other materials necessary to conduct preclinical studies or clinical trials of our product candidates may be insufficient or inadequate;
- regulators may revise the requirements for approving our product candidates or such requirements may not be as we anticipate; and
- any future collaborators may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.



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

- incur unplanned costs;
- be delayed in obtaining marketing approval for our product candidates or not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain marketing approval for indications or patient populations that are not as broad as intended or desired;
- obtain marketing approval with labeling that includes significant use or distribution restrictions or safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

In addition, disruptions caused by the COVID-19 pandemic may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. 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 the Data Safety Monitoring Board, or DSMB, for such trial or by the FDA or other regulatory authorities. Such authorities may suspend or terminate a clinical trial 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 authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial.

Further, conducting clinical trials in foreign countries, as we plan to do for certain of our product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as a result of differences in healthcare services or cultural customs and managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks.

Principal investigators for our clinical trials 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 a regulatory authority 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 the marketing application we submit. Any such delay or rejection could prevent or delay us from commercializing our current or future product candidates.

If we experience delays in the completion, or termination, of any preclinical study or clinical trial of our product candidates, the commercial prospects of our product candidates may be harmed, and our ability to generate revenues from any of these product candidates will be delayed or not realized at all. In addition, any delays in completing our clinical trials may increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may materially and adversely affect our business, financial condition, results of operations and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. If one or more of our product candidates proves to be ineffective, unsafe or commercially unviable, our business, financial condition, results of operations and prospects may be materially and adversely affected.

***If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.***

We may not be able to initiate or continue clinical trials on a timely basis or at all for any product candidates we identify or develop if we are unable to locate and enroll a sufficient number of eligible patients to participate in the trials as required by applicable regulations or as needed to provide appropriate statistical power for a given trial. The timely completion of clinical trials in accordance with their protocols depends on, among other things, our ability to enroll a sufficient number of patients who remain in the study until its conclusion. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The enrollment of patients depends on many factors, including:

- the severity and difficulty of diagnosing the disease under investigation;

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- the patient eligibility and exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the existing body of safety and efficacy data with respect to the study drug and safety concerns;
- patient referral practices of physicians;
- risk that enrolled subjects will drop out before completion of the trial, including as a result of contracting COVID-19 or other health conditions or being forced to quarantine;
- ability to monitor patients adequately during and after treatment;
- availability and efficacy of approved medications or therapies, or other clinical trials, for the disease or condition under investigation;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating; and
- our ability to obtain and maintain patient consents.

In addition, our clinical trials may compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Because the number of qualified clinical investigators is limited, we may conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site. Delays in patient enrollment may result in increased costs or may affect the timing or outcome of the planned clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

***Our product candidates may cause undesirable and unforeseen side effects or have other properties that could halt their clinical development, delay or prevent their regulatory approval, limit their commercial potential or result in significant negative consequences.***

Adverse events or other undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. If unacceptable side effects arise in the development of our product candidates, we, the FDA, the IRBs at the institutions in which our studies are conducted or the DSMB could suspend or terminate our clinical trials or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete any of our clinical trials or result in potential product liability claims. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We expect to have to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in patient injury or death. Any of these occurrences may materially and adversely affect our business, financial condition, results of operations and prospects.

In addition, early clinical trials may only include a limited number of subjects and limited duration of exposure to our product candidates. In particular, we are pursuing a novel approach to inhibiting upstream molecules of the classical complement pathway, primarily C1q, and as a result, our product candidates may cause unforeseen safety events when evaluated in larger patient populations. Further, clinical trials may not be sufficient to determine the effect and safety consequences of taking our product candidates over a multi-year period.



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If any of our product candidates receives marketing approval, and we or others later identify undesirable and unforeseen side effects caused by such product, a number of potentially significant negative consequences could result, including but not limited to:

- regulatory authorities may suspend, limit or withdraw approvals of such product, or seek an injunction against its manufacture or distribution;
- we may be required to conduct additional clinical trials or post-approval studies;
- we may be required to recall a product or change the way such product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing processes for the product or any component thereof;
- regulatory authorities may require the addition of labeling statements, 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 REMS or create a Medication Guide outlining the risks of such side effects for distribution to patients, a communication plan for healthcare providers and/or other elements to assure safe use;
- we could be sued and held liable for harm caused to patients;
- we may be subject to fines, injunctions or the imposition of criminal penalties;
- the product may become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and result in the loss of significant revenues to us, which would materially and adversely affect our results of operations and business. In addition, if one or more of our product candidates prove to be unsafe, our business, financial condition, results of operations and prospects may be materially and adversely affected.

***Interim “top-line” and preliminary data from studies or trials that we announce or publish from time to time may change as more data become available and are subject to audit and verification procedures that could result in material changes in the final data.***

From time to time, we may publish interim “top-line” or preliminary data from preclinical studies or clinical trials. Interim data are subject to the risk that one or more of the outcomes may materially change as more data become available. 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 when we publish such data. As a result, the “top-line” 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. Preliminary or “top-line” 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, interim and preliminary data should be viewed with caution until the final data are available. Additionally, 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, 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. Any information we determine not to disclose may ultimately be deemed significant by you or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the top-line data that we report differ from final results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, product candidates may be harmed, which could significantly harm our business prospects.

***Clinical trials of ANX005 in combination with IVIg in patients with GBS will provide no evidence of the efficacy of ANX005.***

While not approved for use in GBS in the United States due to differing levels of efficacy in GBS patients, IVIg has developed as the standard of care in the Western world and parts of Asia for patients with GBS and has been shown to be a reasonably effective treatment in some but not all GBS patients. We have initiated a Phase 1b drug-drug, or DDI, interaction trial evaluating ANX005 with IVIg. The purpose of our DDI clinical trial is to assess safety and if there are any pharmacokinetic or pharmacodynamic effects on ANX005's dosing profile by administering the two drug products in combination. Any objective responses observed in this trial will be in patients receiving ANX005 together with IVIg, and attribution of objective responses to the effects of ANX005 as a monotherapy will not be possible. Moreover, the trial is not powered to show a statistically significant efficacious outcome with the combined administration of ANX005 and IVIg. As a result, this clinical trial evaluating ANX005 with IVIg will provide no evidence of the efficacy of ANX005, which may not be fully understood by investors or market participants, potentially leading to negative effects on our stock price.

***Even if our current or future product candidates obtain regulatory approval, they may fail to achieve the broad degree of physician and patient adoption and use necessary for commercial success.***

Even if one or more of our product candidates receive FDA or other regulatory approvals, the commercial success of any of our current or future product candidates will depend significantly on the broad adoption and use of the resulting product by physicians and patients for approved indications. Our product candidates may not be commercially successful. For a variety of reasons, including, among other things, competitive factors, pricing or physician preference, reimbursement by insurers, the degree and rate of physician and patient adoption of our current or future product candidates, if approved, will depend on a number of factors, including:

- the clinical indications for which the product is approved and patient demand for approved products that treat those indications;
- the safety and efficacy of our product as compared to other available therapies;
- the availability of coverage and adequate reimbursement from managed care plans, insurers and other healthcare payors for any of our product candidates that may be approved;
- acceptance by physicians, operators of clinics and patients of the product as a safe and effective treatment;
- physician and patient willingness to adopt a new therapy over other available therapies to treat approved indications;
- overcoming any biases physicians or patients may have toward particular therapies for the treatment of approved indications;
- proper training and administration of our product candidates by physicians and medical staff;
- public misperception regarding the use of our therapies, if approved for commercial sale;
- patient satisfaction with the results and administration of our product candidates and overall treatment experience, including, for example, the convenience of any dosing regimen;
- the cost of treatment with our product candidates in relation to alternative treatments and reimbursement levels, if any, and willingness to pay for the product, if approved, on the part of insurance companies and other third-party payors, physicians and patients;
- the revenue and profitability that our products may offer a physician as compared to alternative therapies;
- the prevalence and severity of side effects;
- limitations or warnings contained in the FDA-approved labeling for our products;
- the willingness of physicians, operators of clinics and patients to utilize or adopt our products as a solution;
- any FDA requirement to undertake a REMS;
- the effectiveness of our sales, marketing and distribution efforts;
- adverse publicity about our products or favorable publicity about competitive products; and
- potential product liability claims.

We cannot assure you that our current or future product candidates, if approved, will achieve broad market acceptance among physicians and patients. Any failure by our product candidates that obtain regulatory approval to achieve market acceptance or commercial success would adversely affect our results of operations.

***We have received Orphan Drug designation for ANX005 for the treatment of GBS, and we may seek Orphan Drug designation for certain future product candidates. We may be unable to obtain such designations or to maintain the benefits associated with Orphan Drug designation, including market exclusivity, which may cause any revenue from product sales to be reduced.***

We have received Orphan Drug designation in the United States for ANX005 for the treatment of GBS. Although we may seek Orphan product designation for some or all of our other product candidates, we may never receive such designations. Under the Orphan Drug Act, the FDA may designate a drug or biologic product as an Orphan Drug if it is intended to treat a rare disease or condition, defined as a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Orphan Drug designation must be requested before submitting a biologics license application, or BLA. In the European Union, the EMA's Committee for Orphan Medicinal Products, or COMP, grants Orphan Drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union. Additionally, designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biological product or where there is no satisfactory method of diagnosis, prevention or treatment, or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

In the United States, Orphan Drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and application fee waivers. After the FDA grants Orphan Drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA.

In addition, if a product receives the first FDA approval for the indication for which it has orphan designation, the product is entitled to Orphan Drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority over the product with Orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity the orphan patient population. Exclusive marketing rights in the United States may also be unavailable if we or our collaborators seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective. In the European Union, Orphan Drug designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following drug or biological product approval. This period may be reduced to six years if the Orphan Drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable to not justify maintenance of market exclusivity.

Even if we obtain Orphan Drug designation, we may not be the first to obtain marketing approval for any particular orphan indication due to the uncertainties associated with developing pharmaceutical products. Further, even if we obtain Orphan Drug exclusivity for a product candidate, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an Orphan Drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is safer, more effective or makes a major contribution to patient care. Orphan Drug designation neither shortens the development time or regulatory review time of a drug or biologic nor gives the drug or biologic any advantage in the regulatory review or approval process.

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

We may seek a Breakthrough Therapy designation for our product candidates if the clinical data support such a designation for one or more product candidates. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug, or biologic in our case, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Biologics designated as breakthrough therapies by the FDA may also be eligible for priority review.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster

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development process, review or approval compared to drugs considered for approval under non-expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

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

The FDA has granted Fast Track designation for ANX005 in GBS, and, in the future, we may seek Fast Track designation for other of our product candidates. If a drug or biologic, in our case, is intended for the treatment of a serious or life-threatening condition and the biologic demonstrates the potential to address unmet medical needs for this condition, the biologic sponsor may apply for Fast Track designation. The FDA has broad discretion whether or not to grant this designation. Even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Fast Track designation may not result in a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. Many biologics that have received Fast Track designation have failed to obtain approval.

***Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny.***

If one of our product candidates is approved, it will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. We and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMPs and adherence to commitments made in any approved marketing application. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

We will have to comply with requirements concerning advertising and promotion for our products. Promotional communications with respect to prescription drugs and biologics are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. We may not promote our products "off-label" for indications or uses for which they do not have approval. The holder of an approved application must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling or manufacturing process. We could also be asked to conduct post-marketing clinical studies to verify the safety and efficacy of our products in general or in specific patient subsets. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, the regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our clinical studies;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- seize or detain products, or require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

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Moreover, the policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive 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 unable to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

***Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business.***

The ability of the FDA to review and/or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs and biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most foreign inspections of manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

***We have conducted, and in the future plan to conduct, clinical trials for product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.***

We have conducted clinical trials of our product candidates outside the United States, and plan to continue to do so in the future. For example, we conducted our Phase 1b clinical trial of ANX005 in Bangladesh. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA, any comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice; (ii) the trials were performed pursuant to good clinical practice, or GCP, requirements; and (iii) if necessary, the FDA is able to validate the data through an on-site inspection. Many foreign regulatory authorities have similar requirements. In addition, foreign trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in product candidates that we may develop not receiving approval or clearance for commercialization in the applicable jurisdiction.

***If the product candidates that we develop receive regulatory approval in the United States or another jurisdiction, they may never receive approval in other jurisdictions, which would limit market opportunities for our product candidates and adversely affect our business.***

Approval of a product candidate in the United States by the FDA or by the requisite regulatory agencies in any other jurisdiction does not ensure approval of such product candidate by regulatory authorities in other countries or jurisdictions. The approval process varies among countries and may limit our or any future collaborators' ability to develop, manufacture, promote and sell product

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candidates internationally. Failure to obtain marketing approval in international jurisdictions would prevent the product candidates from being marketed outside of the jurisdictions in which regulatory approvals have been received. In order to market and sell product candidates in the European Union, or EU, and many other jurisdictions, we and any future collaborators must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and may involve additional preclinical studies or clinical trials both before and after approval. In many countries, any product candidate for human use must be approved for reimbursement before it can be approved for sale in that country. In some cases, the intended price for such product is also subject to approval. Further, while regulatory approval of a product candidate in one country does not ensure approval in any other country, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. If we or any future collaborators fail to comply with the regulatory requirements in international markets or to obtain all required marketing approvals, the target market for a particular potential product will be reduced, which would limit our ability to realize the full market potential for the product and adversely affect our business.

### ***Any 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, 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 Biologics License Application, or BLA, for the competing product containing the sponsor's own pre-clinical 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.

There is a risk that any of our product candidates approved as a biological product under a BLA would not qualify for the 12-year period of exclusivity or 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 generic competition sooner than anticipated. Other aspects of the BPCIA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of 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.

### ***We rely on third-party suppliers to manufacture our product candidates, and we intend to rely on third parties to produce commercial supplies of any approved product. The loss of these suppliers, or their failure to comply with applicable regulatory requirements or to provide us with sufficient quantities at acceptable quality levels or prices, or at all, would materially and adversely affect our business.***

We do not have nor do we plan to build or acquire the infrastructure or capability internally to manufacture supplies of our product candidates or the materials necessary to produce our product candidates for use in the conduct of our preclinical studies or clinical trials, and we lack the internal resources and the capability to manufacture any of our product candidates on a preclinical, clinical or commercial scale. The facilities used by our contract manufacturers to manufacture our product candidates are subject to various regulatory requirements and may be subject to the inspection of the FDA or other regulatory authorities. We do not control the manufacturing processes of, and are completely dependent on, our contract manufacturing partners for compliance with the regulatory requirements, known as cGMPs. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable regulatory authorities in foreign jurisdictions, we may not be able to rely on their manufacturing facilities for the manufacture of our product candidates. In addition, we have limited control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority finds these facilities inadequate for the manufacture of our product candidates or if such facilities are subject to enforcement action in the future or are otherwise inadequate, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates.

We currently intend to supply our product candidates in all territories for our clinical development programs. We currently rely on third parties at key stages in our supply chain. For instance, the supply chains for our two clinical-stage product candidates involve several manufacturers that specialize in specific operations of the manufacturing process, specifically, raw materials manufacturing, drug substance manufacturing and drug product manufacturing. As a result, the supply chain for the manufacturing of our product candidates is complicated, and we expect the logistical challenges associated with our supply chain to grow more complex as our product candidates are further developed.



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We do not have any control over the process or timing of the acquisition or manufacture of materials by our manufacturers. We generally do not begin preclinical or clinical trials unless we believe we have access to a sufficient supply of a product candidate to complete such study. In addition, any significant delay in, or quality control problems with respect to, the supply of a product candidate, or the raw material components thereof, for an ongoing study could considerably delay completion of our preclinical or clinical trials, product testing and potential regulatory approval of our product candidates.

We have not yet engaged any manufacturers for the commercial supply of our product candidates. Although we intend to enter into such agreements prior to commercial launch of any of our product candidates, we may be unable to enter into any such agreement or do so on commercially reasonable terms, which could have a material adverse impact upon our business. Moreover, if there is a disruption to one or more of our third-party manufacturers' or suppliers' relevant operations, or if we are unable to enter into arrangements for the commercial supply of our product candidates, we will have no other means of producing our product candidates until they restore the affected facilities or we or they procure alternative manufacturing facilities or sources of supply. Our ability to progress our preclinical and clinical programs could be materially and adversely impacted if any of the third-party suppliers upon which we rely were to experience a significant business challenge, disruption or failure due to issues such as financial difficulties or bankruptcy, issues relating to other customers such as regulatory or quality compliance issues, or other financial, legal, regulatory or reputational issues. Additionally, any damage to or destruction of our third-party manufacturers' or suppliers' facilities or equipment may significantly impair our ability to manufacture our product candidates on a timely basis.

In addition, to manufacture our product candidates in the quantities which we believe would be required to meet anticipated market demand, our third-party manufacturers would likely need to increase manufacturing capacity and we may need to secure alternative sources of commercial supply, which could involve significant challenges and may require additional regulatory approvals. In addition, the development of commercial-scale manufacturing capabilities may require us and our third-party manufacturers to invest substantial additional funds and hire and retain the technical personnel who have the necessary manufacturing experience. Neither we nor our third-party manufacturers may successfully complete any required increase to existing manufacturing capacity in a timely manner, or at all. If our manufacturers or we are unable to purchase the raw materials necessary for the manufacture of our product candidates on acceptable terms, at sufficient quality levels or in adequate quantities, if at all, the commercial launch of our product candidates would be delayed or there would be a shortage in supply, which would impair our ability to generate revenues from the sale of such product candidates, if approved.

***We rely on third parties in the conduct of all of our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties, fail to comply with applicable regulatory requirements or meet expected deadlines, we may be unable to obtain regulatory approval for our product candidates.***

We currently do not have the ability to independently conduct preclinical studies or clinical trials that comply with the regulatory requirements known as good laboratory practice, or GLP, requirements or GCP requirements, respectively. The FDA and regulatory authorities in other jurisdictions require us to comply with GCP requirements for conducting, monitoring, recording and reporting the results of clinical trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. We rely on medical institutions, clinical investigators, contract laboratories and other third parties, such as CROs, to conduct GLP-compliant preclinical studies and GCP-compliant clinical trials on our product candidates properly and on time. While we have agreements governing their activities, we control only certain aspects of their activities and have limited influence over their actual performance. The third parties with whom we contract for execution of our GLP-compliant preclinical studies and our GCP-compliant clinical trials play a significant role in the conduct of these studies and the subsequent collection and analysis of data. These third parties are not our employees and, except for restrictions imposed by our contracts with such third parties, we have limited ability to control the amount or timing of resources that they devote to our programs. Although we rely on these third parties to conduct our GLP-compliant preclinical studies and GCP-compliant clinical trials, we remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

Many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities that could harm our competitive position. If the third parties conducting our preclinical studies or our clinical trials do not adequately perform their contractual duties or obligations, experience significant business challenges, disruptions or failures, do not meet expected deadlines, terminate their agreements with us or need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our protocols or to GLPs or GCPs, or for any other reason, we may need to enter into new arrangements with alternative third parties. This could be difficult, costly or impossible, and our preclinical studies or clinical trials may need to be extended, delayed, terminated or repeated. As a result we may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable product candidate, our business, financial results and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

***If we are not successful in identifying, developing and commercializing additional product candidates, our ability to expand our business and achieve our strategic objectives would be impaired.***

Although a substantial amount of our effort will focus on the continued development and potential approval of our current product candidates, a key element of our strategy is to identify, develop and commercialize a portfolio of products that address classical complement-mediated autoimmune and neurodegenerative diseases. A component of our strategy is to evaluate our product candidates in multiple indications based, in part, on our evaluation of certain biomarkers in a disease area. For example, we intend to evaluate ANX005 in neurodegenerative diseases, including amyotrophic lateral sclerosis, or ALS, and Huntington’s disease, or HD; however, we have not yet evaluated ANX005 in these patient populations and we may find that while we have seen promising results in one neurodegenerative disease, that effect is not replicated across other neurodegenerative or autoimmune diseases. Even if we successfully identify product candidates, we may still fail to yield product candidates for development and commercialization for many reasons, including the following:

- competitors may develop alternatives that render our product candidates obsolete;
- product candidates we develop may be covered by third parties’ patents or other exclusive rights;
- a product candidate may be shown to have harmful side effects or other characteristics that indicate it is unlikely to be effective or otherwise does not meet applicable regulatory criteria;
- a product candidate may not be capable of being produced in commercial quantities at an acceptable cost, or at all; and
- a product candidate may not be accepted as safe and effective by physicians and patients.

We therefore cannot provide any assurance that we will be able to successfully identify or acquire additional product candidates, advance any of these additional product candidates through the development process, successfully commercialize any such additional product candidates, if approved, or assemble sufficient resources to identify, acquire, develop or, if approved, commercialize additional product candidates. If we are unable to successfully identify, acquire, develop and commercialize additional product candidates, our commercial opportunities may be limited.

***We face significant competition in an environment of rapid technological and scientific change, and our product candidates, if approved, will face significant competition, which may prevent us from achieving significant market penetration. Most of our competitors have significantly greater resources than we do, and we may not be able to successfully compete.***

The pharmaceutical, biopharmaceutical and biotechnology industries in particular are characterized by rapidly advancing technologies, intense competition and a strong emphasis on developing proprietary therapeutics. Numerous companies are engaged in the development, patenting, manufacturing and marketing of healthcare products competitive with those that we are developing. We face competition from a number of sources, such as pharmaceutical, biopharmaceutical and biotechnology companies, generic drug companies and academic and research institutions, many of which have greater financial resources, marketing capabilities, sales forces, manufacturing capabilities, research and development capabilities, clinical trial expertise, intellectual property portfolios, experience in obtaining patents and regulatory approvals for product candidates and other resources than we do. Some of the companies also have a broad range of other product offerings, large direct sales forces and long-term customer relationships with our target physicians, which could inhibit our market penetration efforts. Mergers and acquisitions in the pharmaceutical, biopharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Certain alternative treatments offered by competitors may be available at lower prices and may offer greater efficacy or better safety profiles. Furthermore, currently approved products could be discovered to have application for the intended indication of our product candidates, which could give such products significant regulatory and market timing advantages over any of our product candidates. Our competitors also may obtain FDA, European Medicines Agency, or EMA, or other regulatory approval for their products more rapidly than we may obtain approval for ours and may obtain orphan product exclusivity from the FDA for indications our product candidates are targeting, which could result in our competitors establishing a strong market position before we are able to enter the market. For additional information regarding our competition, see the section of the Prospectus captioned “Business—Competition.”



*The successful commercialization of our product candidates will depend in part on the extent to which governmental authorities and health insurers establish adequate coverage, reimbursement levels and pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates, if approved, could limit our ability to market those products and decrease our ability to generate revenue.*

The availability and adequacy of coverage and reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as our product candidates, if approved. Our ability to achieve acceptable levels of coverage and reimbursement for products by governmental authorities, private health insurers and other organizations will have an effect on our ability to successfully commercialize our product candidates. Obtaining coverage and adequate reimbursement for our products may be particularly difficult because of the higher prices often associated with drugs administered under the supervision of a physician. Even if we obtain coverage for our product candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the European Union or elsewhere will be available for our product candidates or any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical, biopharmaceutical and biotechnology products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar or a less expensive therapy is available. It is possible that a third-party payor may consider our product candidates as substitutable and only offer to reimburse patients for the cost of the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing third-party therapeutics may limit the amounts we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates and may not be able to obtain a satisfactory financial return on our investment in the development of product candidates.

There is significant uncertainty related to the insurance coverage and reimbursement of newly-approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models in the United States for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. We cannot predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other foreign jurisdictions have and will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amounts that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our product candidates may be reduced compared with the United States and may be insufficient to generate commercially-reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products, and, as a result, they may not cover or provide adequate payment for our product candidates. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed health care, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and biologics and surgical procedures and other treatments, has become intense. As a result, increasingly high barriers are being erected to the entry of new products.

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***We previously identified a material weakness in our internal control over financial reporting and may identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, which may result in material misstatements of our financial statements or cause us to fail to meet our periodic reporting obligations.***

Prior to our initial public offering in July 2020, we were a private company and had limited accounting and financial reporting personnel and other resources with which to address our internal controls and procedures. In connection with the audit of our consolidated financial statements for the year ended December 31, 2018, we and our independent registered public accounting firm identified a material weakness in our internal control over financial reporting. The material weakness that was identified related to an inadequate number of qualified personnel within our accounting function, which impacted our ability to perform effective reviews over non-routine transactions. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected and corrected on a timely basis.

We have implemented measures designed to improve our internal control over financial reporting to address the underlying causes of this material weakness, including the hiring of accounting personnel and establishing new accounting and financial reporting policies, processes and controls to have in place an appropriate level of internal control over financial reporting. As a result of these measures, we remediated the material weakness as of December 31, 2019. However, we can give no assurance that additional material weaknesses in our internal control over financial reporting will not be identified in the future. Our failure to implement and maintain effective internal control over financial reporting could result in errors in our financial statements that could result in a restatement of our financial statements and cause us to fail to meet our reporting obligations.

Effective internal control over financial reporting is necessary for us to provide reliable and timely financial reports and, together with adequate disclosure controls and procedures, are designed to reasonably detect and prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. For as long as we are an “emerging growth company” under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404. We could be an “emerging growth company” for up to five years. An independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management’s assessment might not. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation.

***We currently have no sales organization. If we are unable to establish sales capabilities on our own or through third parties, we may not be able to market and sell our product candidates, if approved, effectively in the United States and foreign jurisdictions or generate product revenue.***

We currently do not have a marketing or sales organization. In order to commercialize our product candidates in the United States and foreign jurisdictions, we must build our marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. If any of our product candidates receive regulatory approval, we expect to establish a sales organization with technical expertise and supporting distribution capabilities to commercialize each such product candidate, which will be expensive and time consuming. We have no prior experience in the marketing, sale and distribution of pharmaceutical, biopharmaceutical and biotechnology products, and there are significant risks involved in building and managing a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may choose to collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. If we are unable to enter into such arrangements on acceptable terms or at all, we may not be able to successfully commercialize our product candidates. If we are not successful in commercializing our product candidates or any future product candidates, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses.

***We will need to increase the size of our organization, and we may experience difficulties in managing growth.***

As of June 30, 2020, we had 30 full-time employees. We will need to continue to expand our managerial, operational, finance and other resources in order to manage our operations and clinical trials, continue our development activities and commercialize our two clinical-stage product candidates or any future product candidates. Our management and personnel, systems and facilities currently in place may not be adequate to support this future growth. Our need to effectively execute our growth strategy requires that we:

- manage our clinical trials effectively;

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- identify, recruit, retain, incentivize and integrate additional employees, including sales personnel;
- manage our internal development and operational efforts effectively while carrying out our contractual obligations to third parties; and
- continue to improve our operational, financial and management controls, reports systems and procedures.

### ***If we fail to attract and retain senior management and key scientific personnel, our business may be materially and adversely affected.***

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management and clinical and scientific personnel. We are highly dependent upon members of our senior management, particularly our President and Chief Executive Officer, Douglas Love, Esq., Executive Vice President and Chief Medical Officer, Sanjay Keswani, MBBS, BSc, FRCP, and Executive Vice President and Chief Scientific Officer, Ted Yednock, Ph.D., as well as our senior scientists and other members of our senior management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our planned clinical trials or the commercialization of our product candidates or any future product candidates.

Competition for qualified personnel in the pharmaceutical, biopharmaceutical and biotechnology field is intense due to the limited number of individuals who possess the skills and experience required by our industry. We will need to hire additional personnel as we expand our clinical development and if we initiate commercial activities. We may not be able to attract and retain quality personnel on acceptable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output.

### ***If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our current or future product candidates.***

We face an inherent risk of product liability as a result of the clinical testing of our product candidates and will face an even greater risk if we commercialize any products. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability and breach of warranty. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our current or future product candidates;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs to defend the related litigation;
- diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- regulatory investigations, product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize our current or any future product candidates.

If we are unable to obtain and maintain sufficient product liability insurance at an acceptable cost and scope of coverage to protect against potential product liability claims, the commercialization of our current or any future product candidates we develop could be inhibited or prevented. We currently carry product liability insurance covering our clinical trials. Although we maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions and deductibles, and we may be subject to a product liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient funds to pay such amounts. Moreover, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses. If and when we obtain approval for marketing any of our product candidates, we intend to expand our insurance coverage to include the sale of such product candidate; however, we may be unable to obtain this liability insurance on commercially reasonable terms or at all.

*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 product candidates.*

While we have not entered into any collaboration agreements to date, we may seek collaboration arrangements for the commercialization, or potentially for the development, of certain of our product candidates depending on the merits of retaining commercialization rights for ourselves as compared to entering into collaboration arrangements. For example, certain of the disease areas that we believe our product candidates address, including, among others, ophthalmic indications, require large, costly and later-stage clinical trials, which a collaboration partner may be better positioned to finance and/or conduct. In addition, a component of our strategy is to maximize the commercial value of our current and future product candidates, which may also strategically align with partnering commercial rights with partners that have larger and established sales organizations. To the extent that we decide to enter into collaboration agreements, we may face significant competition for appropriate collaborators. Moreover, collaboration arrangements are complex and time-consuming to negotiate, document, implement and maintain and challenging to manage. We may not be successful in our efforts to enter into collaboration agreements. The terms of collaborations or other arrangements that we may establish may not be favorable to us.

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 risks 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 product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in their strategic focus due to their acquisition of competitive products or their internal development of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or product candidates;
- collaborators 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 collaborators that cause the delay or termination of the research, development or commercialization of our current or future product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, this may result in a need for additional capital to pursue further development or commercialization of the applicable current or future product candidates;
- collaborators may own or co-own intellectual property covering products that result from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property;
- disputes may arise with respect to the ownership of any intellectual property developed pursuant to our collaborations; and
- collaborators' sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

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

Our business is susceptible to general conditions in the global economy and in the global financial markets. A global financial crisis or a global or regional political disruption could cause extreme volatility in the capital and credit markets. A severe or prolonged economic downturn, including a recession or depression resulting from the current COVID-19 pandemic, or political disruption could result in a variety of risks to our business, including weakened demand for our product candidates or any future product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our potential products. Any of the foregoing could materially and adversely affect our business, financial condition, results of operations and prospects, and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could adversely impact our business.

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

Our corporate headquarters and other facilities are located in the San Francisco Bay Area, which has experienced both severe earthquakes and the effects of wildfires. We do not carry earthquake insurance. Earthquakes, wildfires or other natural disasters could severely disrupt our operations, and could materially and adversely affect our business, financial condition, results of operations and prospects.

If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently are limited and are unlikely to prove adequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, 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 similarly vulnerable to natural disasters or other sudden, unforeseen and severe adverse events. If such an event were to affect our supply chain, it could have a material adverse effect on our business.

***Significant disruptions of information technology systems, breaches of data security and other incidents could materially adversely affect our business, results of operations and financial condition.***

We collect and maintain information in digital and other forms that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the privacy, security, confidentiality and integrity of such confidential information. We have established physical, electronic and organizational measures designed to safeguard and secure our systems to prevent a data compromise, and rely on commercially available systems, software, tools and monitoring to provide security for our information technology systems and the processing, transmission and storage of digital information. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may have access to our confidential information. Our internal information technology systems and infrastructure, and those of any future collaborators and our contractors, consultants, vendors and other third parties on which we rely, are vulnerable to damage or unauthorized access or use resulting from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, denial or degradation of service attacks, ransomware, hacking, phishing and other social engineering attacks, attachments to emails, persons inside our organization or persons with access to systems inside our organization.

The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. The prevalent use of mobile devices that access confidential information also increases the risk of lost or stolen devices, security incidents and data security breaches, which could lead to the loss of confidential information or other intellectual property. As a result of the COVID-19 pandemic, we may face increased risks of a security breach or disruption due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. The costs to us to investigate, mitigate and remediate security incidents, breaches, disruptions, network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service, negative publicity and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Any security compromise affecting us, our partners or our industry, whether real or perceived, could harm our reputation, erode confidence in the effectiveness of our security measures and lead to



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regulatory scrutiny. Moreover, if a computer security breach affects our systems or results in the unauthorized access to or unauthorized use, disclosure, release or other processing of personally identifiable information or clinical trial data, it may be necessary to notify individuals, governmental authorities, supervisory bodies, the media and other parties pursuant to privacy and security laws, and our reputation could be materially damaged. We would also be exposed to a risk of loss, governmental investigations or enforcement, or litigation and potential liability, which could materially adversely affect our business, results of operations and financial condition.

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

We and any future collaborators are subject to or affected by federal, state and foreign data protection laws and regulations which address privacy and data security. In the United States, numerous federal and state laws and regulations, including the U.S. 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 and its implementing regulations, or HITECH, state data breach notification laws, state health information privacy laws and federal and state consumer protection laws, including Section 5 of the Federal Trade Commission Act, which govern the collection, use, disclosure and protection of health-related and other personal information, may apply to our operations and the operations of any future 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 HIPAA, as amended by HITECH, and other privacy and data security laws. Depending on the facts and circumstances, we could be subject to significant administrative, civil and criminal penalties if we 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. Further, various states have implemented similar privacy laws and regulations. For example, California also recently enacted the California Consumer Privacy Act of 2018, or CCPA. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing and receive detailed information about how their personal information is used. The CCPA also 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 went into effect on January 1, 2020, and the California Attorney General may bring enforcement actions for violations beginning July 1, 2020. The CCPA has been amended from time to time, and it remains unclear what, if any, further modifications will be made to this legislation or how it will be interpreted. As currently written, the CCPA may impact our business activities and as a result may increase our compliance costs and potential liability. Many similar privacy laws have been proposed at the federal level and in other states.

Foreign data protection laws, including Regulation 2016/679, known as the General Data Protection Regulation, or GDPR, may also apply to health-related and other personal information data subjects in the EU or the United Kingdom, or UK. The GDPR went into effect on May 25, 2018. Companies that must comply with the GDPR face increased compliance obligations and risk, including robust regulatory enforcement of data protection requirements as well as potential fines for noncompliance of up to €20 million or 4% of annual global revenue of the noncompliance company, whichever is greater. The GDPR imposes numerous requirements for the collection, use, storage and disclosure of personal information of EU or UK data subjects, including requirements relating to providing notice to and obtaining consent from data subjects, personal data breach notification, cross-border transfers of personal information, and honoring and providing for the rights of EU or UK individuals in relation to their personal information, including the right to access, correct and delete their data.

Compliance with U.S. and foreign data protection laws and regulations could require us to take on more onerous obligations in our contracts, require us to engage in costly compliance exercises, restrict our ability to collect, use and disclose data, or in some cases, impact our or our partners' or suppliers' ability to operate in certain jurisdictions. Failure to comply with U.S. and foreign data protection laws and regulations could result in government investigations and/or enforcement actions, fines, civil or criminal penalties, private litigation or adverse publicity and could negatively affect our operating results and business.

Moreover, clinical trial subjects about whom we or any of 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 materially and adversely affect our business, financial condition, results of operations and prospects.

***Our employees and independent contractors, including principal investigators, consultants, any future commercial collaborators, service providers and other vendors, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have an adverse effect on our results of operations.***

We are exposed to the risk that our employees and independent contractors, including principal investigators, consultants, any future commercial collaborators, service providers and other vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or other unauthorized activities that violate the laws and

regulations of the FDA and other similar regulatory bodies, including those laws that require the reporting of true, complete and accurate information to such regulatory bodies; manufacturing standards; U.S. federal and state healthcare fraud and abuse, data privacy laws and other similar non-U.S. laws; or laws that require the true, complete and accurate reporting of financial information or data. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our preclinical studies or clinical trials, or illegal misappropriation of product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other U.S. healthcare programs, other sanctions, imprisonment, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

***Our business involves the use of hazardous materials, and we and our third-party manufacturers and suppliers must comply with environmental laws and regulations, which can be expensive and restrict how we do business.***

Our research and development activities and our third-party manufacturers' and suppliers' activities involve the controlled storage, use and disposal of hazardous materials owned by us, including the components of our product candidates and other hazardous compounds. We and any third-party manufacturers and suppliers are subject to numerous federal, state and local environmental, health and safety laws, regulations and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological and radioactive materials. Our operations also produce hazardous waste. In some cases, these hazardous materials and various wastes resulting from their use are stored at our and our manufacturers' facilities pending their use and disposal. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, and environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products.

We cannot guarantee that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials comply with the standards prescribed by these laws and regulations, nor can we eliminate the risk of accidental contamination or injury from these materials. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources, and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, product development and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from hazardous materials or wastes. 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 carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could have a material adverse effect on our business, results of operations and financial condition.

#### **Risks Related to Intellectual Property**

***Our current and any future product candidates or products could be alleged to infringe patent rights and other proprietary rights of third parties, which may require costly litigation and, if we are not successful, could cause us to pay substantial damages and/or limit our ability to commercialize our products.***

Our commercial success depends on our ability to develop, manufacture and market our current and any future product candidates that may be approved for sale, and to use our proprietary technology without infringing the patents and other proprietary rights of third parties. Intellectual property disputes can be costly to defend and may cause our business, operating results and financial condition to

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suffer. We operate in an industry with extensive intellectual property litigation. As the pharmaceutical, biopharmaceutical and biotechnology industries expand and more patents are issued, the risk increases that there may be patents issued to third parties that relate to our products and technology of which we are not aware or that we may need to challenge to continue our operations as currently contemplated.

Whether merited or not, we may face allegations that we have infringed the trademarks, copyrights, patents and other intellectual property rights of third parties, including patents held by our competitors or by non-practicing entities. We may also face allegations that our employees have misappropriated the intellectual property rights of their former employers or other third parties. Litigation may make it necessary to defend ourselves by determining the scope, enforceability and validity of third-party proprietary rights, or to establish our proprietary rights. Regardless of whether claims that we are infringing patents or other intellectual property rights have merit, the claims can be time consuming, divert management attention and financial resources and are costly to evaluate and defend. Results of any such litigation are difficult to predict and may require us to stop treating certain conditions, obtain licenses or modify our products and features while we develop non-infringing substitutes, or may result in significant settlement costs. For example, litigation can involve substantial damages for infringement, and if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees. We may also be prohibited from selling or licensing our products unless the third party licenses rights to us, which it is not required to do at a commercially reasonable price or at all. If a license is available from a third party, we may have to pay substantial royalties or upfront fees or grant cross-licenses to intellectual property rights for our products. We may also have to redesign our products so they do not infringe third-party intellectual property rights, which may not be possible or may require substantial monetary expenditures and time, during which our products may not be available for manufacture, use or sale.

Although we have reviewed certain third-party patents and patent filings that we believe may be relevant to our product candidates, we have not conducted a freedom-to-operate search or analysis for any of our product candidates, and we may not be aware of patents or pending or future patent applications that, if issued, would block us from commercializing our product candidates. Thus, we cannot guarantee that our product candidates, or our commercialization thereof, do not and will not infringe any third party's intellectual property.

In addition, patent applications in the United States and many international jurisdictions are typically not published until 18 months after the filing of certain priority documents (or, in some cases, are not published until they issue as patents), and publications in the scientific literature often lag behind actual discoveries. Therefore, we cannot be certain that others have not filed patent applications or made public disclosures relating to our technology or our contemplated technology. A third party may have filed, and may in the future file, patent applications covering our product candidates or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, depending on whether the timing of the filing date falls under certain patent laws, we may have to participate in a priority contest (such as an interference proceeding) declared by the United States Patent and Trademark Office, or USPTO, to determine priority of invention in the United States. The costs of patent litigation and other proceedings could be substantial, and it is possible that such efforts would be unsuccessful if it is determined that the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such invention.

From time to time, we may be subject to legal proceedings and claims in the ordinary course of business with respect to intellectual property. We may receive claims from third parties asserting infringement of their intellectual property rights. Future litigation may be necessary to establish our intellectual property rights or to defend ourselves by determining the scope, enforceability and validity of third-party intellectual property rights. There can be no assurance with respect to the outcome of any current or future litigation brought by or against us, and the outcome of any such litigation could have a material adverse impact on our business, operating results and financial condition. Litigation is inherently unpredictable, and outcomes are uncertain. Further, as the costs and outcome of these types of claims and proceedings can vary significantly, it is difficult to estimate potential losses that may occur. Accordingly, we are unable at this time to estimate the effects of these potential future lawsuits on our financial condition, operations or cash flows.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. Any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.



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***If we are unable to obtain, maintain and enforce intellectual property protection directed to our current and any future technologies that we develop, others may be able to make, use or sell products substantially the same as ours, which could adversely affect our ability to compete in the market.***

We have not pursued or maintained, and may not pursue or maintain in the future, patent protection for our product candidates in every country or territory in which we may sell our products. In addition, we cannot be sure that any of our pending patent applications or pending trademark applications will issue or that, if issued, they will issue in a form that will provide adequate protection. The U.S. Patent and Trademark Office, or USPTO, international patent offices or judicial bodies may deny or significantly narrow claims made under our patent applications, and our issued patents may be successfully challenged, may be designed around or may otherwise be of insufficient scope to provide us with protection for our products. Further, the USPTO, international trademark offices or judicial bodies may deny our trademark applications and, even if published or registered, these trademarks may not effectively protect our brand and goodwill. Like patents, trademarks also may be successfully opposed or challenged.

We cannot be certain that the steps we have taken will prevent unauthorized use or unauthorized reverse engineering of our technology. Moreover, third parties may independently develop technologies that are competitive with ours and such competitive technologies may or may not infringe our intellectual property. The enforcement of our intellectual property rights also depends on the success of any legal actions we may take against these infringers in the respective country or forum, but these actions may not be successful. As with all granted intellectual property, such intellectual property may be challenged, invalidated or circumvented, may not provide protection and/or may not prove to be enforceable in actions against specific alleged infringers.

The market for pharmaceuticals and biopharmaceuticals is highly competitive and subject to rapid technological change. Our success depends, in part, upon our ability to maintain a competitive position in the development and protection of technologies and any future products for use in these fields and upon our ability to obtain, maintain and enforce our intellectual property rights. We seek to obtain and maintain patents and other intellectual property rights to restrict the ability of others to market products that misappropriate our technology and/or infringe our intellectual property to unfairly and illegally compete with any future products. If we are unable to protect our intellectual property and proprietary rights, our competitive position and our business could be harmed, as third parties may be able to make, use or sell products that are substantially the same as any future products we may sell without incurring the sizeable development and licensing costs that we have incurred, which would adversely affect our ability to compete in the market.

We use a combination of patents, trademarks, know-how, confidentiality procedures and contractual provisions to protect our proprietary technology. However, these protections may not be adequate and may not provide us with any competitive advantage. For example, patents may not issue from any of our currently pending or any future patent applications, and our issued patents and any future patents that may issue may not survive legal challenges to their scope, validity or enforceability, or provide significant protection for us.

If we or any future collaborators we may have were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates or future product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including obviousness or lack of novelty, enablement or written description. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before the USPTO even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to validity, for example, we cannot be certain that there is no invalidating prior art of which we and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our product candidates. Such a loss of patent protection would have a material adverse impact on our business.

Even if our patents are determined by a court to be valid and enforceable, they may not be interpreted sufficiently broadly to prevent others from marketing products similar to ours or designing around our patents. For example, third parties may be able to make products that are similar to ours but that are not covered by the claims of our patents. Third parties may assert that we or our licensors were not the first to make the inventions covered by our issued patents or pending patent applications. The claims of our issued patents or patent applications when issued may not cover our product candidates or any future products that we develop. We may not have freedom to commercialize unimpeded by the patent rights of others. Third parties may have patents that dominate, block or are otherwise relevant to our technology. There may be prior public disclosures or other art that could be deemed to invalidate one or more of our patent claims. Further, we may not develop additional proprietary technologies in the future, and, if we do, they may not be patentable.

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Patent law can be highly uncertain and involve complex legal and factual questions for which important principles remain unresolved. In the United States and in many international jurisdictions, policies regarding the breadth of claims allowed in patents can be inconsistent. The U.S. Supreme Court and the Court of Appeals for the Federal Circuit have made, and will likely continue to make, changes in how the patent laws of the United States are interpreted. Similarly, international courts have made, and will likely continue to make, changes in how the patent laws in their respective jurisdictions are interpreted. We cannot predict future changes in the interpretation of patent laws or changes to patent laws that might be enacted into law by U.S. and international legislative bodies. Those changes may materially affect the patents and patent applications of our licensors, our existing or future patents and patent applications and our ability to obtain additional patents in the future.

Patent reform legislation in the United States could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. For example, on September 16, 2011, the Leahy-Smith America Invents Act, or Leahy-Smith Act, was signed into law. The Leahy-Smith Act included a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art, may affect patent litigation and switch the U.S. patent system from a “first-to-invent” system to a “first-to-file” system. Under a “first-to-file” system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether another inventor had made the invention earlier. The USPTO has developed regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first-to-file provisions, only became effective on March 16, 2013. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, which could have a material adverse effect on our business and financial condition. Any future changes in the patent laws of the United States, or even the possibility of such changes, may further increase these uncertainties and costs.

In addition, we have a number of international patents and patent applications, and expect to continue to pursue patent protection in many of the significant markets in which we intend to do business. The laws of some international jurisdictions may not protect intellectual property rights to the same extent as laws in the United States, and many companies have encountered significant difficulties in obtaining, protecting and defending such rights in international jurisdictions. If we encounter such difficulties or we are otherwise precluded from effectively protecting our intellectual property rights in international jurisdictions, our business, financial condition, results of operations and prospects could be materially and adversely affected. Earlier patent filings in certain international countries may also permit third parties to allege priority to certain technology in those countries.

Patent terms may be shortened or lengthened by, for example, terminal disclaimers, patent term adjustments, supplemental protection certificates and patent term extensions. Patent term extensions and supplemental protection certificates, and the like, may be impacted by the regulatory process and may not significantly lengthen patent term. Non-payment or delay in payment of patent fees or annuities, delay in patent filings or delay in extension filing (including any patent term extension or adjustment filing), whether intentional or unintentional, may also result in the loss of patent rights important to our business. Certain countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to other parties. In addition, many countries limit the enforceability of patents against other parties, including government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of any patents.

In addition to the protection afforded by patents, we rely on confidentiality agreements to protect confidential information and proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. We seek to protect our proprietary technology and processes, in part, by entering into confidentiality agreements with our employees, consultants, scientific advisors and contractors. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our confidential information or proprietary technology and processes. We also seek to preserve the integrity and confidentiality of our data and other confidential information by maintaining physical security of our premises and physical and electronic security of our information technology systems. Agreements or security measures may be breached, and detecting the disclosure or misappropriation of confidential information and enforcing a claim that a party illegally disclosed or misappropriated confidential information is difficult, expensive and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach. In addition, our confidential information may otherwise become known or be independently discovered by competitors, in which case we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. We rely on trade secret protection, which would be subject to the risks identified above with respect to confidential information.

Monitoring unauthorized use of our intellectual property is difficult and costly. From time to time, we review our competitors’ products, and may in the future seek to enforce our patents or other rights against potential infringement. However, the steps we have taken to protect our proprietary rights may not be adequate to prevent misappropriation of our intellectual property. We may not be able to detect unauthorized use of, or take appropriate steps to enforce, our intellectual property rights. Our competitors may also independently develop similar technology. Any inability to meaningfully protect our intellectual property could result in competitors offering products competitive to our products. In addition, we may need to defend our patents from third-party challenges, such as interferences, derivation proceedings, re-examination proceedings, post-grant review, inter partes review, third-party submissions, oppositions, nullity actions or other patent proceedings. We may need to initiate infringement claims or litigation.

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Adverse proceedings such as litigation can be expensive, time consuming and may divert the efforts of our technical and managerial personnel, which could in turn materially and adversely affect our business, financial condition, results of operations and prospects, whether or not we receive a determination favorable to us. In addition, in an infringement proceeding, a court or other judicial body may decide that the patent we seek to enforce is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that the patent in question does not cover the technology in question or that stopping the other party would harm the public interest. An adverse result in any litigation could put one or more of our patents at risk of being invalidated or interpreted narrowly. Some of our competitors may be able to devote significantly more resources to intellectual property litigation, and may have significantly broader patent portfolios to assert against us if we assert our rights against them. Further, because of the substantial discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be disclosed or otherwise compromised during litigation.

We may not be able to correctly estimate or control our future operating expenses in relation to obtaining intellectual property, enforcing intellectual property and/or defending intellectual property, which could affect operating expenses. Our operating expenses may fluctuate significantly in the future as a result of a variety of factors, including the costs of preparing, filing, prosecuting, defending and enforcing patent and trademark claims and other intellectual property-related costs, including adverse proceedings and litigation costs.

***We license patent rights from third-party owners. Such licenses may be subject to early termination if we fail to comply with our obligations in our licenses with third parties, which could result in the loss of rights or technology that are material to our business.***

We are a party to licenses that give us rights to third-party intellectual property that are necessary or useful for our business, and we may enter into additional licenses in the future. Under these license agreements we are obligated to pay the licensor fees, which may include annual license fees, milestone payments, royalties, a percentage of revenues associated with the licensed technology and a percentage of sublicensing revenue. In addition, under certain of such agreements, we are required to diligently pursue the development of products using the licensed technology. If we fail to comply with these obligations and fail to cure our breach within a specified period of time, the licensor may have the right to terminate the applicable license, in which event we could lose valuable rights and technology that are material to our business.

If the licensor retains control of prosecution of the patents and patent applications licensed to us, we may have limited or no control over the manner in which the licensor chooses to prosecute or maintain its patents and patent applications and have limited or no right to continue to prosecute any patents or patent applications that the licensor elects to abandon.

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

Certain provisions in our intellectual property agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could affect the scope of our rights to the relevant intellectual property or technology, or affect financial or other obligations under the relevant agreement, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

***We jointly own certain patent rights with third parties. Our ability to out-license these patent rights, or to prevent the third party from out-licensing these patent rights, may be limited in certain countries.***

We jointly own certain patents and patent applications with third parties, and may jointly own patents and patent applications with third parties in the future. Unless we enter into an agreement with the joint owner, we will be subject to certain default rules pertaining to joint ownership. Certain countries require the consent of all joint owners to license jointly owned patents, and if we are unable to obtain such consent from the joint owner, we may not be able to license our rights under these patents and patent applications. In certain other countries, including the United States, the joint owner could license its rights under these patents and patent applications to another party without our consent and without any duty of accounting to us.

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

We may also be subject to claims that former employees, any future collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights and could even face litigation for infringing patents that we had regarded as ours. 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 distraction to management and other employees.

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and 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 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 any future products we may sell, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals and biopharmaceuticals, 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 generally. 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.

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

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented, declared generic or conflict with third-party rights. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition with potential partners, physicians or patients in our markets of interest. In addition, third parties may file first for our trademarks in certain countries. If they succeeded in registering such trademarks, and if we are not successful in challenging such third-party rights, we may not be able to use these trademarks to market our future products in those countries. In such cases, over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then our commercial success abilities may be impacted.

**Risks Related to Government Regulation**

***Even if we obtain regulatory approval for a product candidate, our products will remain subject to regulatory scrutiny.***

If our product candidates are approved, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping, conduct of post-marketing studies and submission of safety, efficacy and other post-market information, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities.

Manufacturers and manufacturers' facilities are required to comply with extensive FDA and comparable foreign regulatory authority requirements, including ensuring that quality control and manufacturing procedures conform to cGMP regulations. As such, we and our contract manufacturers will be subject to continual review and inspections to assess compliance with cGMPs and adherence to commitments made in any approved marketing application. Accordingly, we and others with whom we work must continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control.

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We will have to comply with requirements concerning advertising and promotion for any future products. Promotional communications with respect to prescription drugs and biologics are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved label. We may not promote products for indications or uses for which they do not have approval. The holder of an approved application must submit new or supplemental applications and obtain approval for certain changes to the approved product, product labeling or manufacturing process. We could also be asked to conduct post-marketing clinical trials to verify the safety and efficacy of our products in general or in specific patient subsets. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval.

If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, such regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If we fail to comply with applicable regulatory requirements, a regulatory agency or enforcement authority may, among other things:

- issue warning letters;
- impose civil or criminal penalties;
- suspend or withdraw regulatory approval;
- suspend any of our clinical trials;
- refuse to approve pending applications or supplements to approved applications submitted by us;
- impose restrictions on our operations, including closing our contract manufacturers' facilities; or
- seize or detain products, or require a product recall.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response, and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenue from any future products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

Moreover, the policies of the FDA and of other regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. For example, certain policies of the Trump administration may impact our business and industry. Namely, the Trump administration has taken several executive actions, including the issuance of a number of Executive Orders, that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine oversight activities such as implementing statutes through rulemaking, issuance of guidance and review and approval of marketing applications. It is difficult to predict how these orders will be implemented, and the extent to which they will impact the FDA's ability to exercise its regulatory authority. If these executive actions impose restrictions on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted. In addition, 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.

***Enacted and future healthcare legislation may increase the difficulty and cost for us to obtain marketing approval of and commercialize our product candidates and may affect the prices we may set.***

In the United States, the European Union and other jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes and proposed changes to the healthcare system that could affect our future results of operations. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively the Affordable Care Act, was enacted, which substantially changed the way healthcare is financed by both governmental and private insurers. Among the provisions of the Affordable Care Act, those of greatest importance to the pharmaceutical, biopharmaceutical and biotechnology industries include the following:

- an annual, non-deductible fee payable by any entity that manufactures or imports certain branded prescription drugs and biologic agents (other than those designated as Orphan Drugs), which is apportioned among these entities according to their market share in certain government healthcare programs;



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- a new Medicare Part D coverage gap discount program, in which manufacturers must 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;
- new requirements to report certain financial arrangements with physicians and teaching hospitals, including reporting "transfers of value" made or distributed to prescribers and other healthcare providers and reporting investment interests held by physicians and their immediate family members;
- an increase in the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program to 23.1% and 13.0% of the average manufacturer price for branded and generic drugs, respectively;
- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- extension of a manufacturer's Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations;
- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- a licensure framework for follow on biologic products;
- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research; and
- establishment of a Center for Medicare and Medicaid Innovation at the Centers for Medicare & Medicaid Services, or CMS, to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending.

Since its enactment, there have been judicial, Congressional and executive branch challenges to certain aspects of the Affordable Care Act, and we expect there will be additional challenges and amendments to the Affordable Care Act in the future. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the Affordable Care Act such as removing penalties for not complying with the Affordable Care Act's individual mandate to carry health insurance and delaying the implementation of certain fees mandated by the Affordable Care Act. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or Texas District Court Judge, ruled that the individual mandate is a critical and inseparable feature of the Affordable Care Act, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the Affordable Care Act are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court's decision that the individual mandate was unconstitutional but 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, although it is unclear when a decision will be made or how the Supreme Court will rule. It is also unclear how other efforts to challenge, repeal or replace the Affordable Care Act will impact the law or our business.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, led to aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2030 unless additional action is taken by Congress. The Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, which was signed into law on March 27, 2020, designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended these reductions from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. In addition, 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. These new laws or any other similar laws introduced in the future may result in additional reductions in Medicare and other health care funding, which could negatively affect our customers and accordingly, our financial operations.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency

to drug pricing, reduce the cost of prescription drugs under government payor programs, and review the relationship between pricing and manufacturer patient programs. 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 increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump 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. The Trump administration previously released a "Blueprint," or plan, to lower drug prices and reduce out of pocket costs of prescription 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. In addition, in July 2020, President Trump also signed a number of executive orders that attempt to implement several of the Administration's proposals. While some measures may require additional authorization through additional legislation 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. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally-mandated price controls on payment amounts by third-party payors or other restrictions could materially and adversely affect our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates or put pressure on our product pricing.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In addition to continuing pressure on prices and cost containment measures, legislative developments at the European Union or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved. In markets outside of the United States and EU, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or judicial action in the United States, the European Union or any other jurisdiction. If we or any third parties we may engage are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we or such third parties are not able to maintain regulatory compliance, our product candidates may lose any regulatory approval that may have been obtained and we may not achieve or sustain profitability.

***If we develop a small molecule product candidate that obtains regulatory approval, additional competitors could enter the market with generic versions of such drugs, which may result in a material decline in sales of affected products.***

Under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Act, a pharmaceutical manufacturer may file an abbreviated new drug application, or ANDA, seeking approval of a generic version of an approved, small molecule innovator product. Under the Hatch-Waxman Act, a manufacturer may also submit a new drug application, or NDA, under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act that references the FDA's prior approval of the small molecule innovator product. A 505(b)(2) NDA product may be for a new or improved version of the original innovator product. The Hatch-Waxman Act also provides for certain periods of regulatory exclusivity, which preclude FDA approval (or in some circumstances, FDA filing and review) of an ANDA or 505(b)(2) NDA. In addition to the benefits of regulatory exclusivity, an innovator NDA holder may have patents claiming the active ingredient, product formulation or an approved use of the drug, which would be listed with the product in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," known as the Orange Book. If there are patents listed in the Orange Book for a product, a generic or 505(b)(2) applicant that seeks to market its product before expiration of the patents must include in their applications what is known as a "Paragraph IV" certification, challenging the validity or enforceability of, or claiming non-infringement of, the listed patent or patents. Notice of the certification must be given to the patent owner and NDA holder and if, within 45 days of receiving notice, either the patent owner or NDA holder sues for patent infringement, approval of the ANDA or 505(b)(2) NDA is stayed for up to 30 months.

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Accordingly, if we choose to develop a small molecule product candidate, and the product is approved, competitors could file ANDAs for generic versions of our small molecule drug products or 505(b)(2) NDAs that reference our small molecule drug products. If there are patents listed for our small molecule drug products in the Orange Book, those ANDAs and 505(b)(2) NDAs would be required to include a certification as to each listed patent indicating whether the ANDA applicant does or does not intend to challenge the patent. We cannot predict which, if any, patents in our current portfolio or patents we may obtain in the future will be eligible for listing in the Orange Book, how any generic competitor would address such patents, whether we would sue on any such patents, or the outcome of any such suit.

We may not be successful in securing or maintaining proprietary patent protection for products and technologies we develop or license. Moreover, if any of our owned or in-licensed patents that are listed in the Orange Book are successfully challenged by way of a Paragraph IV certification and subsequent litigation, the affected product could immediately face generic competition and its sales would likely decline rapidly and materially.

***Our business operations and current and future relationships with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.***

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute our product candidates, if approved. Such laws include, without limitation:

- the U.S. federal civil and criminal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under U.S. federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the U.S. federal false claims laws, including the False Claims Act, which can be enforced through whistleblower actions, and civil monetary penalties laws, which, among other things, impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services; similar to the U.S. federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the HITECH and its implementing regulations, which also imposes certain obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without appropriate authorization by covered entities, such as health plans, healthcare clearinghouses and healthcare providers, as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;



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- the U.S. Physician Payments Sunshine Act and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the government information related to certain payments and other transfers of value to physicians, as defined by such law, and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members. Effective January 1, 2022, the U.S. federal physician transparency reporting requirements will extend to include transfers of value made during the previous year to certain non-physician providers such as physician assistants and nurse practitioners;
- analogous U.S. state laws and regulations, including: state anti-kickback and false claims laws, which may apply to our business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by any third-party payor, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and local laws that require the registration of pharmaceutical sales representatives; state laws and regulations that require drug manufacturers to file reports relating to pricing and marketing information, which requires tracking gifts and other remuneration and items of value provided to healthcare professionals and entities; and state laws governing the privacy, security and disposal of personal information and health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts;
- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office and foreign political parties or officials thereof; and
- similar data protection and healthcare laws and regulations in the European Union and other jurisdictions, including reporting requirements detailing interactions with and payments to healthcare providers and laws governing the privacy and security of personal data, including the GDPR, which imposes obligations and restrictions on the collection and use of personal data relating to individuals located in the European Union and European Economic Area (including with regard to health data).

Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices, such as the provision of stock options to physicians who may influence the ordering, prescribing or use of our product candidates, if approved, as compensation for consulting services, do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental laws and regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, exclusion from government-funded healthcare programs, such as Medicare and Medicaid or similar programs in other countries or jurisdictions, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits and the curtailment or restructuring of our operations. Further, defending against any such actions can be costly and time-consuming and may require significant personnel resources. Even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

### ***Changes in tax laws and regulations may have a material adverse effect on our business, financial condition and 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 any of our future 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, the U.S. government recently enacted significant tax reform, and certain provisions of the new law may adversely affect us. Changes include, but are not limited to, a federal corporate tax rate decrease to 21% for tax years beginning after December 31, 2017, a reduction to the maximum deduction allowed for net operating losses generated in tax years after December 31, 2017, eliminating carrybacks of net operating losses, and providing for indefinite carryforwards for losses generated in tax years after December 31, 2017. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, and will be subject to interpretations and implementing regulations by the Treasury and Internal Revenue Service, any of which could mitigate or increase certain adverse effects of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation. Generally, future changes in applicable U.S. tax laws and regulations, or their interpretation and application could have an adverse effect on our business, financial conditions and results of operations.

*We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws, and anti-money laundering laws and regulations. Compliance with these legal standards could impair our ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations, which can harm our business.*

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors and other collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties to sell our products outside the United States, to conduct clinical trials and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors and other collaborators, even if we do not explicitly authorize or have actual knowledge of such activities. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

### **Risks Related to Our Common Stock**

*Our stock price may be volatile and you may not be able to resell shares of our common stock at or above the price you paid.*

The trading price of our common stock may be highly volatile and subject to wide fluctuations in response to various factors, some of which are beyond our control. In particular, the trading prices for pharmaceutical, biopharmaceutical and biotechnology companies have been highly volatile as a result of the COVID-19 pandemic. These factors include those discussed in this "Risk Factors" section and others such as:

- results from, and any delays in, our clinical trials for our two clinical-stage product candidates or any other future clinical development programs, including any delays related to the COVID-19 pandemic;
- announcements of regulatory approval or disapproval of our current or any future product candidates;
- failure or discontinuation of any of our research and development programs;
- the termination of any of our existing license agreements;
- announcements relating to any future licensing, collaboration or development agreements;
- delays in the commercialization of our current or any future product candidates;
- public misperception regarding the use of our product candidates;
- acquisitions and sales of new products or product candidates, technologies or businesses;
- manufacturing and supply issues related to our product candidates for clinical trials or future product candidates for commercialization;
- quarterly variations in our results of operations or those of our competitors;
- changes in earnings estimates or recommendations by securities analysts;
- announcements by us or our competitors of new products or product candidates, significant contracts, commercial relationships, acquisitions or capital commitments;

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- developments with respect to intellectual property rights;
- our commencement of, or involvement in, litigation;
- changes in financial estimates or guidance;
- any major changes in our board of directors or management;
- new legislation or regulation in the United States relating to the sale or pricing of pharmaceuticals;
- FDA or other U.S. or foreign regulatory actions affecting us or our industry;
- product liability claims or other litigation or public concern about the safety of our product candidates;
- market conditions in the pharmaceutical, biopharmaceutical and biotechnology sectors; and
- general economic conditions in the United States and abroad, including as a result of an economic recession or depression and market volatility related to the COVID-19 pandemic and global health concerns.

In addition, the stock markets in general, and the markets for pharmaceutical, biopharmaceutical and biotechnology stocks in particular, have experienced extreme volatility that may have been unrelated to the operating performance of the issuer. These broad market fluctuations may adversely affect the trading price or liquidity of our common stock.

***An active, liquid and orderly market for our common stock may not develop, and you may not be able to resell your common stock at or above the price you paid.***

Prior to our initial public offering in July 2020, there was no public market for shares of our common stock, and an active public trading market for our shares may not develop or, if it is developed, may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other product candidates, businesses or technologies using our shares as consideration.

***If securities or industry analysts do not publish research or reports about our business, or if they issue an adverse or misleading opinion regarding our stock, our stock price and trading volume could decline.***

The trading market for our common stock is influenced by the research and reports that industry or securities analysts publish about us or our business. We do not currently have and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, the trading price for our stock would be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue an adverse or misleading opinion regarding us, our business model, our intellectual property or our stock performance, or if our clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

***We are an “emerging growth company,” and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies, our common stock may be less attractive to investors.***

We are an “emerging growth company,” as defined in the JOBS Act, and we intend to take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and 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. As a result, our consolidated financial statements may not be comparable to the financial statements of issuers who are required to comply with the effective dates for new or revised accounting standards that are applicable to public companies, which may make comparison of our financials to those of other public companies more difficult.

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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 following the fifth anniversary of our initial public offering, (2) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.07 billion, (3) the last day of the fiscal year in which we are deemed to be a “large accelerated filer” as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded \$700.0 million as of the last business day of the second fiscal quarter of such year, or (4) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period.

***We incur significant costs as a result of operating as a public company, and our management needs to devote substantial time to new compliance initiatives. We may fail to comply with the rules that apply to public companies, including Section 404 of the Sarbanes-Oxley Act of 2002, which could result in sanctions or other penalties that could materially and adversely affect our business, financial condition, results of operations and prospects.***

We incur significant legal, accounting and other expenses as a public company, including costs resulting from public company reporting obligations under the Exchange Act and regulations regarding corporate governance practices. The listing requirements of The Nasdaq Stock Market LLC and the rules of the Securities and Exchange Commission, or SEC, require that we satisfy certain corporate governance requirements relating to director independence, filing annual and interim reports, stockholder meetings, approvals and voting, soliciting proxies, conflicts of interest and a code of conduct. Our management and other personnel needs to devote a substantial amount of time to ensure that we comply with all of these requirements. Moreover, the reporting requirements, rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly in comparison to when we operated as a private company. Any changes we make to comply with these obligations may not be sufficient to allow us to satisfy our obligations as a public company on a timely basis, or at all. These reporting requirements, rules and regulations, coupled with the increase in potential litigation exposure associated with being a public company, could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors or board committees or to serve as executive officers, or to obtain certain types of insurance, including directors’ and officers’ insurance, on acceptable terms.

We are subject to Section 404 and the related rules of the SEC, which generally require our management and independent registered public accounting firm to report on the effectiveness of our internal control over financial reporting. Beginning with the second annual report that we are required to file with the SEC, Section 404 requires an annual management assessment of the effectiveness of our internal control over financial reporting. However, for so long as we remain an emerging growth company as defined in the JOBS Act, we intend to take advantage of certain exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404. Once we are no longer an emerging growth company or, if prior to such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting.

During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. Furthermore, if we identify any material weaknesses, we may not detect errors on a timely basis and our financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could materially and adversely affect our business, financial condition, results of operations and prospects, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, we are required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. In order to report our results of operations and financial statements on an accurate and timely basis, we depend in part on CROs to provide timely and accurate notice of their costs to us. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from the Nasdaq Global Select Market or other adverse consequences that would materially and adversely affect our business, financial condition, results of operations and prospects.

***If we sell shares of our common stock in future financings, stockholders may experience immediate dilution and, as a result, our stock price may decline.***

We may from time to time issue additional shares of common stock at a discount from the current trading price of our common stock. As a result, our stockholders would experience immediate dilution upon the purchase of any shares of our common stock sold at such discount. In addition, as opportunities present themselves, we may enter into financing or similar arrangements in the future, including the issuance of debt securities, preferred stock or common stock. If we issue common stock or securities convertible into common stock, our common stockholders would experience additional dilution and, as a result, our stock price may decline.

***Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.***

As of the completion of our initial public offering, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 62.7% of our outstanding voting stock. Therefore, these stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

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

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lock-up and other legal restrictions on resale discussed in the prospectus for our initial public offering lapse, the trading price of our common stock could decline. As of the completion of our initial public offering, we had outstanding a total of 38,148,090 shares of common stock. Of these shares, substantially all of the shares of our common stock sold in the initial public offering (excluding any shares sold to our directors or officers in the directed share program) are freely tradable, without restriction, in the public market.

The lock-up agreements pertaining to our initial public offering will expire on January 19, 2021. After the lock-up agreements expire, based on shares outstanding as of the completion of our initial public offering, up to approximately 21,258,687 additional shares of common stock will be eligible for sale in the public market, approximately 11,732,146 of which shares are held by directors, executive officers and other affiliates and are subject to Rule 144 under the Securities Act of 1933, as amended, or the Securities Act. J.P. Morgan Securities LLC, BofA Securities, Inc. and Cowen and Company, LLC may, however, in their sole discretion, permit our officers, directors and other stockholders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements.

In addition, based on shares outstanding as of the completion of our initial public offering, approximately 6,987,434 shares of common stock that are either subject to outstanding options or reserved for future issuance under our equity incentive plans are eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

As of the completion of our initial public offering, the holders of approximately 20,824,938 shares of our common stock, or approximately 54.6% of our total outstanding shares of common stock, are entitled to rights with respect to the registration of their shares under the Securities Act, subject to the lock-up agreements described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares purchased by affiliates. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

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

Under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an “ownership change,” generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, the corporation’s ability to use its pre-change net operating loss carryforwards, or NOLs, and other pre-change tax attributes (such as research and development tax credits) to offset its post-change income or taxes may be limited. If finalized, Treasury Regulations currently proposed under Section 382 of the Code may further limit our ability to utilize our pre-change NOLs or credits if we undergo a future ownership change. We may have experienced ownership changes in the past and may experience ownership changes and/or subsequent shifts in our stock ownership (some of which are outside our control). As a result, our ability to use our pre-change NOLs and tax credits to offset future taxable income, if any, could be subject to limitations. Similar provisions of state tax law may also apply. As a result, even if we attain profitability, we may be unable to use a material portion of our NOLs and tax credits.

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### ***Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.***

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent changes in control or changes in our management without the consent of our board of directors. These provisions include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors to elect a director to fill a vacancy, however occurring, including by an expansion of the board of directors, which prevents stockholders from being able to fill vacancies on our board of directors;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including voting or other rights or preferences, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;
- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;
- the required approval of at least 66 2/3% of the shares entitled to vote at an election of directors to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- the requirement that a special meeting of stockholders may be called only by the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

### ***As a California-domiciled public company, we are required to have at least two or three women on our board of directors by the end of 2021, depending on the size of our board at the time.***

Our success depends in part on our continued ability to attract, retain and motivate highly qualified individuals to our board of directors. As a public company headquartered in California, we are required to have two or three women on our board of directors by the end of 2021, depending on the size of our board of directors at the time. While we currently have two women on the board of directors, recruiting and retaining board members carries uncertainty, and failure to comply with this California requirement will result in financial penalties.

### ***Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.***

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.



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In addition, as permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful;
- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;
- we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;
- we are not obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification;
- the rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and
- we may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

While we maintain a directors' and officers' insurance policy, such insurance may not be adequate to cover all liabilities that we may incur, which may reduce our available funds to satisfy third-party claims and may adversely impact our cash position.

***Our amended and restated certificate of incorporation and amended and restated bylaws provide that the Court of Chancery of the State of Delaware is the exclusive forum for certain 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 and amended and restated bylaws provide that the Court of Chancery of the State of Delaware (or, in the event that the Court of Chancery does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided that, the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction; and provided further that, if and only if the Court of Chancery of the State of Delaware dismisses any such action for lack of subject matter jurisdiction, such action may be brought in another state or federal court sitting in the State of Delaware. Our amended and restated certificate of incorporation and amended and restated bylaws also provide that the federal district courts of the United States of America are the exclusive forum for the resolution of any complaint asserting a cause of action against us or any of our directors, officers, employees or agents and arising under the Securities Act. Nothing in our amended and restated certificate of incorporation and amended and restated bylaws precludes stockholders that assert claims under the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, other employees or stockholders, which may discourage lawsuits with respect to such claims, although our stockholders will not be deemed to have waived our compliance with federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. 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, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find the choice of forum provision that will be contained in our amended and restated certificate of incorporation and amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

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***We do not currently intend to pay dividends on our common stock, and, consequently, your ability to achieve a return on your investment will depend on appreciation in the price of our common stock.***

We do not currently intend to pay any cash dividends on our common stock for the foreseeable future. We currently intend to invest our future earnings, if any, to fund our growth. Therefore, you are not likely to receive any dividends on your common stock for the foreseeable future. Since we do not intend to pay dividends, your ability to receive a return on your investment will depend on any future appreciation in the market value of our common stock. There is no guarantee that our common stock will appreciate or even maintain the price at which our holders have purchased it.

***We may be subject to securities litigation, which is expensive and could divert our management's attention.***

In the past, companies that have experienced volatility in the market price of their securities have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Regardless of the merits or the ultimate results of such litigation, securities litigation brought against us could result in substantial costs and divert our management's attention from other business concerns.



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

**(a) Sales of Unregistered Securities**

None.

**(b) Use of Proceeds from Public Offering of Common Stock**

On July 28, 2020, we completed our IPO and issued 14,750,000 shares of our common stock at an initial offering price of \$17.00 per share. On August 4, 2020, we issued 2,139,403 shares of our common stock to the underwriters of the IPO pursuant to the exercise of their option to purchase additional shares at a price of \$17.00 per share less underwriting discounts and commissions. We received net proceeds from the IPO of approximately \$262.7 million, after deducting underwriting discounts and commissions of approximately \$20.1 million and expenses of approximately \$4.3 million. None of the expenses associated with the IPO were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to their associates. J.P. Morgan Securities LLC, BofA Securities, Inc. and Cowen and Company, LLC acted as book-running managers for the IPO.

Shares of our common stock began trading on The Nasdaq Global Select Market on July 24, 2020. The offer and sale of the shares were registered under the Securities Act on a registration statement on Form S-1 (Registration No. 333-239647), which was declared effective on July 23, 2020.

There has been no material change in the planned use of proceeds from our IPO as described in the registration statement on Form S-1. We invested the funds received in cash equivalents and other marketable securities in accordance with our investment policy.

**(c) Issuer Purchases of Equity Securities**

None.

**Item 3. Defaults Upon Senior Securities.**

None.

**Item 4. Mine Safety Disclosures.**

Not applicable.

**Item 5. Other Information.**

None.

**Item 6. Exhibits.**

## EXHIBIT INDEX

Exhibit No	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	<a href="#">Amended and Restated Certificate of Incorporation.</a>	8-K	001-39402	3.1	07/28/20	
3.2	<a href="#">Amended and Restated Bylaws.</a>	8-K	001-39402	3.2	07/28/20	
4.1	Reference is made to <a href="#">Exhibits 3.1</a> through <a href="#">3.2</a> .					
4.2	<a href="#">Form of Common Stock Certificate.</a>	S-1	333-239647	4.2	07/02/20	
10.1	<a href="#">Amended and Restated Investors' Rights Agreement, dated June 30, 2020, by and among the Registrant and the investors listed therein.</a>	S-1	333-239647	10.1	07/02/20	
10.2†	<a href="#">Exclusive (Equity) Agreement, dated November 21, 2011, by and between the Registrant and The Board of Trustees of the Leland Stanford Junior University.</a>	S-1	333-239647	10.2	07/02/20	
10.3	<a href="#">Lease, dated December 19, 2016, by and between the Registrant and Bayside Acquisition, LLC.</a>	S-1	333-239647	10.3	07/02/20	
10.4(a)+	<a href="#">2011 Incentive Award Plan.</a>	S-1/A	333-239647	10.4(a)	07/20/20	
10.4(b)+	<a href="#">Form of Stock Option Agreement under 2011 Equity Incentive Plan.</a>	S-1	333-239647	10.4(b)	07/02/20	
10.5(a)+	<a href="#">2020 Incentive Award Plan.</a>	S-8	333-240101	99.2(a)	07/24/20	
10.5(b)+	<a href="#">Form of Stock Option Grant Notice and Stock Option Agreement under the 2020 Incentive Award Plan.</a>	S-1	333-239647	10.5(b)	07/02/20	
10.5(c)+	<a href="#">Form of Restricted Stock Award Grant Notice and Restricted Stock Award Agreement under the 2020 Incentive Award Plan.</a>	S-1	333-239647	10.5(c)	07/02/20	
10.5(d)+	<a href="#">Form of Restricted Stock Unit Award Grant Notice and Restricted Stock Unit Award Agreement under the 2020 Incentive Award Plan.</a>	S-1	333-239647	10.5(d)	07/02/20	
10.6+	<a href="#">Employee Stock Purchase Plan.</a>	S-8	333-240101	99.3	07/24/20	
10.7+	<a href="#">Employment Agreement by and between the Registrant and Douglas Love, Esq.</a>	S-1	333-239647	10.7	07/02/20	
10.8+	<a href="#">Employment Agreement by and between the Registrant and Sanjay Keswani, MBBS, BSc, FRCP.</a>	S-1	333-239647	10.8	07/02/20	
10.9+	<a href="#">Employment Agreement by and between the Registrant and Jennifer Lew.</a>	S-1	333-239647	10.9	07/02/20	

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Exhibit No	Description of Exhibit	Incorporated by Reference				Filed Herewith
		Form	File No.	Exhibit	Filing Date	
10.10+	<a href="#">Employment Agreement by and between the Registrant and Ted Yednock, Ph.D.</a>	S-1	333-239647	10.10	07/02/20	
10.11+	<a href="#">Employment Agreement by and between the Registrant and Michael Overdorf.</a>	S-1/A	333-239647	10.11	07/20/20	
10.12+	<a href="#">Non-Employee Director Compensation Program.</a>	S-1/A	333-239647	10.12	07/20/20	
10.13	<a href="#">Form of Indemnification and Advancement Agreement for directors and officers</a>	S-1	333-239647	10.12	07/02/20	
31.1	<a href="#">Certification of the Chief Executive Officer Pursuant to Securities Exchange Act of Rules 13A-14(A) and 15D-14(A).</a>					X
31.2	<a href="#">Certification of the Chief Financial Officer Pursuant to Securities Exchange Act Rules 13A-14(A) and 15D-14(A).</a>					X
32.1*	<a href="#">Certification Pursuant to 18 U.S.C. Section 1350, As Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</a>					X
101.INS	XBRL Instance Document					X
101.SCH	XBRL Taxonomy Extension Schema Document					X
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document					X

+ Indicates management contract or compensatory plan.

† Certain portions of this document that constitute confidential information have been redacted in accordance with Regulation S-K, Item 601(b)(10).

\* The certification attached as Exhibit 32.1 that accompanies this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, is not deemed “filed” by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

**SIGNATURES**

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

Annexon, Inc.

Date: September 8, 2020

By: /s/ Douglas Love, Esq.  
Douglas Love, Esq.  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: September 8, 2020

By: /s/ Jennifer Lew  
Jennifer Lew  
Executive Vice President and Chief Financial Officer  
(Principal Financial and Accounting Officer)





**CERTIFICATION OF CHIEF EXECUTIVE OFFICER AND CHIEF FINANCIAL OFFICER  
PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Annexon, Inc. (the "Company") on Form 10-Q for the quarter ended June 30, 2020 (the "Report"), Douglas Love, President and Chief Executive Officer of the Company, and Jennifer Lew, Executive Vice President and Chief Financial Officer of the Company, each hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

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.

Date: September 8, 2020

/s/ Douglas Love

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Douglas Love, Esq.  
President and Chief Executive Officer  
*(Principal Executive Officer)*

/s/ Jennifer Lew

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Jennifer Lew  
Executive Vice President and Chief Financial Officer  
*(Principal Financial and Accounting Officer)*