

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

(Mark One)

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

For the quarterly period ended **June 30, 2021**

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**

**ANNEXON, INC.**

(Exact name of Registrant as specified in its Charter)

**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**

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 LLC

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 10, 2021 was 38,332,276.

# Table of Contents

	<u>Page</u>
<b>PART I—FINANCIAL INFORMATION</b>	
Item 1. Financial Statements	
<a href="#">Condensed Consolidated Balance Sheets as of June 30, 2021 (unaudited) and December 31, 2020</a>	3
<a href="#">Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2021 and 2020 (unaudited)</a>	4
<a href="#">Condensed Consolidated Statements of Comprehensive Loss for the three and six months ended June 30, 2021 and 2020 (unaudited)</a>	5
<a href="#">Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit) for the three and six months ended June 30, 2021 and 2020 (unaudited)</a>	6
<a href="#">Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2021 and 2020 (unaudited)</a>	8
<a href="#">Notes to the Condensed Consolidated Financial Statements (unaudited)</a>	10
Item 2. <a href="#">Management's Discussion and Analysis of Financial Condition and Results of Operations</a>	22
Item 3. <a href="#">Quantitative and Qualitative Disclosures About Market Risk</a>	31
Item 4. <a href="#">Controls and Procedures</a>	31
<b>PART II—OTHER INFORMATION</b>	
Item 1. <a href="#">Legal Proceedings</a>	32
Item 1A. <a href="#">Risk Factors</a>	32
Item 2. <a href="#">Unregistered Sales of Equity Securities and Use of Proceeds</a>	75
Item 3. <a href="#">Defaults Upon Senior Securities</a>	75
Item 4. <a href="#">Mine Safety Disclosures</a>	75
Item 5. <a href="#">Other Information</a>	75
Item 6. <a href="#">Exhibits</a>	76
<a href="#">EXHIBIT INDEX</a>	76
<a href="#">SIGNATURES</a>	77

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)

	June 30, 2021 (Unaudited)	December 31, 2020
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 99,588	\$ 268,565
Short-term investments	202,798	82,641
Prepaid expenses and other current assets	2,007	2,805
Total current assets	304,393	354,011
Restricted cash	1,166	—
Property and equipment, less accumulated depreciation of \$3,047 and \$1,971 as of June 30, 2021 and December 31, 2020, respectively	5,129	1,935
Operating lease right-of-use assets	21,096	—
Total assets	<u>\$ 331,784</u>	<u>\$ 355,946</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 4,184	\$ 3,734
Accrued liabilities	5,850	6,497
Deferred rent, current	—	391
Operating lease liabilities, current	250	—
Total current liabilities	10,284	10,622
Deferred rent	—	1,046
Operating lease liabilities, non-current	26,165	—
Total liabilities	36,449	11,668
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Common stock	38	38
Additional paid-in capital	518,708	510,309
Accumulated other comprehensive loss	(65)	(77)
Accumulated deficit	(223,346)	(165,992)
Total stockholders' equity	295,335	344,278
Total liabilities and stockholders' equity	<u>\$ 331,784</u>	<u>\$ 355,946</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 June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	\$ 24,572	\$ 9,287	\$ 45,268	\$ 19,504
General and administrative	6,801	2,950	12,307	5,189
Total operating expenses	<u>31,373</u>	<u>12,237</u>	<u>57,575</u>	<u>24,693</u>
Loss from operations	(31,373)	(12,237)	(57,575)	(24,693)
Other income, net	79	1	221	116
Net loss before taxes	(31,294)	(12,236)	(57,354)	(24,577)
Provision for income taxes	—	4	—	4
Net loss	(31,294)	(12,240)	(57,354)	(24,581)
Accretion on redeemable convertible preferred stock	—	281	—	560
Net loss attributable to common stockholders	<u>\$ (31,294)</u>	<u>\$ (12,521)</u>	<u>\$ (57,354)</u>	<u>\$ (25,141)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.82)</u>	<u>\$ (28.87)</u>	<u>\$ (1.50)</u>	<u>\$ (57.96)</u>
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	<u>38,277,950</u>	<u>433,749</u>	<u>38,219,143</u>	<u>433,749</u>

See accompanying notes to unaudited condensed consolidated financial statements.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Net loss	\$ (31,294)	\$ (12,240)	\$ (57,354)	\$ (24,581)
Other comprehensive gain (loss):				
Foreign currency translation adjustment	(20)	9	(2)	(2)
Unrealized gain on available for sale securities	38	—	14	—
Comprehensive loss	<u>\$ (31,276)</u>	<u>\$ (12,231)</u>	<u>\$ (57,342)</u>	<u>\$ (24,583)</u>

See accompanying notes to unaudited condensed consolidated financial statements.

**ANNEXON, INC.**  
**Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (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' Equity
	Shares	Cost	Shares	Cost				
<b>Balances as of December 31, 2020</b>	—	\$ —	38,157,618	\$ 38	\$ 510,309	\$ (77)	\$ (165,992)	\$ 344,278
Stock-based compensation	—	—	—	—	2,962	—	—	2,962
Stock option exercises	—	—	74,930	—	268	—	—	268
Foreign currency translation adjustment	—	—	—	—	—	18	—	18
Unrealized loss on available-for-sale securities	—	—	—	—	—	(24)	—	(24)
Net loss	—	—	—	—	—	—	(26,060)	(26,060)
<b>Balances as of March 31, 2021</b>	—	—	38,232,548	38	513,539	(83)	(192,052)	321,442
Stock-based compensation	—	—	—	—	4,517	—	—	4,517
Stock option exercises	—	—	82,805	—	534	—	—	534
Issuance of common stock per ESPP purchase	—	—	6,759	—	118	—	—	118
Foreign currency translation adjustment	—	—	—	—	—	(20)	—	(20)
Unrealized gain on available-for-sale securities	—	—	—	—	—	38	—	38
Net loss	—	—	—	—	—	—	(31,294)	(31,294)
<b>Balances as of June 30, 2021</b>	—	\$ —	38,322,112	\$ 38	\$ 518,708	\$ (65)	\$ (223,346)	\$ 295,335

See accompanying notes to unaudited condensed consolidated financial statements.

**ANNEXON, INC.**  
**Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity (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 Cash Flows**  
(in thousands)  
(Unaudited)

	Six Months Ended June 30,	
	2021	2020
<b>Operating activities:</b>		
Net loss	\$ (57,354)	\$ (24,581)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,076	262
Accretion of discount on available-for-sale securities	480	—
Stock-based compensation	7,479	1,426
Reduction in the carrying amount of right-of-use assets	510	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	359	568
Other long-term assets	—	44
Accounts payable	42	787
Accrued liabilities	(647)	1,425
Deferred rent	—	(178)
Operating lease liabilities	(19)	—
Net cash used in operating activities	<u>(48,074)</u>	<u>(20,247)</u>
<b>Investing activities:</b>		
Purchases of property and equipment	(32)	(16)
Purchases of available-for-sale securities	(159,616)	—
Proceeds from sale of available-for-sale securities	5,993	—
Proceeds from maturities of available-for-sale securities	33,000	—
Net cash used in investing activities	<u>(120,655)</u>	<u>(16)</u>
<b>Financing activities:</b>		
Deferred offering cost payments	—	(890)
Proceeds from the exercise common stock options	802	—
Proceeds from employee stock plan purchases	118	—
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
Net cash provided by financing activities	<u>920</u>	<u>101,095</u>
Net (decrease) increase in cash, cash equivalents and restricted cash	(167,809)	80,832
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(2)	(2)
<b>Cash, cash equivalents and restricted cash</b>		
Beginning of period	268,565	43,931
End of period	<u>\$ 100,754</u>	<u>\$ 124,761</u>
<b>Supplemental disclosure of cash flow information:</b>		
Cash paid for amounts included in the measurement of lease liability	<u>\$ 744</u>	<u>\$ —</u>
<b>Non-cash investing and financing activities:</b>		
Accretion on redeemable convertible preferred stock	<u>\$ —</u>	<u>\$ 560</u>
Purchase of property and equipment included in accounts payable	<u>\$ 408</u>	<u>\$ 156</u>
Right-of-use assets obtained in exchange for lease liability	<u>\$ 21,084</u>	<u>\$ —</u>
Construction-in-progress obtained in exchange for tenant improvement allowance from lessors	<u>\$ 3,830</u>	<u>\$ —</u>
Beneficial conversion feature recognized upon issuance of redeemable convertible preferred stock	<u>\$ —</u>	<u>\$ 6,297</u>
Deferred offering costs included in accounts payable and accrued liabilities	<u>\$ —</u>	<u>\$ 171</u>
Issuance costs of redeemable convertible preferred stock included in accounts payable and accrued liability	<u>\$ —</u>	<u>\$ 5,178</u>



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 developing a class of new complement medicines for patients with classical complement-mediated 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 its 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 \$262.4 million from the IPO, after deducting underwriting discounts and commissions of \$20.1 million and offering costs of \$4.6 million. 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.

***Reverse Stock Split***

On July 17, 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, 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 unaudited condensed consolidated financial statements have been retroactively adjusted to reflect the effect of the Reverse Stock Split for all periods presented.

***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, 2021, had an accumulated deficit of \$223.3 million and cash and cash equivalents and short-term investments of \$302.4 million.

The Company has historically funded its operations through the issuance of shares of its redeemable convertible preferred stock and common stock. Based on projected activities, management projects that cash on hand is 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.

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

The condensed consolidated balance sheet as of June 30, 2021, and the condensed consolidated statements of operations, comprehensive loss, changes in redeemable convertible preferred stock and stockholders' equity (deficit) and cash flows for the three and six months ended June 30, 2021 and 2020 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, 2021 and its results of operations and cash flows for the three and six months ended June 30, 2021 and 2020. 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, 2021 are not necessarily indicative of the results to be expected for the year ending December 31, 2021 or for any other future annual or interim period. The condensed consolidated balance sheet as of December 31, 2020 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 Company's Annual Report on Form 10-K for the year ended December 31, 2020, filed with the SEC on March 25, 2021.

***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 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.

***Cash, Cash Equivalents and Restricted Cash***

The Company considers all highly liquid instruments with an original maturity of three months or less at time of purchase to be cash equivalents. Cash equivalents, which includes amounts invested in money market funds, are stated at fair value.

Restricted cash as of June 30, 2021 relates to the letters of credit established for the Company's office leases.

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the condensed consolidated balance sheets that sum to the total of the same amounts shown in the condensed consolidated statements of cash flows:

	<b>June 30, 2021</b>	<b>December 31, 2020</b>
Cash	\$ 587	\$ 597
Cash equivalents	99,001	267,968
Cash and cash equivalents	99,588	268,565
Restricted cash	1,166	—
Cash, cash equivalents and restricted cash	<u>\$ 100,754</u>	<u>\$ 268,565</u>

### **Short-Term Investments**

Short-term investments have been classified as available-for-sale and are carried at estimated fair value as determined based upon quoted market prices or pricing models for similar securities. The Company determines the appropriate classification of its investments in debt securities at the time of purchase. Available-for-sale securities with original maturities beyond three months at the date of purchase are classified as current based on their availability for use in current operations. Unrealized gains and losses are excluded from earnings and are reported as a component of other comprehensive loss. The Company periodically evaluates whether declines in fair values of its marketable securities below their book value are other-than-temporary. This evaluation consists of several qualitative and quantitative factors regarding the severity and duration of the unrealized loss as well as the Company's ability and intent to hold the marketable security until a forecasted recovery occurs. Additionally, the Company assesses whether it has plans to sell the security or it is more likely than not it will be required to sell any marketable securities before recovery of its amortized cost basis. Impairment assessments are made at the individual security level each reporting period. When the fair value of an available-for-sale security is less than its cost at the balance sheet date, a determination is made as to whether the impairment is other-than-temporary and, if it is other-than-temporary, an impairment loss is recognized in other income, net, equal to the difference between the investment's amortized cost and fair value at such date. The cost of investments sold is based on the specific-identification method. Interest on marketable securities is included in other income, net.

### **Leases**

The Company determines if an arrangement is a lease at inception. Upon adoption of Accounting Standards Codification 842, *Leases*, as of January 1, 2021, the Company includes operating leases in operating lease right of use ("ROU") assets, current and noncurrent operating lease liabilities in the Company's condensed consolidated balance sheets. The ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. As most of the leases do not provide an implicit rate, the Company generally uses its incremental borrowing rate based on the estimated rate of interest for collateralized borrowing over a similar term of the lease payments at the commencement date. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise the option. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

As a practical expedient, the Company elected, for all facility leases, not to separate non-lease components from lease components and instead to account for each separate lease component and its associated non-lease components as a single lease component. The Company elected to exclude from its balance sheets recognition of leases having a term of 12 months or less (short-term leases).

### **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 condensed consolidated balance sheets. Foreign currency translation adjustments for the three months ended June 30, 2021 and 2020 were a \$20,000 loss and a \$9,000 gain, respectively. Foreign currency translation adjustments for the six months ended June 30, 2021 and 2020 were a \$2,000 loss and a \$2,000 loss, respectively.

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.

### **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-

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

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.

#### ***Concentration of Credit Risk***

Financial instruments that potentially subject the Company to concentrations of credit risk consist primarily of cash and cash equivalents and short-term investments. The Company's cash and cash equivalents and short-term investments are held by high credit quality financial institutions in the United States. At times, such deposits may be in excess of the Federal Depository Insurance Corporation insured limits. Management believes that the financial institutions are financially sound, and accordingly, minimal credit risk exists with respect to the financial institutions.

#### ***Recently Adopted Accounting Pronouncements***

In August 2018, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, No. 2018-15, *Customer's Accounting for Implementation Costs Incurred in a Cloud Computing Arrangement that is a Service Contract (Topic*

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

350). 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 early adoption is permitted. The standard can be adopted either using the prospective or retrospective transition approach. The Company adopted ASU No. 2018-15 on January 1, 2021 and the adoption did not have a material impact on its condensed consolidated financial statements.

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. This standard is effective for the Company on January 1, 2022, early adoption is permitted. 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.

In the second quarter of 2021, the Company adopted ASU No. 2016-02 using the modified retrospective approach as of January 1, 2021. The adoption of Topic 842 as of January 1, 2021 resulted in the recognition of ROU assets of \$461,000, corresponding lease liabilities of \$605,000, the derecognition of the deferred rent liability of \$1.4 million, and the recognition of a liability of \$1.3 million related to the reallocation of the consideration of the Company's lease pending the commencement of the second lease component in May 2021 (see Note 5—*Commitments and Contingencies*). The adoption resulted in additional \$54,000 of rent expense for the first quarter of 2021. Under the optional transition method, the Company does not need to restate the comparative periods in transition and will continue to present financial information and disclosures for periods before January 1, 2021 in accordance with Topic 840.

As part of the Topic 842 adoption, the Company elected certain practical expedients outlined in the guidance. The Company has chosen to apply the package of practical expedients for existing leases, which provides relief from reassessing: (i) whether a contract is or contains a lease, (ii) lease classification, and (iii) whether initial direct costs can be capitalized. The Company did not elect the hindsight practical expedient to reassess the lease term for existing leases. The Company elected the short-term lease exemption, under which any lease less than 12 months is excluded from recognition on the balance sheet. Additionally, the Company elected the non-separation of lease and non-lease components.

### **Recently Issued Accounting Pronouncements**

In June 2016, the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. ASU 2016-13 requires an entity to utilize a new impairment model that requires measurement and recognition of expected credit losses for most financial assets and certain other instruments, including but not limited to available-for-sale debt securities. Credit losses relating to available-for-sale debt securities will be recorded through an allowance for credit losses rather than as a direct write-down to the security. The new guidance requires the use of forward-looking expected credit loss models based on historical experience, current conditions, and reasonable and supportable forecasts that affect the collectability of the reported amount, which may result in earlier recognition of credit losses under the new guidance. The new guidance also modifies the impairment models for available-for-sale debt securities and for purchased financial assets with credit deterioration since their origination. Subsequent to the issuance of ASU 2016-13, the FASB issued ASU 2018-19, *Codification Improvements to Topic 326, Financial Instrument—Credit Losses*. This ASU does not change the core principle of the guidance in ASU 2016-13, instead these amendments are intended to clarify and improve operability of certain topics included within the credit losses guidance. The FASB also subsequently issued ASU No. 2019-04, *Codification Improvements to Topic 326, Financial Instruments—Credit Losses, Derivatives and Hedging (Topic 815), and Financial Instruments (Topic 825)*, which did not change the core principle of the guidance in ASU 2016-13 but clarified that expected recoveries of amounts previously written off and expected to be written off should be included in the valuation account and should not exceed amounts previously written off and expected to be written off. In March 2020, the FASB issued ASU No. 2020-3, *Codification Improvements to Financial Instruments* which makes narrow-scope improvements to various financial instruments topics, including the new credit losses standard and clarifies the following areas (i) the contractual term of a net investment in a lease should be the contractual term used to measure expected credit losses; (ii) when an entity regains control of financial assets sold, an allowance for credit losses should be recorded. The guidance is effective for fiscal years, and interim periods within those years, beginning after December 15, 2019 for public business entities, excluding smaller reporting companies. The ASU 2016-13 will be effective for the Company for the year ending December 31, 2021 upon the Company no longer qualifying as an emerging growth or smaller reporting company. The Company is in the process of assessing the impact adoption will have on its condensed consolidated financial statements.

### **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 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.

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

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, 2021			
Valuation Hierarchy	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value	
<b>Assets:</b>					
Cash equivalents:					
Money market funds	Level 1	\$ 99,001	\$ —	\$ —	\$ 99,001
Short-term investments:					
Commercial paper	Level 2	114,838	—	—	114,838
Corporate debt	Level 2	62,515	14	(9)	62,520
Government bonds	Level 2	25,437	3	—	25,440
Total assets		<u>\$ 301,791</u>	<u>\$ 17</u>	<u>\$ (9)</u>	<u>\$ 301,799</u>
		December 31, 2020			
Valuation Hierarchy	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value	
<b>Assets:</b>					
Cash equivalents:					
Money market funds	Level 1	\$ 267,968	\$ —	\$ —	\$ 267,968
Short-term investments:					
Commercial paper	Level 2	59,930	—	—	59,930
Corporate bonds	Level 2	22,717	1	(7)	22,711
Total assets		<u>\$ 350,615</u>	<u>\$ 1</u>	<u>\$ (7)</u>	<u>\$ 350,609</u>

For the three and six months ended June 30, 2021 and 2020, the Company recognized no material realized gains or losses on financial instruments.

#### 4. Balance Sheet Components

##### *Prepaid Expenses and Other Current Assets*

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

	June 30, 2021	December 31, 2020
Prepaid research and development costs	\$ 1,507	\$ 1,039
Prepaid insurance	265	1,236
Other prepaid expenses	235	527
Other receivables	—	3
Total prepaid expenses and other current assets	<u>\$ 2,007</u>	<u>\$ 2,805</u>



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

**Accrued Liabilities**

Accrued liabilities consisted of the following (in thousands):

	June 30, 2021	December 31, 2020
Accrued research and development expenses	\$ 3,382	\$ 3,260
Accrued compensation	1,826	2,543
Accrued professional services	344	524
Other accrued expenses	298	170
Total accrued liabilities	<u>\$ 5,850</u>	<u>\$ 6,497</u>

**5. Commitments and Contingencies**

**Leases**

The Company leases its offices and laboratory in South San Francisco, California, or the South San Francisco Lease, under a seven-year noncancelable lease agreement that ends in June 2024 with a five-year renewal option. In December 2020, the Company entered into an agreement to lease office and laboratory space in Brisbane, California, or the Brisbane Lease, with an affiliate of its current landlord. In May 2021, the Brisbane Lease commenced when the Company started the tenant improvements which are expected to be completed by the end of October 2021. The contractual term of the Brisbane Lease is expected to begin in November 2021, the expected move-in date, for a ten-year term, with an option by the Company to extend for an additional ten years. The base rent will be abated for three months and the landlord will provide the Company with a tenant improvement allowance of up to \$10.8 million. In connection with the Brisbane Lease, the Company is required to maintain a letter of credit for the benefit of the landlord in the amount of \$1.0 million, which was delivered in January 2021 and is included in restricted cash on the condensed consolidated balance sheet. Concurrent with the execution of the Brisbane Lease, the Company entered into an agreement to terminate its existing lease in South San Francisco, California, on the day immediately preceding the day when the tenant improvements are completed. The South San Francisco Lease and the Brisbane Lease are accounted for as one lease with two lease components. Accordingly, upon adoption of Topic 842, the total consideration for the lease was reallocated to each lease component based on standalone selling price. As the Brisbane Lease commenced in May 2021, \$1.3 million of the consideration allocated to the Brisbane Lease was recorded as a liability as of January 1, 2021 when the deferred rent balance of the South San Francisco Lease was derecognized.

In connection with the Brisbane Lease, the Company recognized operating lease right-of-use assets of \$21.1 million as of June 30, 2021, and lease liabilities of \$26.4 million in its condensed consolidated balance sheet. The weighted average remaining lease term is 10.2 years.

The weighted average incremental borrowing rate used to measure the operating lease liability is 8.4%.

Operating lease cost for the three and six months ended June 30, 2021 was \$716,000 and \$858,000, respectively. Variable lease payments for the three and six months ended June 30, 2021 were \$36,000 and \$70,000, respectively.

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

Future minimum lease payments and related lease liabilities as of June 30, 2021, were as follows:

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

<b>As of June 30, 2021:</b>	<b>(in thousands)</b>
2021 (remaining six months)	\$ 252
2022	4,203
2023	4,742
2024	4,906
2025	5,079
Thereafter	32,833
Total undiscounted lease payments	52,015
Less: Imputed interest	(18,570)
Less: Tenant improvement allowance	(7,030)
Total	<u>\$ 26,415</u>

The Company's future undiscounted lease payments under non-cancellable operating leases (as defined by prior guidance) as of December 31, 2020 were as follows:

<b>As of December 31, 2020:</b>	<b>(in thousands)</b>
2021	\$ 618
2022	4,189
2023	4,756
2024	5,035
2025 and thereafter	38,332
Total	<u>\$ 52,930</u>

***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 \$500,000, and royalty payments at a rate equal to a low single-digit percentage of worldwide net sales of licensed products. The Company did not achieve any milestones or make any milestone payments for the three and six months ended June 30, 2021 and 2020.

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, as amended, the Company may receive up to \$651,000 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 \$590,000 in funding to date, including \$135,000 received during the six months ended June 30, 2021, which was recorded as other income. No income was recognized for the three months ended June 30, 2021 and 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, 2021, the Company did not have any material indemnification claims that were probable or reasonably possible and consequently has not recorded related liabilities.

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

**6. Stockholders' Equity**

**Common Stock**

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

	June 30, 2021	December 31, 2020
Options issued and outstanding	5,673,023	3,909,873
Options available for future grant	2,313,366	2,707,947
Reserved for employee stock purchase plan	734,903	360,086
Total common stock reserved	<u>8,721,292</u>	<u>6,977,906</u>

**7. Equity Incentive Plan**

In July 2020, the Company's board of directors and stockholders adopted and approved 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 may not grant any additional awards under the 2011 Equity Incentive Plan, or the 2011 Plan. The 2011 Plan will continue to govern outstanding equity awards granted thereunder.

**2020 Equity Incentive Plan**

The number of shares of common stock reserved for issuance under the 2020 Plan automatically increases on the first day of January, commencing on January 1, 2021 and ending in 2030, in an amount equal to 4% of the total number of shares of the Company's capital stock outstanding on the last day of the preceding year, or a lesser number of shares determined by the Company's board of directors.

Awards granted under the 2020 Plan expire no later than ten years from the date of grant. For the Incentive Stock Options, or ISOs, and Nonstatutory Stock Options, or NSOs, the option price shall not be less than 100% of the estimated fair value on the date of grant. Options granted typically vest over a four-year period but may be granted with different vesting terms. As of June 30, 2021, there were 2,313,366 shares available for issuance under the 2020 Plan.

Stock option activity under the 2011 Plan and the 2020 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, 2020	2,707,947	3,909,873	\$ 10.78	8.40	\$ 56,128
Additional shares authorized	1,526,304	—			
Stock options granted	(2,122,600)	2,122,600	28.09		
Stock options exercised	—	(157,735)	5.08		
Stock options forfeited	201,715	(201,715)	22.69		
Balances as of June 30, 2021	<u>2,313,366</u>	<u>5,673,023</u>	\$ 16.99	8.56	\$ 43,667
Exercisable as of June 30, 2021		<u>1,676,944</u>	\$ 7.89	7.02	\$ 25,467

The total intrinsic value of options exercised during the three and six months ended June 30, 2021 were \$2.2 million and \$3.3 million, respectively. There were no options exercised during the three and six months ended June 30, 2020. The intrinsic value is the difference between the fair value of the Company's common stock at the time of exercise and the exercise price of the stock option.

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

**Employee Stock Purchase Plan**

The ESPP enables eligible employees to purchase shares of the Company's common stock at the end of each offering period at a price equal to 85% of the fair market value of the shares on the first business day or the last business day of the offering period, whichever is lower. Eligible employees generally include all employees. Share purchases are funded through payroll deductions of at least 1%, and up to 15% of an employee's eligible compensation for each payroll period. The number of shares reserved for issuance under the ESPP increase automatically on the first day of each fiscal year, beginning on January 1, 2021, by a number equal to the least of 360,086 shares, 1% of the shares of common stock outstanding on the last day of the immediately preceding fiscal year, or such number of shares determined by the Company's board of directors. As of June 30, 2021, 734,903 shares were available for future purchase. The ESPP generally provides for six-month consecutive offering periods beginning on December 15, 2020. The ESPP is a compensatory plan as defined by the authoritative guidance for stock compensation. As such, stock-based compensation expense has been recorded for the three and six months ended June 30, 2021.

**Stock-Based Compensation Expense**

The total stock-based compensation expense recognized related to the Company's equity incentive plans was as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Research and development	\$ 2,402	\$ 335	\$ 3,948	\$ 660
General and administrative	2,115	428	3,531	766
Total stock-based compensation expense	\$ 4,517	\$ 763	\$ 7,479	\$ 1,426

The stock-based compensation expense related to the ESPP for the three and six months ended June 30, 2021 was \$34,000 and \$65,000, respectively.

As of June 30, 2021, the total unrecognized stock-based compensation cost related to outstanding unvested stock options that are expected to vest was \$59.2 million, which the Company expects to recognize over an estimated weighted-average period of 3.36 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.

*Fair Value of Common Stock*—Historically, for all periods prior to the IPO in July 2020, fair values of the shares of common stock underlying the Company's share-based awards were estimated on each grant date by the Company's board of directors. The board of directors considered, among other things, valuations of the Company's common stock which were prepared by an independent third-party valuation firm in accordance with the guidance provided by the American Institute of Certified Public Accountants 2013 Practice Aid, *Valuation of Privately-Held-Company Equity Securities Issued as Compensation*. After the completion of the IPO in July 2020, the fair value of each share of underlying common stock is based on the closing price of the Company's common stock as reported on the date of grant on the Nasdaq Global Select Market.

*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 does not have sufficient 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 and to align with the Company's expected term.

*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.

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

*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.

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,	
	2021	2020	2021	2020
Expected term (in years)	5.50 - 6.08	5.00 - 6.08	4.33 - 6.08	5.00 - 6.08
Expected volatility	89.50% - 90.70%	85%	89.50% - 90.70%	85%
Risk-free interest rate	0.88% - 1.01%	0.33% - 0.45%	0.35% - 1.02%	0.33% - 1.45%
Dividend yield	—	—	—	—

**8. Income Taxes**

For the three and six months ended June 30, 2021 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.

**9. 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,	
	2021	2020	2021	2020
Stock options to purchase common stock	5,673,023	3,026,480	5,673,023	3,026,480
Shares subject to employee stock purchase plan	3,030	—	3,030	—
Redeemable convertible preferred stock on an as-converted basis	—	20,824,938	—	20,824,938
Total	<u>5,676,053</u>	<u>23,851,418</u>	<u>5,676,053</u>	<u>23,851,418</u>

## 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 consolidated financial statements and related notes thereto for the year ended December 31, 2020, included in our Annual Report on Form 10-K, or Annual Report, filed with the Securities and Exchange Commission, or SEC, on March 25, 2021.*

*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, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, 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 class of new complement medicines 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.

We are advancing a portfolio of innovative product candidates designed to block the activity of C1q and the entire classical complement pathway in a broad set of complement-mediated diseases. Our first clinical candidate, ANX005, is a full-length monoclonal antibody formulated for intravenous administration in autoimmune and neurodegenerative disorders. Our second clinical candidate, ANX007, is an antigen-binding fragment, or Fab, formulated for intravitreal administration for the treatment of neurodegenerative ophthalmic disorders. Our third clinical candidate, ANX009, is a subcutaneous formulation of a Fab designed for the treatment of antibody-mediated autoimmune diseases of blood and vascular tissues. 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 clinical trials. We recently completed a Phase 1 dose-escalation study of ANX009 in healthy volunteers, in which ANX009 was well-tolerated and demonstrated complete and sustained C1q inhibition supporting the potential for twice weekly subcutaneous administration. Our preclinical candidates include ANX105, an investigational monoclonal antibody designed for chronic neurodegenerative diseases, and ANX1502, an oral small molecule program designed for chronic autoimmune diseases.

We are conducting ongoing clinical trials in multiple serious autoimmune, neurodegenerative and ophthalmic diseases, including GBS, warm autoimmune hemolytic anemia, Huntington’s Disease, amyotrophic lateral sclerosis and geographic atrophy, and planning to advance into lupus nephritis and Multifocal Motor Neuropathy (MMN). Data from these clinical trials are anticipated over the next two years through 2023. Based on learnings from our initial trials, we are evaluating additional orphan and large market indications that are driven by aberrant or excess classical complement activation. Additionally, we are deploying a rigorous, biomarker-driven development strategy designed to improve the probability of technical success of our portfolio. 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.

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 \$31.3 million and \$12.2 million for the three months ended June 30, 2021 and 2020, respectively. Our net losses were \$57.4 million and \$24.6 million for the six months ended June 30, 2021 and 2020, respectively. As of June 30, 2021, we had an accumulated deficit of \$223.3 million and cash and cash equivalents and short-term investments of \$302.4 million.

### **Initial Public Offering**

On July 28, 2020, we completed an IPO 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 \$262.4 million from the IPO, after deducting underwriting discounts and commissions of \$20.1 million and offering costs of \$4.6 million.

### **Impact of COVID-19 Pandemic**

The COVID-19 pandemic continues to rapidly evolve, and its ongoing impact is uncertain and subject to change. For instance, we have experienced shortages in clinical site staff and longer timelines for clinical site initiation. We will continue to monitor the COVID-19 situation closely. The extent of the impact of the COVID-19 pandemic on our clinical trials, business, financial condition, results of operations and clinical development timelines and plans remains uncertain, and will depend on, among other factors, the duration of the outbreak, the emergence of variants, rates of infection in the locations in which we do business, restrictions that may be requested or mandated by governmental authorities, and the impact of the pandemic 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.

### **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.

### **Other Income, Net**

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

## **Results of Operations**

### **Comparison of the Three Months Ended June 30, 2021 and 2020**

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>2021</b>	<b>2020</b>		
	<b>(in thousands)</b>			
Operating expenses:				
Research and development	\$ 24,572	\$ 9,287	\$ 15,285	165%
General and administrative	6,801	2,950	3,851	131%
Total operating expenses	31,373	12,237	19,136	156%
Loss from operations	(31,373)	(12,237)	(19,136)	156%
Other income, net	79	1	78	*
Net loss before taxes	(31,294)	(12,236)	(19,058)	156%
Provision for income taxes	—	4	—	*
Net loss	\$ (31,294)	\$ (12,240)	\$ (19,058)	156%

\* Not meaningful



### Research and Development Expenses

	Three Months Ended June 30,		Dollar Change	% Change
	2021	2020		
	(in thousands)			
Direct costs:				
Clinical and nonclinical outside services	\$ 10,108	\$ 4,038	\$ 6,070	150%
Consulting and professional services	2,111	764	1,347	176%
Contract manufacturing	4,513	1,784	2,729	153%
Laboratory supplies and materials	319	216	103	48%
Indirect costs:				
Compensation and personnel-related (including stock-based compensation)	6,391	2,224	4,167	187%
Facilities and depreciation	1,112	228	884	*
Other	18	33	(15)	(45%)
Total research and development expenses	<u>\$ 24,572</u>	<u>\$ 9,287</u>	<u>\$ 15,285</u>	165%

\* Not meaningful

Research and development expenses increased by \$15.3 million, or 165%, for the three months ended June 30, 2021 compared to the same period in 2020. The increase was primarily due to an increase of \$6.1 million in direct clinical outside services related to our multiple ongoing and planned clinical trials for ANX005, ANX007 and ANX009 as well as preclinical outside services to support pre-IND activities for our ANX105 and our small molecule program. Contract manufacturing expense increased by \$2.7 million related to the production of ANX005 and ANX009 as well as pre-IND manufacturing activities for ANX105 and our small molecule program. Compensation and personnel-related expenses increased by \$4.2 million, including an increase of \$2.1 million in stock-based compensation, due to an increase in headcount. Direct consulting and professional services costs increased by \$1.3 million related to external research and development during the three months ended June 30, 2021. Facilities and depreciation costs increased by \$0.9 million due to the commencement of our new office lease in Brisbane, California.

### General and Administrative Expenses

	Three Months Ended June 30,		Dollar Change	% Change
	2021	2020		
	(in thousands)			
Compensation and personnel-related (including stock-based compensation)	\$ 3,540	\$ 998	\$ 2,542	*
Consulting and professional services	2,533	1,735	798	46%
Facilities and depreciation	523	120	403	*
Other	205	97	108	111%
Total general and administrative expenses	<u>\$ 6,801</u>	<u>\$ 2,950</u>	<u>\$ 3,851</u>	131%

\* Not meaningful

General and administrative expenses increased by \$3.9 million, or 131%, for the three months ended June 30, 2021 compared to the same period in 2020. The increase was primarily due to an increase of \$2.5 million in compensation and personnel-related expenses, including an increase of \$1.7 million in stock-based compensation, due to an increase in headcount. Consulting and professional services for accounting, legal and audit fees, and directors and officers liability insurance increased by \$0.8 million during the three months ended June 30, 2021. Facilities and depreciation costs increased by \$0.4 million due to the commencement of our new office lease in Brisbane, California.

### Comparison of the Six Months Ended June 30, 2021 and 2020

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

	Six Months Ended June 30,		Dollar Change	% Change
	2021	2020		
	(in thousands)			
<b>Operating expenses:</b>				
Research and development	\$ 45,268	\$ 19,504	\$ 25,764	132%
General and administrative	12,307	5,189	7,118	137%
Total operating expenses	57,575	24,693	32,882	133%
Loss from operations	(57,575)	(24,693)	(32,882)	133%
Other income, net	221	116	105	91%
Net loss before taxes	(57,354)	(24,577)	(32,777)	133%
Provision for income taxes	—	4	-	*
Net loss	<u>\$ (57,354)</u>	<u>\$ (24,581)</u>	<u>\$ (32,777)</u>	133%

\* Not meaningful

### Research and Development Expenses

	Six Months Ended June 30,		Dollar Change	% Change
	2021	2020		
	(in thousands)			
<b>Direct costs:</b>				
Clinical and nonclinical outside services	\$ 18,017	\$ 8,086	\$ 9,931	123%
Consulting and professional services	3,843	1,372	2,471	180%
Contract manufacturing	9,705	4,785	4,920	103%
Laboratory supplies and materials	601	273	328	120%
<b>Indirect costs:</b>				
Compensation and personnel-related (including stock-based compensation)	11,311	4,463	6,848	153%
Facilities and depreciation	1,686	444	1,242	*
Other	105	81	24	30%
Total research and development expenses	<u>\$ 45,268</u>	<u>\$ 19,504</u>	<u>\$ 25,764</u>	132%

\* Not meaningful

Research and development expenses increased by \$25.8 million, or 132%, for the six months ended June 30, 2021 compared to the same period in 2020. The increase was primarily due to an increase of \$9.9 million in direct clinical outside services related to our multiple ongoing and planned clinical trials for ANX005, ANX007 and ANX009 as well as preclinical outside services to support pre-IND activities for our ANX105 and our small molecule program. Contract manufacturing expense increased by \$4.9 million related to the production of ANX005 and ANX009 as well as pre-IND manufacturing activities for ANX105 and our small molecule program. Compensation and personnel-related expenses increased by \$6.8 million, including an increase of \$3.3 million in stock-based compensation, due to an increase in headcount. Direct consulting and professional services costs increased by \$2.5 million related to external research and development during the six months ended June 30, 2021. Facilities and depreciation costs increased by \$1.2 million due to the commencement of our new office lease in Brisbane, California.

### General and Administrative Expenses

	Six Months Ended June 30,		Dollar Change	% Change
	2021	2020		
	(in thousands)			
Compensation and personnel-related (including stock-based compensation)	\$ 6,119	\$ 1,935	\$ 4,184	*
Consulting and professional services	4,881	2,806	2,075	74%
Facilities and depreciation	909	233	676	*
Other	398	215	183	85%
<b>Total general and administrative expenses</b>	<b>\$ 12,307</b>	<b>\$ 5,189</b>	<b>\$ 7,118</b>	<b>137%</b>

\* Not meaningful

General and administrative expenses increased by \$7.1 million, or 137%, for the six months ended June 30, 2021 compared to the same period in 2020. The increase was primarily due to an increase of \$4.2 million in compensation and personnel-related expenses, including an increase of \$2.8 million in stock-based compensation, due to an increase in headcount. Consulting and professional services for accounting, legal and audit fees, and directors and officers liability insurance increased by \$2.1 million during the six months ended June 30, 2021. Facilities and depreciation costs increased by \$0.7 million due to the commencement of our new office lease in Brisbane, California.

### 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, 2021, we have raised net cash proceeds of \$233.9 million from private placements of our redeemable convertible preferred stock and \$262.4 million from the IPO of our common stock. As of June 30, 2021, we had available cash and cash equivalents and short-term investments of \$302.4 million and an accumulated deficit of \$223.3 million.

#### Historical Cash Flows

	Six Months Ended June 30,	
	2021	2020
	(in thousands)	
Cash used in operating activities	\$ (48,074)	\$ (20,247)
Cash used in investing activities	(120,655)	(16)
Cash provided by financing activities	920	101,095
<b>Net (decrease) increase in cash, cash equivalents and restricted cash</b>	<b>\$ (167,809)</b>	<b>\$ 80,832</b>

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

Cash used in operating activities for the six months ended June 30, 2021 was \$48.1 million, which consisted of a net loss of \$57.4 million, partially offset by \$9.5 million in non-cash charges and a net change of \$0.3 million in our net operating assets and liabilities. The non-cash charges consisted of stock-based compensation of \$7.5 million, depreciation and amortization of \$1.0 million, and accretion of discount on available-for sale securities of \$0.5 million, and reduction in the carrying amount of right-of-use assets of \$0.5 million.

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 Flows from Investing Activities***

Cash used in investing activities for the six months ended June 30, 2021 was \$120.7 million, which consisted of \$159.6 million of purchases of available-for-sale securities, \$33.0 million of maturities of available-for-sale securities, and \$6.0 million of proceeds from sale of available-for-sale securities.

Cash used in investing activities for the six months ended June 30, 2020 was related to immaterial purchase of property and equipment.

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

Cash provided by financing activities for the six months ended June 30, 2021 was \$0.9 million, related to proceeds from exercise of common stock options and employee stock purchase plan purchases.

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 a Paycheck Protection Program loan, partially offset by payments for deferred offering costs of \$0.9 million and repayments of \$0.5 million of the Paycheck Protection Program loan.

### ***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;
- 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;
- 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.

### **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 and Smaller Reporting 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 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.

As of June 30, 2021, we retained our eligibility as a smaller reporting company as well as an emerging growth company.

Because (i) the aggregate worldwide market value of our voting common stock held by non-affiliates (or “public float”) exceeded \$700 million on June 30, 2021, (ii) we will have been subject to the reporting requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, for at least twelve calendar months, (iii) we have previously filed an annual report under Section 13(a) or 15(d) of the Exchange Act and (iv) we will not be eligible for smaller reporting company status because we exceed the public float and revenue threshold for such status, we will qualify as a “large accelerated filer” under Rule 12b-2 of the Exchange Act as of the end of the current fiscal year. As a large accelerated filer, we will no longer qualify as an emerging growth company. As a result of these changes, we are in the process of assessing the impacts of this to our internal control over financial reporting and the accounting standards applicable for the Company. We will remain eligible to take advantage of smaller reporting company reporting requirements through our Annual Report on Form 10-K for the current fiscal year.

## 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.

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 our Annual Report except for the adoption of ASU No. 2016-02, Leases (Topic 842) on January 1, 2021 as discussed below.

In the second quarter of 2021, we adopted ASU No. 2016-02 using the modified retrospective approach as of January 1, 2021.

Upon adoption of Accounting Standards Codification 842, *Leases*, as of January 1, 2021, we include operating leases in operating lease right-of-use, or ROU assets, current and noncurrent operating lease liabilities in our condensed consolidated balance sheets. The ROU assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at the commencement date based on the present value of lease payments over the lease term. As most of the leases do not provide an implicit rate, we generally use our incremental borrowing rate based on the estimated rate of interest for collateralized borrowing over a similar term of the lease payments at the commencement date. Our lease terms may include options to extend or terminate the lease when it is reasonably certain that we will exercise the option. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

As a practical expedient, we elected, for all facility leases, not to separate non-lease components from lease components and instead to account for each separate lease component and its associated non-lease components as a single lease component. We elected to exclude from our balance sheets recognition of leases having a term of 12 months or less (short-term leases).

## 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**

Not required for the Company as a smaller reporting company.

**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 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***

During our quarter ended March 31, 2021, we launched the NetSuite enterprise resource planning system, or ERP, to support our financial reporting. The implementation of the ERP resulted primarily in changes to reports, interfaces and IT dependent controls. Therefore, we have modified the design and documentation of internal control processes and procedures relating to the new systems to enhance existing internal controls. The system changes were undertaken as an ongoing business initiative to improve and enhance our internal control over financial reporting.

Except as described in the previous paragraph, we identified 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, 2021 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.*

#### Risk Factor Summary

The following summarizes the most material risks that make an investment in our securities risky or speculative. If any of the following risks occur or persist, our business, financial condition and results of operations could be materially harmed and the price of our common stock could significantly decline.

- 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 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.
- Our business is heavily dependent on the successful development, regulatory approval and commercialization of our product candidates which are in early stages of clinical development.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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.



## 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 years ended December 31, 2020 and 2019 was approximately \$63.4 million and \$37.2 million, respectively, and our net loss for the three and six months ended June 30, 2021 was approximately \$31.3 million and \$57.4 million, respectively. As of June 30, 2021, we had an accumulated deficit of \$223.3 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.

As of June 30, 2021, we had capital resources consisting of cash and cash equivalents and short-term investments of approximately \$302.4 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, and 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 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 product candidates 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.

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 product candidates which are in early stages of clinical development.***

We have no products approved for sale, and our 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. 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;
- 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 the COVID-19 pandemic. 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 continue to be negatively affected by the COVID-19 pandemic, which could materially and adversely affect our business, financial condition and results of operations. For instance, we have experienced interruption in clinical trial activities in Bangladesh due to quarantines, shortages in clinical site staff, longer timelines for clinical site initiation and temporary shortages in lab kits and supplies. 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 have been 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. These 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;
- 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 pandemic could worsen or could return in 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.

In particular, the COVID-19 pandemic has adversely impacted hospitals and medical facilities where we are currently conducting our clinical trials, and has resulted in increased competition among companies conducting clinical trials for more limited hospital space.

The COVID-19 pandemic continues to rapidly evolve. The extent to which the outbreak may continue to affect our clinical trials, business, financial condition, results of operations, and clinical development timelines and plans will depend on future developments, which are highly uncertain and cannot be predicted at this time, such as the duration of the outbreak, the emergence of variants, rates of infection in the locations in which we and our CROs, third-party manufacturers, regulatory authorities and other third parties with whom we do business operate, 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.

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 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 led to clinical responses 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, or the EU, 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 2 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 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.

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. For instance, we have experienced interruption in clinical trial activities in Bangladesh due to quarantines, shortages in clinical site staff, longer timelines for clinical site initiation and temporary shortages in lab kits and supplies. 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;
- 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.

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.***

IVIg, though not FDA-approved in the United States for GBS, is currently the standard of care for GBS. We completed a drug-drug interaction, or DDI, trial evaluating ANX005 co-administered with IVIg to assess safety and tolerability, and to measure the pharmacokinetics and pharmacodynamics of ANX005 when administered in combination with IVIg. Initial results from the DDI study showed the combined use of ANX005 and IVIg in GBS patients was well-tolerated and achieved full target engagement. The DDI trial was not designed or powered for statistical significance on efficacy measures. As a result, the DDI trial provides 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 EU, 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 EU. 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 EU 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 EU, 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 can be approved for the same condition. Even after an Orphan Drug is approved, the FDA can subsequently approve the same drug 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 and rolling review of BLA submissions.

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 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 sponsor of a Fast Track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the product candidate may be eligible for priority review. A Fast Track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA. 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.

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, the results of the 2020 U.S. Presidential Election may impact our business and industry. Namely, the Trump administration took 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 whether or how these orders will be implemented, or whether they will be rescinded and replaced under the Biden administration. The policies and priorities of the new administration are unknown and could materially impact the regulations governing our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action 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. Separately, on April 15, 2021, the FDA issued a guidance document in which the FDA outlined plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites. According to the guidance, the FDA intends to request such remote interactive evaluations in situations where an in-person inspection would not be prioritized, deemed mission-critical or is otherwise limited by travel restrictions, but where the FDA determines that a remote evaluation would still be appropriate. 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 conduct, 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 conduct clinical trials of our product candidates outside the United States, and plan to continue to do so in the future for reasons including the relative impact of the COVID-19 pandemic on U.S. trial sites. 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 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 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.

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 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.

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 our Annual Report on Form 10-K for the fiscal year ended December 31, 2020 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. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. We cannot be sure that coverage and reimbursement in the United States, the EU 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.

***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, 2021, we had 57 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 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;
- 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.

***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 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, such litigation can be time consuming, divert management attention and financial resources and are costly to evaluate and defend. 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 such litigation can vary significantly, it is difficult to estimate potential losses that may occur. As a result of such litigation, we may be required 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 or royalty obligations. 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. Accordingly, we are unable at this time to estimate the effects of these potential future lawsuits on our financial condition, operations or cash flows.

Additionally, 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.

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 comprehensive 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. Additionally, the scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to commercialize our product candidates. Thus, we cannot guarantee that our activities related to their product candidates, or our commercialization, do not and will not infringe any third party's intellectual property.

In addition, patent applications in the United States and many other 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 already 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 related to the protection of our global patent position could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our patent position with respect to such invention.

***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.***

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, including due to the impact of the COVID-19 pandemic on our business operations, 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.

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 for our products. The U.S. Patent and Trademark Office, or USPTO, patent offices in other jurisdictions, or judicial or other bodies in any jurisdiction may deny or significantly narrow claims made under our patent applications, and claims in our issued patents may be invalidated, may be designed around or may otherwise be unable to provide us with protection for our products. Further, the USPTO, trademark offices in other jurisdictions, or judicial or other bodies in any jurisdiction 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 that is material to our business. 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 third parties 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.

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, or that a defendant would not prevail on an assertion of invalidity based on prior art that we were aware of 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 claims in our patents survive assertions of invalidity and unenforceability, they may not be broad enough 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. The claims of our issued patents or patent applications when issued may not cover our product candidates or any future products that we develop.

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 other 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, courts in other jurisdictions 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.

The USPTO and various patent agencies in other jurisdictions require compliance with a number of procedural, documentary, fee, annuity payment and other provisions to maintain patent applications and issued patents. Although an inadvertent lapse, including due to the effect of the COVID-19 pandemic on us or our patent maintenance vendors, can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance with these requirements can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction.

In addition, we have a number of patents and patent applications outside of the United States, 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 do 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 certain jurisdictions outside of the United States. 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 in certain jurisdictions 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 extension filing (including any patent term extension or adjustment filing) fees, 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.

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.

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.

***If we are unable to prevent disclosure of our trade secrets or other confidential information to third parties, our competitive position may be impaired.***

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. Costly and time consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could

adversely affect our competitive business position. Furthermore, the laws of some other jurisdictions do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and in other jurisdictions. 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. The failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

***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 or may become 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 or may become 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. These fees may be significant, which could make it difficult for us to achieve or maintain profitability. In addition, under certain of such agreements, we are or may become required to diligently pursue the development of products using the licensed technology. If we fail to comply with these obligations including due to the impact of the COVID-19 pandemic on our business operations or our use of the intellectual property licensed to us in an unauthorized manner, 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, harming our ability to develop, manufacture and/or commercialize our platform or product candidates. 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.

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.

The licensing and acquisition of third-party intellectual property rights is a competitive practice, and companies that may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their larger size and cash resources or greater clinical development and commercialization capabilities. There can be no assurance that we will be able to successfully complete such negotiations and ultimately acquire the rights to the intellectual property surrounding the additional product candidates that we may seek to acquire.

***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 may wish to form collaborations in the future with respect to our product candidates, but may not be able to do so or to realize the potential benefits of such transactions, which may cause us to alter or delay our development and commercialization plans.***

Our product candidates may also require specific components to work effectively and efficiently, and rights to those components may be held by others. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies, which could harm our business prospects, financial condition, and results of operations.

***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 or our licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as national governments, such that we or our licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our patents, including in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

***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. During trademark registration proceedings, our trademark applications may be rejected. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties can oppose pending trademark applications and seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. Furthermore,, 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. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. In such cases, over the long term, if we are unable to establish and maintain name recognition based on our trademarks and trade names, then our commercial success abilities may be impacted.

Moreover, any name we propose to use with our product candidates in the United States or any other country must be approved by the FDA, EMA or any other relevant health authority regardless of whether we have registered it, or applied to register it, as a trademark. The FDA as well as EMA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA, EMA or any other relevant approval authority objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA, EMA or any other relevant approval authority.

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

Filing and prosecuting patent applications, and defending patents, related to our 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.

### **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.

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 EU 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;
- 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. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA without specifically ruling

on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact the ACA 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, with the exception of a temporary suspension from May 1, 2020 through December 31, 2021, unless additional action is taken by Congress. 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. 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 active 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 EU, 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 EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the EU, 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 EU 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.

Accordingly, if our small molecule program results in a product that 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;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- 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; and 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
- 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

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.

## **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 delays in, our clinical trials for our product candidates or any other future clinical development programs, including 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;
- 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.

***We are an “emerging growth company” and a “smaller reporting company,” and as a result of the reduced disclosure and governance requirements applicable to emerging growth companies and smaller reporting 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.

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 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.

As of June 30, 2021, we retained our eligibility as a smaller reporting company as well as an emerging growth company.

Because (i) the aggregate worldwide market value of our voting common stock held by non-affiliates (or “public float”) exceeded \$700 million on June 30, 2021, (ii) we will have been subject to the reporting requirements of Section 13(a) or 15(d) of the Exchange Act for at least twelve calendar months, (iii) we have previously filed an annual report under Section 13(a) or 15(d) of the Exchange Act and (iv) we will not be eligible for smaller reporting company status because we exceed the public float and revenue threshold for such status, we will qualify as a “large accelerated filer” under Rule 12b-2 of the Exchange Act as of the end of the current fiscal year. As a large accelerated filer, we will no longer qualify as an emerging growth company. We will remain eligible to take advantage of smaller reporting company reporting requirements through our Annual Report on Form 10-K for the current fiscal year. As a smaller reporting company, we may rely on exemptions from certain disclosure requirements that are available to smaller reporting companies, including many of the same exemptions from disclosure requirements as those that are available to emerging growth companies, such as reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

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 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. Even after we no longer qualify as an emerging growth company, we may still qualify as a “smaller reporting company” which may allow us to take advantage of some of the same exemptions from disclosure requirements including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. Because we will be a “large accelerated filer” as of December 31, 2021, we will be subject to the reporting requirements of under Section 404(b) of the U.S. Sarbanes-Oxley Act, and our independent registered public accounting firm must attest to the effectiveness of our internal control over financial reporting as of such date.

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 July 31, 2021 our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 63.4% 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, the trading price of our common stock could decline. As of July 31, 2021, we had outstanding a total of 38,332,276 shares of 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, or the Code, 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 rolling 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 in the future as a result of 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 or income tax liabilities, 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.

***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 a certain number of women and directors from underrepresented communities on our board of directors on certain timeframes, 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 and at least one director from an underrepresented community on our board of directors by the end of 2021 and two or three directors from an underrepresented community on our board of directors by the end of 2022, depending on the size of our board of directors at the time. While we currently have one woman and four directors from underrepresented communities on the board of directors, recruiting and retaining board members carries uncertainty, and failure to comply with these California requirements 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.

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.

***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.

## **General Risk Factors**

***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.

***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. Generally, future changes in applicable U.S. and non-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 unable to predict whether such changes will occur and, if so, the ultimate impact on our business.

***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.

***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 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. Further, the California Privacy Rights Act, or CPRA, recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. 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 European Economic Area, or EEA. 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 data of EEA 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 EEA individuals in relation to their personal information, including the right to access, correct and delete their data. Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EU and the United States remains uncertain. For example, in 2016, the EU and United States agreed to a

transfer framework for data transferred from the EU to the United States, called the Privacy Shield, but the Court of Justice of the EU, or CJEU, invalidated the Privacy Shield in July 2020 and imposed further restrictions on use of the standard contractual clauses, or SCCs. These restrictions include a requirement for companies to carry out a transfer impact assessment which, among other things, assesses the laws governing access to personal data in the recipient country and considers whether supplementary measures that provide privacy protections additional to those provided under SCCs will need to be implemented to ensure an essentially equivalent level of data protection to that afforded in the EEA. The European Commission issued revised SCCs on June 4, 2021 to account for the decision of the CJEU and recommendations made by the European Data Protection Board. The revised SCCs must be used for relevant new data transfers from September 27, 2021; existing standard contractual clauses arrangements must be migrated to the revised clauses by December 27, 2022. There is some uncertainty around whether the revised clauses can be used for all types of data transfers, particularly whether they can be relied on for data transfers to non-EEA entities subject to the GDPR.

Further, from January 1, 2021, companies have to comply with the GDPR and also the United Kingdom GDPR, or the UK GDPR, which, together with the amended UK Data Protection Act 2018, retains the GDPR in United Kingdom, or UK, national law. The UK GDPR mirrors the fines under the GDPR, i.e., fines up to the greater of €20 million (£17.5 million) or 4% of global turnover. The relationship between the UK and the EU in relation to certain aspects of data protection law remains unclear, and it is unclear how UK data protection laws and regulations will develop in the medium to longer term, and how data transfers to and from the United Kingdom will be regulated in the long term. The European Commission has adopted an adequacy decision in favor of the United Kingdom, enabling data transfers from EU member states to the United Kingdom without additional safeguards. However, the UK adequacy decision will automatically expire in June 2025 unless the European Commission re-assesses and renews/ extends that decision.

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.

***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. 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 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 23, 2020, our registration statement on Form S-1, as amended (Registration No. 333-239647), was declared effective in connection with our IPO. 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.**

On August 16, 2021, we entered into a sales agreement with Cowen and Company, LLC, or Cowen, pursuant to which we may issue and sell from time to time, at our option, up to an aggregate of \$100 million of shares of our common stock through or to Cowen acting as sales agent and/or principal. Sales of the shares, if any, will be made pursuant to a Registration Statement on Form S-3, the base prospectus to be filed as part of such registration statement and a prospectus supplement, by any method that is deemed to be an “at the market offering” as defined in Rule 415(a)(4) under the Securities Act, including, without limitation, sales made directly on the Nasdaq Global Select Market or any other existing trading market for our common stock. Cowen will use its commercially reasonable efforts to sell the shares from time to time, based upon our instructions (including any price, time or size limits or other customary parameters or conditions we may impose). We will pay Cowen a commission of up to 3.0% of the gross proceeds from the sale of the shares, if any. We have also agreed to provide Cowen with customary indemnification rights. In accordance with the terms of the sales agreement, the offering of the shares will terminate upon the earliest of (a) the sale of all of the shares or (b) the termination of the sales agreement by Cowen or us.

The foregoing description of the sales agreement is not complete and is qualified in its entirety by reference to the full text of such agreement, a copy of which is filed as Exhibit 10.1 to this Quarterly Report on Form 10-Q and is incorporated herein by reference.

This Quarterly Report on Form 10-Q shall not constitute an offer to sell or the solicitation of any offer to buy the securities discussed herein, nor shall there be any offer, solicitation or sale of the securities in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state.

## 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	<a href="#">Description of Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934</a>					X
10.1	<a href="#">Sales Agreement, dated as of August 16, 2021, by and between Annexon Inc. and Cowen and Company, LLC.</a>					X
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	Inline XBRL Instance Document					X
101.SCH	Inline XBRL Taxonomy Extension Schema Document					X
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document					X
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document					X
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document					X
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document					X
104	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)					X

\* 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.

Date: August 16, 2021

Annexon, Inc.

By: /s/ Douglas Love, Esq.

Douglas Love, Esq.

President and Chief Executive Officer

(Principal Executive Officer)

Date: August 16, 2021

By: /s/ Jennifer Lew

Jennifer Lew

Executive Vice President and Chief Financial Officer

(Principal Financial and Accounting Officer)

**DESCRIPTION OF REGISTRANT'S SECURITIES  
REGISTERED PURSUANT TO SECTION 12 OF THE  
SECURITIES EXCHANGE ACT OF 1934**

Annexon, Inc. has common stock, \$0.001 par value per share, registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and listed on The Nasdaq Global Select Market under the trading symbol "ANNX."

**DESCRIPTION OF CAPITAL STOCK**

The following summary describes our capital stock and the material provisions of our amended and restated certificate of incorporation and our amended and restated bylaws, which will become effective immediately prior to the completion of this offering, the amended and restated investors' rights agreement to which we and certain of our stockholders are parties and the Delaware General Corporation Law. Because the following is only a summary, it does not contain all of the information that may be important to you. For a complete description, you should refer to our amended and restated certificate of incorporation, amended and restated bylaws and amended and restated investors' rights agreement, copies of which are incorporated by reference as Exhibits 3.1, 3.2 and 10.1, respectively, to our Annual Report on Form 10-K.

**General**

Our authorized capital stock consists of 300,000,000 shares of common stock, par value \$0.001 per share, and 5,000,000 shares of preferred stock, par value \$0.001 per share.

**Common Stock**

***Voting Rights***

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. The election of directors by our stockholders shall be determined by a plurality of the votes cast and our stockholders do not have cumulative voting rights in the election of directors. Other matters shall be generally decided by the affirmative vote of the holders of a majority of the votes cast (excluding abstentions and broker non-votes) on such matter. In addition, the affirmative vote of holders of 66 2/3% of the voting power of all of the then outstanding voting stock will be required to take certain actions, including amending certain provisions of our amended and restated certificate of incorporation, including the provisions relating to amending our amended and restated bylaws, the classified board and director liability.

***Dividends***

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of our common stock are entitled to receive dividends as may be declared from time to time by our board of directors out of legally available funds.

***Liquidation***

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

***Rights and Preferences***

Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our common stock. The rights, preferences and privileges of the

---

holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

### ***Fully Paid and Nonassessable***

All of our outstanding shares of common stock are fully paid and nonassessable.

### **Preferred Stock**

Our board of directors has the authority, without further action by our stockholders, to issue up to 5,000,000 shares of preferred stock in one or more series and to fix the rights, preferences, privileges and restrictions thereof. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences, sinking fund terms and the number of shares constituting, or the designation of, such series, any or all of which may be greater than the rights of our common stock. The issuance of our preferred stock could adversely affect the voting power of holders of common stock and the likelihood that such holders will receive dividend payments and payments upon our liquidation. In addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change in control of our company or other corporate action.

### **Registration Rights**

Under our amended and restated investors' rights agreement, as of December 31, 2020, the holders of approximately 20,824,938 million shares of common stock, or their transferees, have the right to require us to register their shares under the Securities Act so that those shares may be publicly resold, and the holders of approximately 20,824,938 shares of common stock, or their transferees, have the right to include their shares in any registration statement we file, in each case as described below.

#### ***Demand Registration Rights***

Certain holders of shares of our common stock are entitled to certain demand registration rights. The holders of at least 60% of such registrable securities may, on not more than two occasions, request that we register all or a portion of their shares, subject to certain specified exceptions.

#### ***Piggyback Registration Rights***

In the event that we propose to register any of our securities under the Securities Act, either for our own account or for the account of other security holders, certain holders of registrable securities will be entitled to certain "piggyback" registration rights allowing them to include their shares in such registration, subject to specified conditions and limitations.

#### ***S-3 Registration Rights***

Certain holders of shares of our common stock are entitled to certain Form S-3 registration rights. The holders of at least 30% of such registrable securities may, on not more than two registrations on Form S-3 within any 12-month period, request that we register all or a portion of their shares on Form S-3 if we are qualified to file a registration statement on Form S-3, subject to specified exceptions. Such request for registration on Form S-3 must cover securities with an aggregate offering price which equals or exceeds \$1.0 million, net of selling expenses. The right to have such shares registered on Form S-3 is further subject to other specified conditions and limitations.

### **Anti-Takeover Effects of Provisions of Delaware Law and Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws**

Certain provisions of Delaware law and our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could make the following transactions more difficult: acquisition of us by means of a tender offer; acquisition of us by means of a proxy contest or otherwise; or removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter

---

transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions that might result in a premium over the market price for our shares.

These provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

#### ***Delaware Anti-Takeover Statute***

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits persons deemed “interested stockholders” from engaging in a “business combination” with a publicly-held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an “interested stockholder” is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation’s voting stock. Generally, a “business combination” includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors, such as discouraging takeover attempts that might result in a premium over the market price of our common stock.

#### ***Undesignated Preferred Stock***

The ability to authorize undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to effect a change in control of our company. These and other provisions may have the effect of deterring hostile takeovers or delaying changes in control or management of our company.

#### ***Special Stockholder Meetings***

Our amended and restated certificate of incorporation provide that a special meeting of stockholders may be called at any time by our board of directors, but such special meetings may not be called by the stockholders or any other person or persons.

#### ***Requirements for Advance Notification of Stockholder Nominations and Proposals***

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

#### ***Stockholder Action by Written Consent***

Our amended and restated certificate of incorporation precludes stockholder action by written consent without a meeting.

#### ***Classified Board; Election and Removal of Directors; Filling Vacancies***

Our board of directors is divided into three classes, divided as nearly as equal in number as possible. The directors in each class serve for a three-year term, one class being elected each year by our stockholders, with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, our stockholders holding a majority of the shares of common stock outstanding will be able to elect all of our directors. Our amended and restated certificate of incorporation provides for the removal of any of our directors only for cause and requires a stockholder vote by the holders of at least a 66 2/3% of the voting power

---



of the then outstanding voting stock. Furthermore, any vacancy on our board of directors, however occurring, including a vacancy resulting from an increase in the size of the board, may only be filled by a resolution of the board of directors unless the board of directors determines that such vacancies shall be filled by the stockholders. This system of electing and removing directors and filling vacancies may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us because it generally makes it more difficult for stockholders to replace a majority of the directors.

### ***Choice of Forum***

Our amended and restated certificate of incorporation and amended and restated bylaws provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will be the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law: any derivative action or proceeding brought on our behalf; any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers or stockholders to us or to our stockholders; 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 (as either may be amended from time to time); or any action asserting a claim against us that is governed by the internal affairs doctrine. As a result, any action brought by any of our stockholders with regard to any of these matters will need to be filed in the Court of Chancery of the State of Delaware and cannot be filed in any other jurisdiction; 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 will also provide that the federal district courts of the United States of America will be 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 preclude stockholders that assert claims under the Exchange Act from bringing such claims in state or federal court, subject to applicable law.

If any action the subject matter of which is within the scope described above is filed in a court other than a court located within the State of Delaware, or a Foreign Action, in the name of any stockholder, such stockholder shall be deemed to have consented to the personal jurisdiction of the state and federal courts located within the State of Delaware in connection with any action brought in any such court to enforce the applicable provisions of our amended and restated certificate of incorporation and amended and restated bylaws and having service of process made upon such stockholder in any such action by service upon such stockholder's counsel in the Foreign Action as agent for such stockholder. Although our amended and restated certificate of incorporation and amended and restated bylaws will contain the choice of forum provision described above, it is possible that a court could find that such a provision is inapplicable for a particular claim or action or that such provision is unenforceable.

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.

### ***Amendment of Charter Provisions***

The amendment of any of the above provisions in our amended and restated certificate of incorporation, except for the provision making it possible for our board of directors to issue undesignated preferred stock, requires approval by a stockholder vote by the holders of at least a 66 2/3% of the voting power of the then outstanding voting stock.

The provisions of the Delaware General Corporation Law, our amended and restated certificate of incorporation and our amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in our management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

---

## **Limitation on Liability and Indemnification**

Our amended and restated certificate of incorporation and our amended and restated bylaws limit our directors' liability, contain provisions that provide that we may indemnify our directors and officers to the fullest extent permitted under Delaware General Corporation Law, or the DGCL. The DGCL provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for any:

- transaction from which the director derives an improper personal benefit;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or redemption of shares; or
- breach of a director's duty of loyalty to the corporation or its stockholders.

These limitations of liability do not apply to liabilities arising under federal securities laws and do not affect the availability of equitable remedies such as injunctive relief or recession.

The DGCL and our amended and restated bylaws provide that we will, in certain situations, indemnify our directors and officers and may indemnify other employees and other agents, to the fullest extent permitted by law. Any indemnified person is also entitled, subject to certain limitations, to advancement, direct payment or reimbursement of reasonable expenses (including attorneys' fees and disbursements) in advance of the final disposition of the proceeding.

In addition, we have entered, and intend to continue to enter, into separate indemnification agreements with our directors and officers. These indemnification agreements, among other things, require us to indemnify our directors and officers for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or officer in any action or proceeding arising out of their services as a director or officer, or any other company or enterprise to which the person provides services at our request.

We also maintain a directors' and officers' insurance policy pursuant to which our directors and officers are insured against liability for actions taken in their capacities as directors and officers.

We believe that these provisions in our amended and restated certificate of incorporation and amended and restated bylaws and these indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or control persons, in the opinion of the SEC, such indemnification is against public policy, as expressed in the Securities Act and is therefore unenforceable.

## **Transfer Agent and Registrar**

The transfer agent and registrar for our common stock is Computershare, Inc. The transfer agent and registrar's address is 462 South 4th Street, Louisville, Kentucky 40202.

ANNEXON, INC.  
COMMON STOCKSALES AGREEMENT

August 16, 2021

Cowen and Company, LLC  
599 Lexington Avenue  
New York, NY 10022

Ladies and Gentlemen:

Annexon, Inc. (the "**Company**") confirms its agreement (this "**Agreement**") with Cowen and Company, LLC ("**Cowen**"), as follows:

1. **Issuance and Sale of Shares.** The Company agrees that, from time to time during the term of this Agreement, on the terms and subject to the conditions set forth herein, it may issue and sell through Cowen, acting as agent and/or principal, shares (the "**Placement Shares**") of the Company's common stock, par value \$0.001 per share (the "**Common Stock**"), having an aggregate offering price of up to \$100,000,000. Notwithstanding anything to the contrary contained herein, the parties hereto agree that compliance with the limitation set forth in this Section 1 on the number of shares of Common Stock issued and sold under this Agreement shall be the sole responsibility of the Company, and Cowen shall have no obligation in connection with such compliance. The issuance and sale of Common Stock through Cowen will be effected pursuant to the Registration Statement (as defined below) filed or to be filed by the Company which automatically became or will become effective under Rule 462(e) of the Securities Act (as defined below) upon filing with the Securities and Exchange Commission (the "**Commission**"), although nothing in this Agreement shall be construed as requiring the Company to use the Registration Statement (as defined below) to issue the Common Stock. The Registration Statement is an "automatic shelf registration statement" (as defined in Rule 405) and the Placement Shares (as defined below) have been and remain eligible for registration by the Company on such automatic shelf registration statement.

The Company shall file, in accordance with the provisions of the Securities Act of 1933, as amended, and the rules and regulations thereunder (collectively, the "**Securities Act**"), with the Commission an automatic registration statement on Form S-3, including a base prospectus, relating to certain securities, including the Common Stock, to be issued from time to time by the Company, and which incorporates by reference documents that the Company has filed or will file in accordance with the provisions of the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder (collectively, the "**Exchange Act**"). The Company has prepared a prospectus specifically relating to the Placement Shares (the "**ATM Prospectus**") to the base prospectus included as part of such registration statement, and shall, if necessary, prepare a prospectus supplement specifically relating to the Placement Shares (the "**Prospectus Supplement**") to the base prospectus included as part of such registration statement. The Company shall furnish to Cowen, for use by Cowen, copies of the prospectus included as part of

---

such registration statement, as supplemented by the Prospectus Supplement, if any, relating to the Placement Shares. Except where the context otherwise requires, such registration statement, and any post-effective amendment thereto, as amended when it becomes effective, including all documents filed as part thereof or incorporated by reference therein, and including any information contained in a Prospectus (as defined below) subsequently filed with the Commission pursuant to Rule 424(b) under the Securities Act or deemed to be a part of such registration statement pursuant to Rule 430B or 462(b) of the Securities Act, or any subsequent registration statement on Form S-3 filed pursuant to Rule 415(a)(6) under the Securities Act by the Company to cover any Placement Shares, is herein called the “**Registration Statement**.” The base prospectus and the ATM Prospectus, including all documents incorporated therein by reference, included in the Registration Statement, as it may be supplemented by any Prospectus Supplement, in the form in which such prospectus, ATM Prospectus and/or Prospectus Supplement have most recently been filed by the Company with the Commission, together with any “issuer free writing prospectus,” as defined in Rule 433 of the Securities Act regulations (“**Rule 433**”), relating to the Placement Shares that (i) is consented to by Cowen, hereinafter referred to as a “**Permitted Free Writing Prospectus**,” (ii) is required to be filed with the Commission by the Company or (iii) is exempt from filing pursuant to Rule 433(d)(5)(i), in each case in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company’s records pursuant to Rule 433(g), is herein called the “**Prospectus**.” Any reference herein to the Registration Statement, the Prospectus or any amendment or supplement thereto shall be deemed to refer to and include the documents incorporated by reference therein, and any reference herein to the terms “amend,” “amendment” or “supplement” with respect to the Registration Statement or the Prospectus shall be deemed to refer to and include the filing after the execution hereof of any document with the Commission deemed to be incorporated by reference therein. For purposes of this Agreement, all references to the Registration Statement, the Prospectus or to any amendment or supplement thereto shall be deemed to include any copy filed with the Commission pursuant to the Electronic Data Gathering Analysis and Retrieval System or any successor thereto (“**EDGAR**”).

2. **Placements.** Each time that the Company wishes to issue and sell the Placement Shares hereunder (each, a “**Placement**”), it will notify Cowen by email notice (or other method mutually agreed to in writing by the parties) (a “**Placement Notice**”) containing the parameters in accordance with which it desires the Placement Shares to be sold, which shall at a minimum include the number of shares of Placement Shares to be issued, the time period during which sales are requested to be made, any limitation on the number of Placement Shares that may be sold in any one Trading Day (as defined in Section 3) and any minimum price below which sales may not be made, a form of which containing such minimum sales parameters necessary is attached hereto as **Schedule 1**. The Placement Notice shall originate from any of the individuals from the Company set forth on **Schedule 2** (with a copy to each of the other individuals from the Company listed on such schedule), and shall be addressed to each of the individuals from Cowen set forth on **Schedule 2**, as such **Schedule 2** may be amended in writing from time to time in accordance herewith. The Placement Notice shall be effective upon receipt by Cowen unless and until (i) in accordance with the notice requirements set forth in Section 4, Cowen declines to accept the terms contained therein for any reason, in its sole discretion, (ii) the entire amount of the Placement Shares have been sold, (iii) in accordance with the notice requirements set forth in Section 4, the Company suspends or terminates the Placement Notice for any reason in its sole discretion, (iv) the Company issues a subsequent Placement Notice with parameters superseding those on the

---

earlier dated Placement Notice, or (v) this Agreement has been terminated under the provisions of Section 11. The amount of any discount, commission or other compensation to be paid by the Company to Cowen in connection with the sale of the Placement Shares shall be calculated in accordance with the terms set forth in Schedule 3. It is expressly acknowledged and agreed that neither the Company nor Cowen will have any obligation whatsoever with respect to a Placement or any Placement Shares unless and until the Company delivers a Placement Notice to Cowen and Cowen does not decline such Placement Notice pursuant to the terms set forth above, and then only upon the terms specified therein and herein. In the event of a conflict between the terms of this Agreement and the terms of a Placement Notice, the terms of the Placement Notice will control.

3. Sale of Placement Shares by Cowen. Subject to the terms and conditions herein set forth, upon the Company's delivery of a Placement Notice, and unless the sale of the Placement Shares described therein has been declined, suspended, or otherwise terminated in accordance with the terms of this Agreement, Cowen, for the period specified in the Placement Notice, will use its commercially reasonable efforts consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of the Nasdaq Stock Market, Inc. ("**Nasdaq**") to sell such Placement Shares up to the amount specified in such Placement Notice, and otherwise in accordance with the terms of such Placement Notice. Cowen will provide written confirmation to the Company (including by email correspondence to each of the individuals of the Company set forth on Schedule 2, if receipt of such correspondence is actually acknowledged by any of the individuals to whom the notice is sent, other than via auto-reply) no later than the opening of the Trading Day (as defined below) immediately following the Trading Day on which it has made sales of Placement Shares hereunder setting forth the number of Placement Shares sold on such day, the volume-weighted average price of the Placement Shares sold, and the Net Proceeds (as defined below) payable to the Company. In the event the Company engages Cowen for a sale of Placement Shares that would constitute a "block" within the meaning of Rule 10b-18(a)(5) under the Exchange Act, the Company will provide Cowen, at Cowen's request and upon reasonable advance notice to the Company, on or prior to the Settlement Date (as defined below), the opinions of counsel, accountant's letter and officers' certificates set forth in Section 8 hereof, each dated the Settlement Date, and such other documents and information as Cowen shall reasonably request. Cowen may sell Placement Shares by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415(a)(4) of the Securities Act, including without limitation sales made through Nasdaq or on any other existing trading market for the Common Stock. Cowen shall not purchase Placement Shares for its own account as principal unless expressly authorized to do so by the Company in a Placement Notice. The Company acknowledges and agrees that (i) there can be no assurance that Cowen will be successful in selling Placement Shares, and (ii) Cowen will incur no liability or obligation to the Company or any other person or entity if it does not sell Placement Shares for any reason other than a failure by Cowen to use its commercially reasonable efforts consistent with its normal trading and sales practices to sell such Placement Shares as required under this Section 3. For the purposes hereof, "**Trading Day**" means any day on which the Company's Common Stock is purchased and sold on the principal market on which the Common Stock is listed or quoted.

Notwithstanding any other provision of this Agreement, the Company shall not offer, sell or deliver, or request the offer or sale, of any Placement Shares pursuant to this Agreement and, by notice to Cowen given by telephone (confirmed promptly by email), shall cancel any instructions

---

for the offer or sale of any Placement Shares, and Cowen shall not be obligated to offer or sell any Placement Shares, (i) during any period in which the Company is, or could be deemed to be, in possession of material non-public information, or (ii) at any time from and including the date on which the Company shall issue a press release containing, or shall otherwise publicly announce, its earnings, revenues or other results of operations (an “**Earnings Announcement**”) through and including the time that the Company files a Quarterly Report on Form 10-Q or an Annual Report on Form 10-K that includes consolidated financial statements as of and for the same period or periods, as the case may be, covered by such Earnings Announcement.

4. Suspension of Sales.

(a) The Company or Cowen may, upon notice to the other party in writing (including by email correspondence to each of the individuals of the other party set forth on **Schedule 2**, if receipt of such correspondence is actually acknowledged by any of the individuals to whom the notice is sent, other than via auto-reply) or by telephone (confirmed immediately by verifiable facsimile transmission or email correspondence to each of the individuals of the other party set forth on **Schedule 2**), suspend any sale of Placement Shares; *provided, however*, that such suspension shall not affect or impair either party’s obligations with respect to any Placement Shares sold hereunder prior to the receipt of such notice. While a suspension is in effect, any obligation under Sections 7(m), 7(n) and 7(o) with respect to delivery of certificates, opinion, or comfort letters to Cowen shall be waived. Each of the parties agrees that no such notice under this **Section 4** shall be effective against the other unless it is made to one of the individuals named on **Schedule 2** hereto, as such schedule may be amended from time to time.

(b) If either Cowen or the Company has reason to believe that the exemptive provisions set forth in Rule 101(c)(1) of Regulation M under the Exchange Act are not satisfied with respect to the Common Stock, it shall promptly notify the other party, and Cowen may, at its sole discretion, suspend sales of the Placement Shares under this Agreement.

(c) Notwithstanding any other provision of this Agreement, during any period in which the Registration Statement is no longer effective under the Securities Act, the Company shall promptly notify Cowen, the Company shall not request the sale of any Placement Shares, and Cowen shall not be obligated to sell or offer to sell any Placement Shares.

5. Settlement.

(a) Settlement of Placement Shares. Unless otherwise specified in the applicable Placement Notice, settlement for sales of Placement Shares will occur on the second (2<sup>nd</sup>) Trading Day (or such earlier day as is industry practice for regular-way trading) following the date on which such sales are made (each, a “**Settlement Date**” and the first such settlement date, the “**First Delivery Date**”). The amount of proceeds to be delivered to the Company on a Settlement Date against receipt of the Placement Shares sold (the “**Net Proceeds**”) will be equal to the aggregate sales price received by Cowen at which such Placement Shares were sold, after deduction for (i) Cowen’s commission, discount or other compensation for such sales payable by the Company pursuant to **Section 2** hereof, (ii) any other amounts due and payable by the Company to Cowen hereunder pursuant to **Section 7(g)** (Expenses) hereof, and (iii) any transaction fees imposed by any governmental or self-regulatory organization in respect of such sales.

---

(b) Delivery of Placement Shares. On or before each Settlement Date, the Company will, or will cause its transfer agent to, electronically transfer the Placement Shares being sold by crediting Cowen's or its designee's account (provided Cowen shall have given the Company written notice of such designee at least one (1) Trading Day prior to the Settlement Date) at The Depository Trust Company through its Deposit and Withdrawal at Custodian System or by such other means of delivery as may be mutually agreed upon by the parties hereto which in all cases shall be freely tradeable, transferable, registered shares in good deliverable form. On each Settlement Date, Cowen will deliver the related Net Proceeds in same day funds to an account designated by the Company on, or prior to, the Settlement Date. Cowen will be responsible for providing DWAC instructions or instructions for delivery by other means with regard to the transfer of the Placement Shares being sold. The Company agrees that if the Company, or its transfer agent (if applicable), defaults in its obligation to deliver duly authorized Placement Shares on a Settlement Date, in addition to and in no way limiting the rights and obligations set forth in Section 9(a) (Indemnification and Contribution) hereto, it will (i) hold Cowen harmless against any loss, claim, damage, or reasonable and documented expense (including reasonable and documented legal fees and expenses), as incurred, arising out of or in connection with such default by the Company and (ii) pay to Cowen (without duplication) any commission, discount, or other compensation to which it would otherwise have been entitled absent such default.

6. Representations and Warranties of the Company. The Company represents and warrants to, and agrees with, Cowen that, unless such representation, warranty or agreement specifies otherwise, as of (i) the date of this Agreement, (ii) each Time of Sale (as defined below), (iii) each Settlement Date, and (iv) each Bring-Down Date (as defined below) (each date included in (i) through (iv), a "**Representation Date**"):

(a) Compliance with Registration Requirements. Other than as of the date of this Agreement, the Registration Statement became or will become effective automatically upon filing with the Commission under the Securities Act. The Registration Statement is an "automatic shelf registration statement" on Form S-3 as defined in Rule 405 of the Securities Act and was filed not earlier than three (3) years prior to the date hereof. No stop order suspending the effectiveness of the Registration Statement or any Rule 462(b) Registration Statement is in effect and no proceedings for such purpose have been instituted or are pending or, to the knowledge of the Company, contemplated or threatened by the Commission. At the time of the initial filing of the Registration Statement, the Company paid or will pay the required Commission filing fees relating to the Placement Shares in accordance with Rules 457(o) and 457(r) under the Securities Act. The Company meets the requirements for use of Form S-3 under the Securities Act. The sale of the Placement Shares hereunder meets the requirements or General Instruction I.B.1 of Form S-3.

(b) No Misstatement or Omission. The Prospectus when filed complied and, as amended or supplemented, if applicable, will comply in all material respects with the Securities Act. Each of the Registration Statement, any Rule 462(b) Registration Statement, the Prospectus and any post-effective amendments or supplements thereto, at the time it became effective or its date, as applicable, complied and as of each Representation Date, complied and will comply in all material respects with the Securities Act and did not and, as of each Representation Date, did not and will not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading. The Prospectus, as amended or supplemented, as of its date, did not and, as of each Representation Date, will not

---

contain any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The representations and warranties set forth in the two immediately preceding sentences do not apply to statements in or omissions from the Registration Statement, any Rule 462(b) Registration Statement, or any post-effective amendment thereto, or the Prospectus, or any amendments or supplements thereto, made in reliance upon and in conformity with information relating to Agent's Information (as defined below). There are no contracts or other documents required to be described in the Prospectus or to be filed as exhibits to the Registration Statement which have not been described or filed as required. As used herein, "**Time of Sale**" means with respect to each offering of Placement Shares pursuant to this Agreement, the time of Cowen's initial entry into contracts with purchasers for the sale of such Placement Shares.

(c) **Offering Materials Furnished to Cowen.** The Company has delivered to Cowen one complete copy of the Registration Statement and a copy of each consent and certificate of experts filed as a part thereof, and conformed copies of the Registration Statement (without exhibits) and the Prospectus, as amended or supplemented, in such quantities and at such places as Cowen has reasonably requested. The Registration Statement, the Prospectus and any Permitted Free Writing Prospectus (to the extent any such Permitted Free Writing Prospectus was required to be filed with the Commission) delivered to Cowen for use in connection with the public offering of the Placement Shares contemplated herein have been and will be identical to the versions of such documents transmitted to the Commission for filing via EDGAR, except to the extent permitted by Regulation S-T.

(d) **Emerging Growth Company Status.** On the date of the initial filing of the Registration Statement with the Commission, the Company has been and is an "emerging growth company," as defined in Section 2(a) of the Securities Act (an "**Emerging Growth Company**"); provided, however, that the Company will cease, or has ceased, to be an Emerging Growth Company as of December 31, 2021.

(e) **Not an Ineligible Issuer.** The Company currently is not an "ineligible issuer," as defined in Rule 405 under the Securities Act. The Company agrees to notify Cowen promptly upon the Company becoming an "ineligible issuer."

(f) **Distribution of Offering Material By the Company.** The Company has not distributed and will not distribute, prior to the completion of Cowen's distribution of the Placement Shares, any offering material in connection with the offering and sale of the Placement Shares other than the Prospectus or the Registration Statement.

(g) **WKSI.** (i) At the time of filing of the Registration Statement, (ii) at the time of the most recent amendment thereto for the purposes of complying with Section 10(a)(3) of the Securities Act (whether such amendment was by post-effective amendment, incorporated report filed pursuant to Section 13 or 15(d) of the Exchange Act or form of prospectus), (iii) at the time the Company or any person acting on its behalf (within the meaning, for this clause only, of Rule 163(c) under the Securities Act) made any offer relating to the Placement Shares in reliance on the exemption of Rule 163 under the Securities Act, and (iv) as of the time of any Placement, the Company was and is a "well known seasoned issuer" as defined in Rule 405; the Registration Statement is an "automatic shelf registration statement," as defined in Rule 405, that has become or became effective automatically not more than three (3) years prior to the date of any Placement;

---



the Company has not received from the Commission any notice pursuant to Rule 401(g)(2) under the Securities Act objecting to use of the automatic shelf registration statement form; and the Company has not otherwise ceased to be eligible to use the automatic shelf registration form.

(h) Preparation of the Financial Statements. The financial statements (including the related notes thereto) of the Company and its consolidated subsidiaries filed with the Commission as a part of or incorporated by reference in the Registration Statement and the Prospectus comply in all material respects with the applicable requirements of the Securities Act or the Exchange Act, as applicable, and present fairly in all material respects the financial position of the Company and its consolidated subsidiaries as of the dates indicated and the results of their operations and the changes in their cash flows for the periods specified; such financial statements have been prepared in conformity with generally accepted accounting principles in the United States (“**GAAP**”) applied on a consistent basis throughout the periods covered thereby, except in the case of unaudited financial statements, which are subject to normal year-end adjustments and do not contain certain footnotes as permitted by the applicable rules of the Commission; and any supporting schedules included in the Registration Statement present fairly in all material respects the information required to be stated therein; and the other financial information included in the Registration Statement and the Prospectus has been derived from the accounting records of the Company and its consolidated subsidiaries and presents fairly in all material respects the information shown thereby.

(i) XBRL. The interactive data in eXtensible Business Reporting Language included or incorporated by reference in each Registration Statement fairly presents the information called for in all material respects and has been prepared in accordance with the Commission’s rules and guidelines applicable thereto.

(j) No Material Adverse Change. Since the date of the most recent financial statements of the Company included or incorporated by reference in the Registration Statement and the Prospectus, (i) there has not been any material change in the capital stock (other than the issuance of shares of Common Stock upon exercise of stock options and warrants described as outstanding in, and the grant of options and awards under existing equity incentive plans described in, the Registration Statement and the Prospectus), short-term debt or long-term debt of the Company or any of its subsidiaries, or any dividend or distribution of any kind declared, set aside for payment, paid or made by the Company on any class of capital stock, or any material adverse change, or any development that would reasonably be expected to result in a material adverse change, in or affecting the business, properties, management, financial position, stockholders’ equity, results of operations or prospects of the Company and its subsidiaries taken as a whole; (ii) neither the Company nor any of its subsidiaries has entered into any transaction or agreement (whether or not in the ordinary course of business) that is material to the Company and its subsidiaries taken as a whole or incurred any liability or obligation, direct or contingent, that is material to the Company and its subsidiaries taken as a whole; and (iii) neither the Company nor any of its subsidiaries has sustained any loss or interference with its business that is material to the Company and its subsidiaries taken as a whole and that is either from fire, explosion, flood or other calamity, whether or not covered by insurance, or from any labor disturbance or dispute or any action, order or decree of any court or arbitrator or governmental or regulatory authority, except in each case as otherwise disclosed in the Registration Statement and the Prospectus.

---

(k) Incorporation and Good Standing of the Company and its Subsidiaries. The Company and each of its subsidiaries have been duly organized and are validly existing and in good standing under the laws of their respective jurisdictions of organization, are duly qualified to do business and are in good standing in each jurisdiction in which their respective ownership or lease of property or the conduct of their respective businesses requires such qualification, and have all power and authority necessary to own or hold their respective properties and to conduct the businesses in which they are engaged, except where the failure to be so qualified or in good standing or have such power or authority would not, individually or in the aggregate, reasonably be expected to have a material adverse effect on the business, properties, management, financial position, stockholders' equity, results of operations or prospects of the Company and its subsidiaries taken as a whole or on the performance by the Company of its obligations under this Agreement (a "**Material Adverse Effect**"). The Company does not own or control, directly or indirectly, any corporation, association or other entity other than the subsidiaries listed in Exhibit 21.1 to the Company's Annual Report on Form 10-K for the most recently ended fiscal year and other than (i) those subsidiaries not required to be listed on Exhibit 21.1 by Item 601 of Regulation S-K under the Exchange Act and (ii) those subsidiaries formed since the last day of the most recently ended fiscal year.

(l) Capital Stock Matters. The Company has an authorized capitalization as set forth in the Registration Statement and the Prospectus under the heading "Description of Capital Stock"; all the outstanding shares of capital stock of the Company and its subsidiaries have been duly and validly authorized and issued and are fully paid and non-assessable and are not subject to any pre-emptive or similar rights that have not been duly waived or satisfied; except as described in the Registration Statement and the Prospectus, there are no outstanding rights (including, without limitation, pre-emptive rights), warrants or options to acquire, or instruments convertible into or exchangeable for, any shares of capital stock or other equity interest in the Company or any of its subsidiaries, or any contract, commitment, agreement, understanding or arrangement of any kind relating to the issuance of any capital stock of the Company or any such subsidiary, any such convertible or exchangeable securities or any such rights, warrants or options; the capital stock of the Company conforms in all material respects to the description thereof contained in the Registration Statement and the Prospectus; and except as described in the Registration Statement and the Prospectus, all the outstanding shares of capital stock or other equity interests of each subsidiary owned, directly or indirectly, by the Company have been duly and validly authorized and issued, are fully paid and non-assessable (except, in the case of any foreign subsidiary, for directors' qualifying shares) and are owned directly or indirectly by the Company, free and clear of any lien, charge, encumbrance, security interest, restriction on voting or transfer or any other claim of any third party.

(m) Stock Options. With respect to the stock options (the "**Stock Options**") granted pursuant to the stock-based compensation plans of the Company and its subsidiaries (the "**Company Stock Plans**"), except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect, (i) each Stock Option intended to qualify as an "incentive stock option" under Section 422 of the Internal Revenue Code of 1986, as amended (the "**Code**") so qualifies, (ii) each grant of a Stock Option was duly authorized no later than the date on which the grant of such Stock Option was by its terms to be effective by all necessary corporate action, including, as applicable, approval by the board of directors of the Company (or a duly constituted and authorized committee thereof) and any required stockholder approval by the

---

necessary number of votes or written consents, and the award agreement governing such grant (if any) was duly executed and delivered by each party thereto, (iii) each such grant was made in accordance with the terms of the Company Stock Plans, the Exchange Act and all other applicable laws and regulatory rules or requirements, and (iv) each such grant was properly accounted for in accordance with GAAP in the financial statements (including the related notes) of the Company.

(n) The Sales Agreement. This Agreement has been duly authorized, executed and delivered by, and is a valid and binding agreement of, the Company, enforceable in accordance with its terms, except as rights to indemnification hereunder may be limited by applicable law and except as the enforcement hereof may be limited by bankruptcy, insolvency, reorganization, moratorium or other similar laws relating to or affecting the rights and remedies of creditors or by general equitable principles.

(o) Authorization of the Common Stock. The Placement Shares, when issued and delivered by the Company hereunder will be duly and validly issued, will be fully paid and nonassessable and will conform in all material respects to the descriptions thereof in the Registration Statement and the Prospectus; and the issuance of the Placement Shares is not subject to any preemptive or similar rights that have not been duly waived or satisfied.

(p) Listing. The Company is subject to and in compliance in all material respects with the reporting requirements of Section 13 or Section 15(d) of the Exchange Act. The Common Stock is registered pursuant to Section 12(b) or Section 12(g) of the Exchange Act and is listed on the Nasdaq, and the Company has taken no action designed to, or reasonably likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or delisting the Common Stock from the Exchange, nor has the Company received any notification that the Commission or Nasdaq is contemplating terminating such registration or listing. All of the Placement Shares that have been or may be sold under this Agreement have been or will have been approved for listing on the Nasdaq prior to the sale of such Placement Shares, subject to official notice of issuance; the Company has taken all necessary actions to ensure that, upon and at all times after the Nasdaq shall have approved the Placement Shares for listing, it will be in compliance with all applicable corporate governance requirements set forth in the Nasdaq's listing rules that are then in effect.

(q) No Violation or Default. Neither the Company nor any of its subsidiaries is (i) in violation of its charter or by-laws or similar organizational documents; (ii) in default, and no event has occurred that, with notice or lapse of time or both, would constitute such a default, in the due performance or observance of any term, covenant or condition contained in any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company or any of its subsidiaries is a party or by which the Company or any of its subsidiaries is bound or to which any property or asset of the Company or any of its subsidiaries is subject; or (iii) in violation of any law or statute or any judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority, except, in the case of clauses (ii) and (iii) above, for any such default or violation that would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(r) No Conflicts. The execution, delivery and performance by the Company of this Agreement, the issuance and sale of the Placement Shares and the consummation of the transactions contemplated by this Agreement and the Prospectus will not (i) conflict with or result

---

in a breach or violation of any of the terms or provisions of, or constitute a default under, result in the termination, modification or acceleration of, or result in the creation or imposition of any lien, charge or encumbrance upon any property, right or asset of the Company or any of its subsidiaries pursuant to, any indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which the Company or any of its subsidiaries is a party or by which the Company or any of its subsidiaries is bound or to which any property, right or asset of the Company or any of its subsidiaries is subject, (ii) result in any violation of the provisions of the charter or by-laws or similar organizational documents of the Company or any of its subsidiaries or (iii) result in the violation of any law or statute or any judgment, order, rule or regulation of any court or arbitrator or governmental or regulatory authority, except, in the case of clauses (i) and (iii) above, for any such conflict, breach, violation, default, lien, charge or encumbrance that would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(s) No Consents Required. No consent, filing, approval, authorization, order, license, registration or qualification of or with any court or arbitrator or governmental or regulatory authority is required for the execution, delivery and performance by the Company of this Agreement, the issuance and sale of the Placement Shares and the consummation of the transactions contemplated by this Agreement, except such as have already been obtained or for the registration of the Placement Shares under the Securities Act and such consents, approvals, authorizations, orders and registrations or qualifications as may be required by Nasdaq, the Financial Industry Regulatory Authority, Inc. (“**FINRA**”) and under applicable state securities laws.

(t) No Material Actions or Proceedings. Except as disclosed in the Registration Statement and the Prospectus, there are no legal, governmental or regulatory investigations, actions, demands, claims, suits, arbitrations, inquiries or proceedings (“**Actions**”) pending to which the Company or any of its subsidiaries is or may reasonably be expected to become a party or to which any property of the Company or any of its subsidiaries is or may reasonably be expected to become the subject that, individually or in the aggregate, if determined adversely to the Company or any of its subsidiaries, would reasonably be expected to have a Material Adverse Effect; to the knowledge of the Company, no such Actions are threatened or contemplated by any governmental or regulatory authority or threatened by others; and (i) there are no current or pending Actions that are required under the Securities Act or Exchange Act, as applicable, to be described in the Registration Statement or the Prospectus that are not so described in the Registration Statement and the Prospectus and (ii) there are no statutes, regulations or contracts or other documents that are required under the Securities Act or the Exchange Act, as applicable, to be filed as exhibits to the Registration Statement or described in the Registration Statement or the Prospectus that are not so filed as exhibits to the Registration Statement or described in the Registration Statement and the Prospectus.

(u) Independent Accountants. KPMG LLP, who has certified certain financial statements of the Company and its subsidiaries is an independent registered public accounting firm with respect to the Company and its subsidiaries within the applicable rules and regulations adopted by the Commission and the Public Company Accounting Oversight Board (United States) and as required by the Securities Act and the Exchange Act.

(v) Title to Real and Personal Property. The Company and its subsidiaries have good and marketable title in fee simple (in the case of real property) to, or have valid rights to lease or

---

otherwise use, all items of real and personal property and assets that are material to the respective businesses of the Company and its subsidiaries, in each case free and clear of all liens, encumbrances, claims and defects and imperfections of title except those that (i) are disclosed in the Registration Statement and the Prospectus, (ii) do not materially interfere with the use made and proposed to be made of such property by the Company and its subsidiaries or (iii) would not reasonably be expected, individually or in the aggregate, to have a Material Adverse Effect.

(w) **Intellectual Property.** Except as disclosed in the Registration Statement and the Prospectus, the Company and its subsidiaries own, or possess valid and enforceable licensed rights to use, all material patents, patent applications, trademarks, service marks, trade names, trademark registrations, service mark registrations, trade dress, designs, data, database rights, Internet domain names, copyrights, works of authorship, licenses, proprietary information and know-how (including trade secrets and other unpatented and/or unpatentable proprietary or confidential information, systems or procedures) necessary for the conduct of their respective businesses as currently conducted and as proposed in the Registration Statement and the Prospectus to be conducted (collectively, “**Intellectual Property**”). The Intellectual Property of the Company has not been adjudged by a court of competent jurisdiction to be invalid or unenforceable, in whole or in part, and the Company is unaware of any facts which would form a reasonable basis for any such adjudication. The Company and its subsidiaries have not received any notice of any claim of infringement, misappropriation or conflict with any intellectual property rights of another, and the Company is unaware of any facts which would form a reasonable basis for any such notice or claim. Except as disclosed in the Registration Statement and the Prospectus, to the Company’s knowledge: (i) there are no third parties who have rights to any Intellectual Property, except for customary reversionary rights of third-party licensors with respect to Intellectual Property that is disclosed in the Registration Statement and the Prospectus as owned by or licensed to the Company or its subsidiaries; and (ii) there is no infringement by third parties of any Intellectual Property. Except as disclosed in the Registration Statement and the Prospectus, there is no pending or, to the Company’s knowledge, threatened action, suit, proceeding or claim by others: (A) challenging the Company’s rights in or to any Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; (B) challenging the validity, enforceability or scope of any Intellectual Property, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim; or (C) asserting that the Company or its subsidiaries infringe, misappropriate, or otherwise violate, or would, upon the commercialization of any product or service described in the Registration Statement and the Prospectus as under development, infringe, misappropriate, or otherwise violate, any intellectual property rights of others, and the Company is unaware of any facts which would form a reasonable basis for any such action, suit, proceeding or claim. The Company and its subsidiaries have complied with the terms of each agreement in all material respects pursuant to which Intellectual Property has been licensed to the Company or its subsidiaries, and all such agreements are in full force and effect. To the Company’s knowledge, there are no material defects in any of the patents or patent applications included in the Intellectual Property. The patents and patent applications included in the Intellectual Property are subsisting and have not lapsed and the patent applications in the Intellectual Property are subsisting and have not been abandoned. The Company and its subsidiaries have taken all reasonable steps to protect, maintain and safeguard their Intellectual Property, including having a policy to execute appropriate nondisclosure, confidentiality agreements and invention assignment agreements and invention assignments with their employees, and, to the Company’s knowledge, no employee of the

---

Company is in or has been in violation of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, nondisclosure agreement, or any restrictive covenant to or with a former employer where the basis of such violation relates to such employee's employment with the Company. To the Company's knowledge, the duty of candor and good faith as required by the United States Patent and Trademark Office during the prosecution of the Company owned United States patents and patent applications included in the Intellectual Property have been complied with; and in all foreign offices having similar requirements, all such requirements have been complied with for the Company owned foreign patents and patent applications included in the Intellectual Property. To the Company's knowledge, none of the Company owned Intellectual Property employed by the Company or its subsidiaries has been obtained or is being used by the Company or its subsidiary in violation of any material contractual obligation binding on the Company or its subsidiaries or any of their respective officers, directors or employees. The product candidates described in the Registration Statement and the Prospectus as under development by the Company or its subsidiaries fall within the scope of the claims of one or more patents or patent applications owned by, or exclusively licensed to, the Company or its subsidiaries.

(x) **Trade Secrets.** The Company and its subsidiaries have taken reasonable and customary actions to protect their rights in and prevent the unauthorized use and disclosure of material trade secrets and confidential business information (including confidential source code, ideas, research and development information, know-how, formulas, compositions, technical data, designs, drawings, specifications, research records, records of inventions, test information, financial, marketing and business data, customer and supplier lists and information, pricing and cost information, business and marketing plans and proposals) owned by the Company and its subsidiaries, and, to the knowledge of the Company, there has been no unauthorized use or disclosure.

(y) **IT Assets.** Except as would not reasonably be expected to have a Material Adverse Effect, (i) the computers, software, hardware, applications, databases, servers, networks, data communications lines, and other information technology assets or systems owned, licensed, leased or otherwise used by the Company or its subsidiaries (excluding any public networks) (collectively, the "**IT Assets**") are adequate for, and operate and perform as is necessary for the operation of the business of the Company and its subsidiaries as currently conducted and as proposed to be conducted as described in the Registration Statement and the Prospectus and (ii) to the knowledge of the Company, such IT Assets are not infected by viruses, disabling code or other harmful code. The Company and its subsidiaries have implemented and maintained commercially reasonable controls, policies, procedures, and safeguards designed to maintain and protect Personal Data (as defined below) and sensitive, confidential or regulated information (collectively, "**Confidential Data**") and the integrity, continuous operation, redundancy and security of all IT Assets used in connection with their businesses. Except as described in the Registration Statement and the Prospectus, and to the knowledge of the Company, (1) there have been no breaches, violations, outages or unauthorized uses of or accesses to same, except for those that have been remedied without material cost or liability or the duty to notify any other person, nor (2) any incidents under internal review or investigations relating to the same. "**Personal Data**" means any information that constitutes "personal data", "personal information", "personally identifiable information", "protected health information" under applicable law.

---

(z) Data Privacy and Security Laws. Except as described in the Registration Statement and the Prospectus, and except where non-compliance would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect, the Company and its subsidiaries are, and have since August 1, 2018 been, in compliance with all applicable state, federal, and foreign data privacy, security and consumer protection laws and regulations, including without limitation, to the extent applicable, the Health Insurance Portability and Accountability Act of 1996 (“**HIPAA**”) as amended by the Health Information Technology for Economic and Clinical Health Act (the “**HITECH Act**”), the California Consumer Privacy Act of 2018 (“**CCPA**”) and the European Union General Data Protection Regulation (“**GDPR**”) (EU 2016/679) (collectively, the “**Privacy Laws**”). Except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect, the Company and its subsidiaries have since August 1, 2018 made all disclosures to users or customers required by Privacy Laws, and none of such disclosures have, to the knowledge of the Company, been inaccurate or in violation of Privacy Laws. Neither the Company nor any subsidiary: (i) has received written notice of any actual or potential liability, including, but not limited to security or data privacy breaches or other unauthorized or unlawful access to, use of, or destruction of its Confidential Data or Personal Data, under or relating to, or actual or potential violation of, any of the Privacy Laws, and to the Company’s knowledge, no such notices are threatened or pending; (ii) is currently conducting or paying for, in whole or in part, any investigation, remediation, or other corrective action pursuant to any Privacy Law; or (iii) is a party to any order, decree, or agreement with any governmental, regulatory or supervisory authority or body that imposes any obligation or liability under any Privacy Law.

(aa) No Complaints. Except as disclosed in the Registration Statement and the Prospectus, there is no complaint to or audit, proceeding, investigation (formal or informal) or claim currently pending against the Company or its subsidiaries, or to the knowledge of the Company, any of its customers (specific to the customer’s use of the products or services of the Company) by any state Attorney General or related office, the Federal Trade Commission, the U.S. Department of Health and Human Services and any office contained therein (“**HHS**”), or any similar authority in any jurisdiction other than the United States or any other governmental entity, or by any person in respect of the collection, use or disclosure of Personal Data by the Company or its subsidiaries, and, to the knowledge of the Company, no such complaint, audit, proceeding, investigation or claim is threatened.

(bb) FDA Compliance. Except as disclosed in the Registration Statement and the Prospectus, and except, in each case, as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect, the Company: (A) is, and has since August 1, 2018 been, in compliance with all applicable statutes, rules or regulations of the FDA relating to the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product under development, manufactured or distributed by the Company (“**Applicable Laws**”); (B) has not received any FDA Form 483, written notice of adverse finding, warning letter, untitled letter or other correspondence or written notice from the FDA or any similar governmental entity in each case alleging or asserting material noncompliance with any Applicable Laws or any licenses, certificates, approvals, clearances, exemptions, authorizations, permits and supplements or amendments thereto required by any such Applicable Laws (“**Authorizations**”); (C) possesses all Authorizations required for the conduct of its business and such Authorizations are valid and in full force and effect and the Company is not in violation of any term of any such Authorizations;

---

(D) has not received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from the FDA or any governmental entity or third party alleging that any product operation or activity is in material violation of any Applicable Laws or Authorizations and has no knowledge that the FDA or any governmental entity or third party has threatened any such claim, litigation, arbitration, action, suit, investigation or proceeding; and (E) has not received written notice that the FDA or any governmental entity has taken, is taking or intends to take action to limit, suspend, modify or revoke any material Authorizations and has no knowledge that the FDA or any governmental entity is considering such action.

(cc) Tests and Preclinical and Clinical Trials. The studies, tests and preclinical and clinical trials conducted by or, to the Company's knowledge, on behalf of the Company were and, if still ongoing, are being conducted in all material respects in accordance with experimental protocols, procedures and controls pursuant to, where applicable, all Applicable Laws, including, without limitation, the Federal Food, Drug and Cosmetic Act and the rules and regulations promulgated thereunder and any applicable rules and regulations of the jurisdiction in which such trials and studies are being conducted; except to the extent disclosed in the Registration Statement and the Prospectus, the Company is not aware of any studies, tests or trials, the results of which the Company believes materially call into question the study, test, or trial results described or referred to in the Registration Statement and the Prospectus when viewed in the context in which such results are described and the clinical state of development; and, except to the extent disclosed in the Registration Statement or the Prospectus, the Company has not received any written notices or correspondence from the FDA or any governmental entity requiring the termination or suspension of any studies, tests or preclinical or clinical trials conducted by or on behalf of the Company, other than ordinary course communications with respect to modifications in connection with the design and implementation of such trials.

(dd) Compliance with Health Care Laws. Except as disclosed in the Registration Statement and the Prospectus, and except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect: the Company and its subsidiaries are, and have since August 1, 2018 been, in compliance with all Health Care Laws. For purposes of this Agreement, "**Health Care Laws**" means: (i) the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder; and (ii) all applicable federal, state, local and foreign health care fraud and abuse laws, including, without limitation, the U.S. Anti-Kickback Statute (42 U.S.C. Section 1320a-7b(b)), the U.S. Civil False Claims Act (31 U.S.C. Section 3729 et seq.), the criminal False Statements Law (42 U.S.C. Section 1320a-7b(a)), 18 U.S.C. Sections 286, 287, 1035, 1347, and 1349 the health care fraud criminal provisions under HIPAA, the civil monetary penalties law (42 U.S.C. Section 1320a-7a), the exclusions law (42 U.S.C. Section 1320a-7), and the Physician Payments Sunshine Act (42 U.S.C Section 1320-7h); and the regulations promulgated pursuant to such laws. Neither the Company nor any of its subsidiaries has received written notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any court or arbitrator or governmental or regulatory authority or third party alleging that any product operation or activity is in material violation of any Health Care Laws nor, to the Company's knowledge, has any such claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action been threatened. Except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect, the Company and its subsidiaries have filed, maintained or submitted all reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any

---



Health Care Laws, and all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete and accurate on the date filed in all respects (or were corrected or supplemented by a subsequent submission). Neither the Company nor any of its subsidiaries, or any of their respective employees, officers, directors, or to the Company's knowledge, any of their respective agents, is a party to any corporate integrity agreements, monitoring agreements, consent decrees, settlement orders, or similar agreements with or imposed by any governmental or regulatory authority. Additionally, neither the Company nor any of its subsidiaries nor any of their respective employees, officers, directors, or to the Company's knowledge, its agents, has been excluded, suspended or debarred from participation in any U.S. federal health care program or human clinical research or, to the knowledge of the Company, is subject to a governmental inquiry, investigation, proceeding, or other similar action that would reasonably be expected to result in debarment, suspension, or exclusion.

(ee) Related Party Transactions. No relationship, direct or indirect, exists between or among the Company or any of its subsidiaries, on the one hand, and the directors, officers, stockholders, customers, suppliers or other affiliates of the Company or any of its subsidiaries, on the other, that is required by the Securities Act or Exchange Act, as applicable, to be described in each of the Registration Statement and the Prospectus and that is not so described in such documents.

(ff) Company Not an "Investment Company". The Company has been advised of the rules and requirements under the Investment Company Act of 1940, as amended, and the rules and regulations of the Commission thereunder (the "Investment Company Act"). The Company is not and, after giving effect to the offering and sale of the Placement Shares and the application of the proceeds thereof as described in the Registration Statement and the Prospectus, will not be required to register as an "investment company" or an entity "controlled" by an "investment company" within the meaning of the Investment Company Act.

(gg) Tax Law Compliance. The Company and its subsidiaries have paid all federal, state, local and foreign taxes and filed all tax returns required to be paid or filed through the date hereof; and except as otherwise disclosed in each of the Registration Statement and the Prospectus, there is no tax deficiency that has been, or is reasonably expected to be, asserted against the Company or any of its subsidiaries or any of their respective properties or assets; in each case, except as would not, individually or in the aggregate, have a Material Adverse Effect.

(hh) All Necessary Permits, etc. The Company and its subsidiaries possess all licenses, certificates, permits and other authorizations issued by, and have made all declarations and filings with, the appropriate federal, state, local or foreign governmental or regulatory authorities that are necessary for the ownership or lease of their respective properties or the conduct of their respective businesses as described in each of the Registration Statement and the Prospectus, except where the failure to possess or make the same would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect; and except as described in each of the Registration Statement and the Prospectus, neither the Company nor any of its subsidiaries has received written notice of any revocation or modification of any such license, certificate, permit or authorization or has any reason to believe that any such license, certificate, permit or authorization will not be renewed in the ordinary course, except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. To the Company's knowledge, no party granting any such licenses, certificates, permits or other authorizations has taken any action to limit,

---

suspend or revoke the same in any material respect. Except as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect, the Company and its subsidiaries have filed, obtained, maintained or submitted all reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required and all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were timely, complete and correct on the date filed (or were corrected or supplemented by a subsequent submission) as required for maintenance of their licenses, certificates, permits and other authorizations that are necessary for the conduct of their respective businesses.

(ii) No Labor Disputes. (i) No labor disturbance by or dispute with employees of the Company or any of its subsidiaries exists or, to the knowledge of the Company, is contemplated or threatened, and (ii) the Company is not aware of any existing or imminent labor disturbance by, or dispute with, the employees of any of its or its subsidiaries' principal suppliers, contractors or customers, except in the case of each of (i) and (ii) above, as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(jj) Compliance with Environmental Laws. (i) The Company and its subsidiaries (x) are in compliance with all, and have not violated any, applicable federal, state, local and foreign laws, rules, regulations, requirements, decisions, judgments, decrees, orders and other legally enforceable requirements relating to pollution or the protection of human health or safety, the environment, natural resources, hazardous or toxic substances or wastes, pollutants or contaminants (collectively, "Environmental Laws"); (y) have received and are in compliance with all, and have not violated any, permits, licenses, certificates or other authorizations or approvals required of them under any Environmental Laws to conduct their respective businesses; and (z) have not received written notice of any actual or potential liability or obligation under or relating to, or any actual or potential violation of, any Environmental Laws, including for the investigation or remediation of any disposal or release of hazardous or toxic substances or wastes, pollutants or contaminants, and have no knowledge of any event or condition that would reasonably be expected to result in any such notice; (ii) there are no costs or liabilities associated with Environmental Laws of or relating to the Company or its subsidiaries, except in the case of each of (i) and (ii) above, for any such matter as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect; and (iii) except as described in the Prospectus, (x) there is no proceeding that is pending, or that is known by the Company to be contemplated, against the Company or any of its subsidiaries under any Environmental Laws in which a governmental entity is also a party, other than such proceeding regarding which the Company reasonably believes no monetary sanctions of \$100,000 or more will be imposed, (y) the Company and its subsidiaries are not aware of any facts or issues regarding compliance with Environmental Laws, or liabilities or other obligations under Environmental Laws or concerning hazardous or toxic substances or wastes, pollutants or contaminants, that would reasonably be expected to have a Material Adverse Effect, and (z) none of the Company or its subsidiaries anticipates material capital expenditures relating to any Environmental Laws.

(kk) Hazardous Materials. There has been no storage, generation, transportation, use, handling, treatment, Release or threat of Release of Hazardous Materials by, relating to or caused by the Company or any of its subsidiaries (or, to the knowledge of the Company and its subsidiaries, any other entity (including any predecessor) for whose acts or omissions the

---

Company or any of its subsidiaries is or could reasonably be expected to be liable) at, on, under or from any property or facility now or previously owned, operated or leased by the Company or any of its subsidiaries, or at, on, under or from any other property or facility, in violation of any Environmental Laws or in a manner or amount or to a location that could reasonably be expected to result in any liability under any Environmental Law, except for any violation or liability which would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect. “**Hazardous Materials**” means any material, chemical, substance, waste, pollutant, contaminant, compound, mixture, or constituent thereof, in any form or amount, including petroleum (including crude oil or any fraction thereof) and petroleum products, natural gas liquids, asbestos and asbestos containing materials, naturally occurring radioactive materials, brine, and drilling mud, regulated or which can give rise to liability under any Environmental Law. “**Release**” means any spilling, leaking, seepage, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, disposing, depositing, dispersing, or migrating in, into or through the environment, or in, into from or through any building or structure.

(II) Compliance with ERISA. (i) Each employee benefit plan, within the meaning of Section 3(3) of the Employee Retirement Income Security Act of 1974, as amended (“**ERISA**”), for which the Company or any member of its “Controlled Group” (defined as any entity, whether or not incorporated, that is under common control with the Company within the meaning of Section 4001(a)(14) of ERISA or any entity that would be regarded as a single employer with the Company under Section 414(b),(c),(m) or (o) of the Code) would have any liability (each, a “**Plan**”) has been maintained in compliance with its terms and the requirements of any applicable statutes, orders, rules and regulations, including but not limited to ERISA and the Code; (ii) no prohibited transaction, within the meaning of Section 406 of ERISA or Section 4975 of the Code, has occurred with respect to any Plan, excluding transactions effected pursuant to a statutory or administrative exemption; (iii) for each Plan that is subject to the funding rules of Section 412 of the Code or Section 302 of ERISA, no Plan has failed (whether or not waived), or is reasonably expected to fail, to satisfy the minimum funding standards (within the meaning of Section 302 of ERISA or Section 412 of the Code) applicable to such Plan; (iv) no Plan is, or is reasonably expected to be, in “at risk status” (within the meaning of Section 303(i) of ERISA) and no Plan that is a “multiemployer plan” within the meaning of Section 4001(a)(3) of ERISA is in “endangered status” or “critical status” (within the meaning of Sections 304 and 305 of ERISA) (v) the fair market value of the assets of each Plan exceeds the present value of all benefits accrued under such Plan (determined based on those assumptions used to fund such Plan); (vi) no “reportable event” (within the meaning of Section 4043(c) of ERISA and the regulations promulgated thereunder) has occurred or is reasonably expected to occur; (vii) each Plan that is intended to be qualified under Section 401(a) of the Code has received a favorable determination letter, or is entitled to rely on an opinion letter, from the Internal Revenue Service, and, to the knowledge of the Company, nothing has occurred, whether by action or by failure to act, which would cause the loss of such qualification; (viii) neither the Company nor any member of the Controlled Group has incurred, nor reasonably expects to incur, any liability under Title IV of ERISA (other than contributions to the Plan or premiums to the Pension Benefit Guarantee Corporation, in the ordinary course and without default) in respect of a Plan (including a “multiemployer plan” within the meaning of Section 4001(a)(3) of ERISA); and (ix) none of the following events has occurred or is reasonably likely to occur: (A) a material increase in the aggregate amount of contributions required to be made to all Plans by the Company or its Controlled Group affiliates in the current fiscal year of the Company and its Controlled Group affiliates compared to the amount of such

---

contributions made in the Company's and its Controlled Group affiliates' most recently completed fiscal year; or (B) a material increase in the Company and its subsidiaries' "accumulated post-retirement benefit obligations" (within the meaning of Accounting Standards Codification Topic 715-60) compared to the amount of such obligations in the Company and its subsidiaries' most recently completed fiscal year, except in each case with respect to the events or conditions set forth in (i) through (ix) hereof, as would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(mm) Disclosure Controls. The Company and its subsidiaries maintain an effective system of "disclosure controls and procedures" (as defined in Rule 13a-15(e) of the Exchange Act) that complies with the requirements of the Exchange Act and that has been designed to ensure that information required to be disclosed by the Company in reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Commission's rules and forms, including controls and procedures designed to ensure that such information is accumulated and communicated to the Company's management as appropriate to allow timely decisions regarding required disclosure. The Company has conducted evaluations of the effectiveness of their disclosure controls as required by Rule 13a-15 of the Exchange Act.

(nn) Accounting System. The Company and its subsidiaries maintain systems of "internal control over financial reporting" (as defined in Rule 13a-15(f) of the Exchange Act) that are designed to comply with the requirements of the Exchange Act and have been designed by, or under the supervision of, their respective principal executive and principal financial officers, or persons performing similar functions, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP, including, but not limited to, internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. Except as disclosed in the Registration Statement and the Prospectus, there are no material weaknesses in the Company's internal controls. The Company's auditors and the Audit Committee of the Board of Directors of the Company have been advised of: (i) all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting which have adversely affected or are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and (ii) any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal controls over financial reporting.

(oo) Insurance. The Company and its subsidiaries have insurance covering their respective properties, operations, personnel and businesses, including business interruption insurance, which insurance is in amounts and insures against such losses and risks as are generally maintained by similarly situated companies and which the Company believes are reasonably adequate to protect the Company and its subsidiaries and their respective businesses; and neither the Company nor any of its subsidiaries has (i) received notice from any insurer or agent of such insurer that capital improvements or other expenditures are required or necessary to be made in order to continue such

---

insurance or (ii) any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage at reasonable cost from similar insurers as may be necessary to continue its business.

(pp) No Unlawful Contributions or Other Payments. Neither the Company nor any of its subsidiaries nor any director, officer, or employee of the Company or any of its subsidiaries nor, to the knowledge of the Company, any agent, affiliate or other person associated with or acting on behalf of the Company or any of its subsidiaries has (i) used any corporate funds for any unlawful contribution, gift, entertainment or other unlawful expense relating to political activity; (ii) made or taken an act in furtherance of an offer, promise or authorization of any direct or indirect unlawful payment or benefit to any foreign or domestic government or regulatory official or employee, including of any government-owned or controlled entity or of a public international organization, or any person acting in an official capacity for or on behalf of any of the foregoing, or any political party or party official or candidate for political office; (iii) violated or is in violation of any provision of the U.S. Foreign Corrupt Practices Act of 1977, as amended, or any applicable law or regulation implementing the OECD Convention on Combating Bribery of Foreign Public Officials in International Business Transactions, or committed an offence under the Bribery Act 2010 of the United Kingdom, or any other applicable anti-bribery or anti-corruption laws; or (iv) made, offered, agreed, requested or taken an act in furtherance of any unlawful bribe or other unlawful benefit, including, without limitation, any rebate, payoff, influence payment, kickback or other unlawful or improper payment or benefit. The Company and its subsidiaries have instituted, maintain and enforce, and will continue to maintain and enforce policies and procedures designed to promote and ensure compliance with all applicable anti-bribery and anti-corruption laws.

(qq) Compliance with Money Laundering Laws. The operations of the Company and its subsidiaries are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements, including those of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the applicable money laundering statutes of all jurisdictions where the Company or any of its subsidiaries conducts business, the rules and regulations thereunder and any related or similar rules, regulations or guidelines issued, administered or enforced by any governmental or regulatory agency (collectively, the “**Anti-Money Laundering Laws**”) and no action, suit or proceeding by or before any court or governmental or regulatory agency, authority or body or any arbitrator involving the Company or any of its subsidiaries with respect to the Anti-Money Laundering Laws is pending or, to the knowledge of the Company, threatened.

(rr) Compliance with OFAC. Neither the Company nor any of its subsidiaries, directors, officers or employees, nor, to the knowledge of the Company, any agent, or affiliate or other person associated with or acting on behalf of the Company or any of its subsidiaries is currently the subject or the target of any sanctions administered or enforced by the U.S. Government, (including, without limitation, the Office of Foreign Assets Control of the U.S. Department of the Treasury or the U.S. Department of State and including, without limitation, the designation as a “specially designated national” or “blocked person”), the United Nations Security Council, the European Union, Her Majesty’s Treasury, or other relevant sanctions authority (collectively, “**Sanctions**”), nor is the Company or any of its subsidiaries located, organized or resident in a country or territory that is the subject or the target of Sanctions, including, without limitation, Cuba, Iran, North Korea, Syria, and the Crimea Region of the Ukraine (each, a “**Sanctioned Country**”); and the Company

---

will not directly or indirectly use the proceeds of the offering of the Placement Shares hereunder, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person or entity (i) to fund or facilitate any activities of or business with any person that, at the time of such funding or facilitation, is the subject or the target of Sanctions, (ii) to fund or facilitate any activities of or business in any Sanctioned Country or (iii) in any other manner that will result in a violation by any person (including any person participating in the transaction, whether as underwriter, advisor, investor or otherwise) of Sanctions. For the past five years, the Company and its subsidiaries have not knowingly engaged in and are not now knowingly engaged in any dealings or transactions with any person that at the time of the dealing or transaction is or was the subject or the target of Sanctions or with any Sanctioned Country.

(ss) Brokers. Except for Cowen, there is no broker, finder or other party that is entitled to receive from the Company any brokerage or finder's fee or other fee or commission as a result of any transactions contemplated by this Agreement.

(tt) No Applicable Registration or Other Similar Rights. There are no persons with registration or other similar rights to have any equity or debt securities registered for sale under the Registration Statement or included in the offering contemplated by this Agreement, except for such rights as have been duly waived.

(uu) No Price Stabilization or Manipulation. Neither the Company nor any of its subsidiaries or, to the Company's knowledge, affiliates have taken, directly or indirectly, any action designed to or that could reasonably be expected to cause or result in any stabilization or manipulation of the price of the Placement Shares.

(vv) Sarbanes-Oxley Act. There is and has been no failure on the part of the Company or any of the Company's directors or officers, in their capacities as such, to comply with any applicable provision of the Sarbanes-Oxley Act of 2002, as amended, and the rules and regulations promulgated in connection therewith, including Section 402 related to loans.

(ww) Statistical and Market Data. Nothing has come to the attention of the Company that has caused the Company to believe that the statistical and market-related data included in each of the Registration Statement and the Prospectus is not based on or derived from sources that are reliable and accurate in all material respects.

(xx) No Ratings. There are no debt securities, convertible securities or preferred stock issued or guaranteed by the Company or any of its subsidiaries that are rated by a "nationally recognized statistical rating organization", as such term is defined in Section 3(a)(62) of the Exchange Act.

(yy) Cybersecurity. Except as described in the Registration Statement and the Prospectus, and except where non-compliance would not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect, the Company and its subsidiaries are presently in compliance with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of IT Assets and Personal Data and to the protection of such IT Assets and Personal Data from unauthorized use, access, misappropriation or modification.

---

(zz) Exchange Act Compliance. The documents incorporated or deemed to be incorporated by reference in the Prospectus, at the time they were or hereafter are filed with the Commission, complied and will comply in all material respects with the requirements of the Exchange Act, and, when read together with the other information in the Prospectus, at the Settlement Dates, will not contain an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(aaa) Reserved.

(bbb) No Reliance. The Company has not relied upon Cowen or legal counsel for Cowen for any legal, tax or accounting advice in connection with the offering and sale of the Placement Shares.

(ccc) Compliance with Laws. The Company has not been advised, and has no reason to believe, that it and each of its subsidiaries are not conducting business in compliance with all applicable laws, rules and regulations of the jurisdictions in which it is conducting business, except where failure to be so in compliance would not result in a Material Adverse Effect.

Any certificate signed by an officer of the Company and delivered to Cowen or to counsel for Cowen pursuant to or in connection with this Agreement shall be deemed to be a representation and warranty by the Company to Cowen as to the matters set forth therein.

The Company acknowledges that Cowen and, for purposes of the opinions to be delivered pursuant to Section 7 hereof, counsel to the Company and counsel to Cowen, will rely upon the accuracy and truthfulness of the foregoing representations and hereby consents to such reliance.

7. Covenants of the Company. The Company covenants and agrees with Cowen that:

(a) Registration Statement Amendments. After the date of this Agreement and during any period in which a Prospectus relating to any Placement Shares is required to be delivered by Cowen under the Securities Act (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act), (i) the Company will notify Cowen promptly of the time when any subsequent amendment to the Registration Statement, other than documents incorporated by reference, has been filed with the Commission and/or has become effective or any subsequent supplement to the Prospectus has been filed and of any request by the Commission for any amendment or supplement to the Registration Statement or Prospectus or for additional information (insofar as it relates to the transactions contemplated hereby), (ii) the Company will prepare and file with the Commission, promptly upon Cowen's reasonable request, any amendments or supplements to the Registration Statement or Prospectus that, in Cowen's reasonable opinion, may be necessary or advisable in connection with the distribution of the Placement Shares by Cowen (*provided, however*, that (x) the failure of Cowen to make such request shall not relieve the Company of any obligation or liability hereunder, or affect Cowen's right to rely on the representations and warranties made by the Company in this Agreement and (y) the only remedy Cowen shall have with respect to the failure by the Company to make such filing (other than Cowen's rights under Section 9 hereof) shall be to cease making sales under this Agreement until such amendment or supplement is filed); (iii) the Company will not file any amendment or supplement to the Registration Statement or Prospectus, other than documents

---

incorporated by reference, relating to the Placement Shares or a security convertible into the Placement Shares unless a copy thereof has been submitted to Cowen within a reasonable period of time before the filing and Cowen has not reasonably objected thereto (*provided, however*, that (x) the failure of Cowen to make such objection shall not relieve the Company of any obligation or liability hereunder, or affect Cowen's right to rely on the representations and warranties made by the Company in this Agreement, (y) the Company has no obligation to provide Cowen any advance copy of such filing or to provide Cowen an opportunity to object to such filing if the filing does not name Cowen and does not relate to the transaction herein and (z) the only remedy Cowen shall have with respect to the failure by the Company to provide Cowen with such copy, to make such filings, or to obtain such consent (other than Cowen's rights under Section 9 hereof) shall be to cease making sales under this Agreement) and the Company will furnish to Cowen at the time of filing thereof a copy of any document that upon filing is deemed to be incorporated by reference into the Registration Statement or Prospectus, except for those documents available via EDGAR; (iv) the Company will cause each amendment or supplement to the Prospectus, other than documents incorporated by reference, to be filed with the Commission as required pursuant to the applicable paragraph of Rule 424(b) of the Securities Act, and (v) prior to the termination of this Agreement, the Company will notify Cowen if at any time the Registration Statement shall no longer be effective as a result of the passage of time pursuant to Rule 415 under the Securities Act or otherwise.

(b) Notice of Commission Stop Orders. The Company will advise Cowen, promptly after it receives notice or obtains knowledge thereof, of the issuance or threatened issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement, of the suspension of the qualification of the Placement Shares for offering or sale in any jurisdiction, or of the initiation or threatening of any proceeding for any such purpose; and it will promptly use its commercially reasonable efforts to prevent the issuance of any stop order or to obtain its withdrawal if such a stop order should be issued.

(c) Delivery of Prospectus; Subsequent Changes. During any period in which a Prospectus relating to the Placement Shares is required to be delivered by Cowen under the Securities Act with respect to a pending sale of the Placement Shares, (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act), the Company will use its commercially reasonable efforts to comply with all requirements imposed upon it by the Securities Act, as from time to time in force, and to file on or before their respective due dates (taking into account any extensions available under the Exchange Act) all reports and any definitive proxy or information statements required to be filed by the Company with the Commission pursuant to Sections 13(a), 13(c), 14, 15(d) or any other provision of or under the Exchange Act. If during such period any event occurs as a result of which the Prospectus as then amended or supplemented would include an untrue statement of a material fact or omit to state a material fact necessary to make the statements therein, in the light of the circumstances then existing, not misleading, or if during such period it is necessary to amend or supplement the Registration Statement or Prospectus to comply with the Securities Act, the Company will promptly notify Cowen to suspend the offering of Placement Shares during such period and the Company will promptly amend or supplement the Registration Statement or Prospectus (at the expense of the Company) so as to correct such statement or omission or effect such compliance; provided, that, the Company may delay the filing of any amendment or supplement, if in the

---



judgment of the Company, it is in the best interest of the Company, during which time of delay of Cowen shall be under no obligation to make any sales of the Placement Shares hereunder.

(d) Listing of Placement Shares. During any period in which the Prospectus relating to the Placement Shares is required to be delivered by Cowen under the Securities Act with respect to a pending sale of the Placement Shares (including in circumstances where such requirement may be satisfied pursuant to Rule 172 under the Securities Act), the Company will use its commercially reasonable efforts to cause the Placement Shares to be listed on Nasdaq and to qualify the Placement Shares for sale under the securities laws of such jurisdictions as Cowen reasonably designates and to continue such qualifications in effect so long as required for the distribution of the Placement Shares; *provided, however*, that the Company shall not be required in connection therewith to qualify as a foreign corporation or dealer in securities or file a general consent to service of process in any jurisdiction.

(e) Delivery of Registration Statement and Prospectus. The Company will furnish to Cowen and its counsel (at the expense of the Company) copies of the Registration Statement, the Prospectus (including all documents incorporated by reference therein) and all amendments and supplements to the Registration Statement or Prospectus that are filed with the Commission during any period in which a Prospectus relating to the Placement Shares is required to be delivered under the Securities Act (including all documents filed with the Commission during such period that are deemed to be incorporated by reference therein), in each case as soon as reasonably practicable and in such quantities as Cowen may from time to time reasonably request and, at Cowen's request, will also furnish copies of the Prospectus to each exchange or market on which sales of the Placement Shares may be made; *provided, however*, that the Company shall not be required to furnish any document (other than the Prospectus) to Cowen to the extent such document is available on EDGAR.

(f) Earnings Statement. The Company will make generally available to its security holders as soon as practicable, but in any event not later than 15 months after the end of the Company's current fiscal quarter, an earnings statement covering a 12-month period that satisfies the provisions of Section 11(a) and Rule 158 of the Securities Act.

(g) Expenses. The Company, whether or not the transactions contemplated hereunder are consummated or this Agreement is terminated, in accordance with the provisions of Section 11 hereunder, will pay the following expenses all incident to the performance of its obligations hereunder, including, but not limited to, expenses relating to (i) the preparation, printing and filing of the Registration Statement and each amendment and supplement thereto, of each Prospectus and of each amendment and supplement thereto, (ii) the preparation, issuance and delivery of the Placement Shares, (iii) the qualification of the Placement Shares under securities laws in accordance with the provisions of Section 7(d) of this Agreement, including filing fees (provided, however, that any fees or disbursements of counsel for Cowen in connection therewith shall be paid by Cowen except as set forth in (vii) below), (iv) the printing and delivery to Cowen of copies of the Prospectus and any amendments or supplements thereto, and of this Agreement, (v) the fees and expenses incurred in connection with the listing or qualification of the Placement Shares for trading on Nasdaq, (vi) the filing fees and expenses, if any, of the Commission, and (vii) the reasonable and documented fees and disbursements of Cowen's counsel in an amount not to exceed \$50,000 in connection with the execution of this Agreement.

---

(h) Use of Proceeds. The Company will use the Net Proceeds as described in the Prospectus in the section entitled "Use of Proceeds."

(i) Notice of Other Sales. During the pendency of any Placement Notice given hereunder, and for five (5) trading days following the termination of any Placement Notice given hereunder, the Company shall provide Cowen notice as promptly as reasonably practicable before it offers to sell, contracts to sell, sells, grants any option to sell or otherwise disposes of any shares of Common Stock (other than Placement Shares offered pursuant to the provisions of this Agreement) or securities convertible into or exchangeable for Common Stock, warrants or any rights to purchase or acquire Common Stock; *provided*, that such notice shall not be required in connection with the (i) issuance, grant or sale of Common Stock, options to purchase shares of Common Stock, restricted shares of Common Stock, restricted stock units or other equity awards or Common Stock issuable upon the exercise of options or other equity awards pursuant to any stock option, stock bonus or other stock plan or arrangement described in the Prospectus, (ii) the issuance of securities in connection with a licensing agreement, joint venture, acquisition, merger or sale or purchase of assets, (iii) the issuance or sale of Common Stock pursuant to any dividend reinvestment plan that the Company may adopt from time to time provided the implementation of such is disclosed to Cowen in advance, (iv) the issuance or sale of Common Stock upon the exchange, conversion or redemption of securities or the exercise of warrants, options or other rights in effect or outstanding or disclosed in filings by the Company available on EDGAR or otherwise in writing to Cowen prior to the date of the applicable Placement Notice or (v) the issuance or sale of Common Stock, or securities convertible into or exercisable for Common Stock, offered and sold in a privately negotiated transaction to vendors, customers, strategic or collaboration partners or potential strategic partners conducted in a manner so as not to be integrated with the offering of Common Stock hereby. Notwithstanding the foregoing provisions, nothing herein shall be construed to restrict the Company's ability, or require the Company to provide notice to Cowen, to file a registration statement under the Securities Act.

(j) Change of Circumstances. The Company will, at any time during the pendency of a Placement Notice, advise Cowen promptly after it shall have received notice or obtained knowledge thereof, of any information or fact that would alter or affect in any material respect any opinion, certificate, letter or other document provided to Cowen pursuant to this Agreement.

(k) Due Diligence Cooperation. The Company will cooperate with any reasonable due diligence review conducted by Cowen or its agents in connection with the transactions contemplated hereby, including, without limitation, providing information and making available documents and senior corporate officers, during regular business hours and at the Company's principal offices, as Cowen may reasonably request.

(l) Required Filings Relating to Placement of Placement Shares. The Company agrees that on such dates as the Securities Act shall require, the Company will (i) file a prospectus supplement with the Commission under the applicable paragraph of Rule 424(b) under the Securities Act, and (ii) deliver such number of copies of each such prospectus supplement to each exchange or market on which such sales were effected as may be required by the rules or regulations of such exchange or market. The Company shall disclose in its quarterly reports on Form 10-Q and in its annual report on Form 10-K, the number of the Placement Shares sold through Cowen under this Agreement, and the gross proceeds and Net Proceeds to the Company from the sale of the Placement Shares and the compensation paid by the Company with respect to

---

sales of the Placement Shares pursuant to this Agreement during the relevant quarter or, in the case of an Annual Report on Form 10-K, during the fiscal year covered by such Annual Report and the fourth quarter of such fiscal year.

(m) **Bring-Down Dates; Certificate.** On or prior to the First Delivery Date and each time (i) the Company files the Prospectus relating to the Placement Shares or amends or supplements the Registration Statement or the Prospectus relating to the Placement Shares (other than a prospectus supplement filed in accordance with Section 7(l) of this Agreement) by means of a post-effective amendment, sticker, or supplement but not by means of incorporation of document(s) by reference to the Registration Statement or the Prospectus relating to the Placement Shares; (ii) the Company files an annual report on Form 10-K under the Exchange Act; (iii) the Company files its quarterly reports on Form 10-Q under the Exchange Act; or (iv) the Company files a report on Form 8-K containing amended financial information (other than an earnings release) under the Exchange Act (each date of filing of one or more of the documents referred to in clauses (i) through (iv) shall be a "**Bring-Down Date**"); the Company shall furnish Cowen with a certificate, in the form attached hereto as Exhibit 7(m) within three (3) Trading Days of any Bring-Down Date if requested by Cowen. The requirement to provide a certificate under this Section 7(m) shall be waived for any Bring-Down Date occurring at a time at which no Placement Notice is pending, which waiver shall continue until the earlier to occur of the date the Company delivers a Placement Notice hereunder (which for such calendar quarter shall be considered a Bring-Down Date) and the next occurring Bring-Down Date. Notwithstanding the foregoing, if the Company subsequently decides to sell Placement Shares following a Bring-Down Date when the Company relied on such waiver and did not provide Cowen with a certificate under this Section 7(m), then before the Company delivers the Placement Notice or Cowen sells any Placement Shares, the Company shall provide Cowen with a certificate, in the form attached hereto as Exhibit 7(m), dated the date of the Placement Notice.

(n) **Legal Opinion.** On or prior to the First Delivery Date and within three (3) Trading Days of each Bring-Down Date with respect to which the Company is obligated to deliver a certificate in the form attached hereto as Exhibit 7(m) for which no waiver is applicable, the Company shall cause to be furnished to Cowen a written opinion of Latham & Watkins LLP ("**Company Counsel**"), or other counsel satisfactory to Cowen, in form and substance reasonably satisfactory to Cowen and its counsel, dated the date that the opinion is required to be delivered, modified, as necessary, to relate to the Registration Statement and the Prospectus as then amended or supplemented; *provided, however*, that in lieu of such opinions for subsequent Bring-Down Dates, counsel may furnish Cowen with a letter to the effect that Cowen may rely on a prior opinion delivered under this Section 7(n) to the same extent as if it were dated the date of such letter (except that statements in such prior opinion shall be deemed to relate to the Registration Statement and the Prospectus as amended or supplemented at such Bring-Down Date).

(o) **Comfort Letter.** On or prior to the First Delivery Date and within three (3) Trading Days of each Bring-Down Date with respect to which the Company is obligated to deliver a certificate in the form attached hereto as Exhibit 7(m) for which no waiver is applicable, the Company shall cause its independent accountants to furnish Cowen letters (the "**Comfort Letters**"), dated the date the Comfort Letter is delivered, in form and substance reasonably satisfactory to Cowen, (i) confirming that they are an independent registered public accounting firm within the meaning of the Securities Act and the Public Company Accounting Oversight

---

Board (United States), (ii) stating, as of such date, the conclusions and findings of such firm with respect to the financial information and other matters ordinarily covered by accountants' "comfort letters" to Cowen in connection with registered public offerings (the first such letter, the "**Initial Comfort Letter**") and (iii) updating the Initial Comfort Letter with any information that would have been included in the Initial Comfort Letter had it been given on such date and modified as necessary to relate to the Registration Statement and the Prospectus, as amended and supplemented to the date of such letter.

(p) Market Activities. The Company will not, directly or indirectly, (i) take any action designed to cause or result in, or that constitutes or might reasonably be expected to constitute, the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Placement Shares or (ii) sell, bid for, or purchase the Common Stock to be issued and sold pursuant to this Agreement, or pay anyone any compensation for soliciting purchases of the Placement Shares other than Cowen; provided, however, that the Company may bid for and purchase shares of its Common Stock in accordance with Rule 10b-18 under the Exchange Act.

(q) Insurance. The Company and its subsidiaries shall use commercially reasonable efforts to maintain, or cause to be maintained, insurance in such amounts and covering such risks as is reasonable and customary for the business for which it is engaged.

(r) Compliance with Laws. The Company and each of its subsidiaries shall maintain, or cause to be maintained, all material environmental permits, licenses and other authorizations required by federal, state and local law in order to conduct their businesses as described in the Prospectus, and the Company and each of its subsidiaries shall conduct their businesses, or cause their businesses to be conducted, in substantial compliance with such permits, licenses and authorizations and with applicable environmental laws, except where the failure to maintain or be in compliance with such permits, licenses and authorizations could not reasonably be expected to result in a Material Adverse Effect.

(s) Investment Company Act. The Company will conduct its affairs in such a manner so as to reasonably ensure that neither it nor its subsidiaries will be or become, at any time prior to the termination of this Agreement, an "investment company," as such term is defined in the Investment Company Act, assuming no change in the Commission's current interpretation as to entities that are not considered an investment company.

(t) Securities Act and Exchange Act. The Company will use its commercially reasonable efforts to comply with all requirements imposed upon it by the Securities Act and the Exchange Act as from time to time in force, so far as necessary to permit the continuance of sales of, or dealings in, the Placement Shares as contemplated by the provisions hereof and the Prospectus.

(u) No Offer to Sell. Other than a Permitted Free Writing Prospectus, neither Cowen nor the Company (including its agents and representatives, other than Cowen in its capacity as such) will make, use, prepare, authorize, approve or refer to any written communication (as defined in Rule 405 under the Securities Act), required to be filed with the Commission, that constitutes an offer to sell or solicitation of an offer to buy Common Stock hereunder.

---

(v) Sarbanes-Oxley Act. The Company and its subsidiaries will use their commercially reasonable efforts to comply with all effective applicable provisions of the Sarbanes-Oxley Act.

(w) Affirmation. Each Placement Notice delivered by the Company to Cowen shall be deemed to be (i) an affirmation that the representations, warranties and agreements of the Company herein contained and contained in any certificate delivered to Cowen pursuant hereto are true and correct at the time of delivery of such Placement Notice, and (ii) an undertaking that such representations, warranties and agreements will be true and correct on any applicable Time of Sale and Settlement Date, as though made at and as of each such time (it being understood that such representations, warranties and agreements shall relate to the Registration Statement and the Prospectus as amended and supplemented to the time of such Placement Notice acceptance).

(x) Renewal. If immediately prior to the third anniversary (the "Renewal Deadline") of the initial effective date of the Registration Statement, the aggregate gross sales price of Placement Shares sold by the Company is less than the Maximum Amount and this Agreement has not expired or been terminated, the Company will, prior to the Renewal Deadline, file, if it has not already done so and is eligible to do so, a new shelf registration statement relating to the Placement Shares, in a form satisfactory to Cowen, and, if not automatically effective, will use its best efforts to cause such registration statement to be declared effective within 60 days after the Renewal Deadline. The Company will take all other action necessary or appropriate to permit the issuance and sale of the Placement Shares to continue as contemplated in the expired registration statement relating to the Placement Shares. References herein to the Registration Statement shall include such new shelf registration statement.

8. Conditions to Cowen's Obligations. The obligations of Cowen hereunder with respect to a Placement Notice will be subject to the continuing accuracy and completeness of the representations and warranties made by the Company herein, to the due performance by the Company of its obligations hereunder and thereunder, to the completion by Cowen of a due diligence review satisfactory to Cowen in its reasonable judgment, and to the continuing satisfaction (or waiver by Cowen in its sole discretion) of the following additional conditions:

(a) Registration Statement Effective. The Registration Statement shall be effective and shall be available for (i) all sales of Placement Shares issued pursuant to all prior Placement Notices and (ii) the sale of all Placement Shares contemplated to be issued pursuant to any Placement Notice.

(b) No Material Notices. None of the following events shall have occurred and be continuing: (i) receipt by the Company or any of its subsidiaries of any request for additional information from the Commission or any other federal or state governmental authority during the period of effectiveness of the Registration Statement, the response to which would require any post-effective amendments or supplements to the Registration Statement or the Prospectus; (ii) the issuance by the Commission or any other federal or state governmental authority of any stop order suspending the effectiveness of the Registration Statement or the initiation of any proceedings for that purpose; (iii) receipt by the Company of any notification with respect to the suspension of the qualification or exemption from qualification of any of the Placement Shares for sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose; or (iv) the occurrence of any event that makes any material statement made in the Registration Statement or the Prospectus or any material document incorporated or deemed to be incorporated therein by

---

reference untrue in any material respect or that requires the making of any changes in the Registration Statement, related Prospectus or such documents so that, in the case of the Registration Statement, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading and, that in the case of the Prospectus, it will not contain any materially untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(c) No Misstatement or Material Omission. Cowen shall not have advised the Company that the Registration Statement or Prospectus, or any amendment or supplement thereto, contains an untrue statement of fact that in Cowen's reasonable opinion is material, or omits to state a fact that in Cowen's reasonable opinion is material and is required to be stated therein or is necessary to make the statements therein not misleading.

(d) Material Changes. Except as contemplated in the Prospectus, or disclosed in the Company's reports filed with the Commission, there shall not have been any material adverse change, on a consolidated basis, in the authorized capital stock of the Company or any Material Adverse Effect or any development that could reasonably be expected to result in a Material Adverse Effect, or any downgrading in or withdrawal of the rating assigned to any of the Company's securities (other than asset backed securities) by any rating organization or a public announcement by any rating organization that it has under surveillance or review its rating of any of the Company's securities (other than asset backed securities), the effect of which, in the case of any such action by a rating organization described above, in the reasonable judgment of Cowen (without relieving the Company of any obligation or liability it may otherwise have), is so material as to make it impracticable or inadvisable to proceed with the offering of the Placement Shares on the terms and in the manner contemplated in the Prospectus.

(e) Company Counsel Legal Opinion. Cowen shall have received the opinions of Company Counsel required to be delivered pursuant to Section 7(n) on or before the date on which such delivery of such opinion is required pursuant to Section 7(n).

(f) Cowen Counsel Legal Opinion. Cowen shall have received from Cooley LLP, counsel for Cowen, such opinion or opinions, on or before the date on which the delivery of the Company Counsel legal opinion is required pursuant to Section 7(n), with respect to such matters as Cowen may reasonably require, and the Company shall have furnished to such counsel such documents as they request for enabling them to pass upon such matters.

(g) Comfort Letter. Cowen shall have received the Comfort Letter required to be delivered pursuant to Section 7(o) on or before the date on which such delivery of such Comfort Letter is required pursuant to Section 7(o).

(h) Representation Certificate. Cowen shall have received the certificate required to be delivered pursuant to Section 7(m) on or before the date on which delivery of such certificate is required pursuant to Section 7(m).

---

(i) Secretary's Certificate. On or prior to the First Delivery Date, Cowen shall have received a certificate, signed on behalf of the Company by its corporate secretary, in form and substance reasonably satisfactory to Cowen and its counsel.

(j) No Suspension. Trading in the Common Stock shall not have been suspended on Nasdaq.

(k) Other Materials. On each date on which the Company is required to deliver a certificate pursuant to Section Z(m), the Company shall have furnished to Cowen such appropriate further information, certificates and documents as Cowen may have reasonably requested. All such opinions, certificates, letters and other documents shall have been in compliance with the provisions hereof. The Company will furnish Cowen with such conformed copies of such opinions, certificates, letters and other documents as Cowen shall have reasonably requested.

(l) Securities Act Filings Made. All filings with the Commission required by Rule 424 under the Securities Act to have been filed prior to the issuance of any Placement Notice hereunder shall have been made within the applicable time period prescribed for such filing by Rule 424.

(m) Approval for Listing. The Placement Shares shall either have been (i) approved for listing on Nasdaq, subject only to notice of issuance, or (ii) the Company shall have filed an application for listing of the Placement Shares on Nasdaq at, or prior to, the issuance of any Placement Notice.

(n) No Termination Event. There shall not have occurred any event that would permit Cowen to terminate this Agreement pursuant to Section 11(a).

9. Indemnification and Contribution.

(a) Company Indemnification. The Company agrees to indemnify and hold harmless Cowen, the directors, officers, partners, employees and agents of Cowen and each person, if any, who (i) controls Cowen within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, or (ii) is controlled by or is under common control with Cowen from and against any and all losses, claims, liabilities, expenses and damages (including, but not limited to, any and all reasonable and documented investigative, legal and other expenses incurred in connection with, and any and all amounts paid in settlement (in accordance with Section 9(c)) of, any action, suit or proceeding between any of the indemnified parties and any indemnifying parties or between any indemnified party and any third party, or otherwise, or any claim asserted), as and when incurred, to which Cowen, or any such person, may become subject under the Securities Act, the Exchange Act or other federal or state statutory law or regulation, at common law or otherwise, insofar as such losses, claims, liabilities, expenses or damages arise out of or are based, directly or indirectly, on (x) any untrue statement or alleged untrue statement of a material fact contained in the Registration Statement or the Prospectus or any amendment or supplement to the Registration Statement or the Prospectus or in any free writing prospectus or in any application or other document executed by or on behalf of the Company or based on written information furnished by or on behalf of the Company filed in any jurisdiction in order to qualify the Common Stock under the securities laws thereof or filed with the Commission, (y) the omission or alleged omission to state in any such document a material fact required to be stated in it or necessary to make the statements in it not misleading or (z) any breach by any of the indemnifying parties of any of their

---

respective representations, warranties and agreements contained in this Agreement; *provided, however*, that this indemnity agreement shall not apply to the extent that such loss, claim, liability, expense or damage arises from the sale of the Placement Shares pursuant to this Agreement and is caused directly or indirectly by an untrue statement or omission made in reliance upon and in conformity with solely Agent's Information. "Agent's Information" means, solely, the following information in the Prospectus: the third sentence of the eighth paragraph and the tenth paragraph under the caption "Plan of Distribution" in the Prospectus. This indemnity agreement will be in addition to any liability that the Company might otherwise have.

(b) Cowen Indemnification. Cowen agrees to indemnify and hold harmless the Company and its directors and each officer of the Company that signed the Registration Statement, and each person, if any, who (i) controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act or (ii) is controlled by or is under common control with the Company against any and all loss, liability, claim, damage and expense described in the indemnity contained in Section 9(a), as incurred, but only with respect to untrue statements or omissions, or alleged untrue statements or omissions, made in the Registration Statement (or any amendments thereto) or the Prospectus (or any amendment or supplement thereto) in reliance upon and in conformity with the Agent's Information.

(c) Procedure. Any party that proposes to assert the right to be indemnified under this Section 9 will, promptly after receipt of notice of commencement of any action against such party in respect of which a claim is to be made against an indemnifying party or parties under this Section 9, notify each such indemnifying party of the commencement of such action, enclosing a copy of all papers served, but the omission so to notify such indemnifying party will not relieve the indemnifying party from (i) any liability that it might have to any indemnified party otherwise than under this Section 9 and (ii) any liability that it may have to any indemnified party under the foregoing provision of this Section 9 unless, and only to the extent that, such omission results in the forfeiture of substantive rights or defenses by the indemnifying party. If any such action is brought against any indemnified party and it notifies the indemnifying party of its commencement, the indemnifying party will be entitled to participate in and, to the extent that it elects by delivering written notice to the indemnified party promptly after receiving notice of the commencement of the action from the indemnified party, jointly with any other indemnifying party similarly notified, to assume the defense of the action, with counsel reasonably satisfactory to the indemnified party, and after notice from the indemnifying party to the indemnified party of its election to assume the defense, the indemnifying party will not be liable to the indemnified party for any legal or other expenses except as provided below and except for the reasonable and documented costs of investigation subsequently incurred by the indemnified party in connection with the defense. The indemnified party will have the right to employ its own counsel in any such action, but the fees, expenses and other charges of such counsel will be at the expense of such indemnified party unless (1) the employment of counsel by the indemnified party has been authorized in writing by the indemnifying party, (2) the indemnified party has reasonably concluded (based on advice of counsel) that there may be legal defenses available to it or other indemnified parties that are different from or in addition to those available to the indemnifying party, (3) a conflict or potential conflict exists (based on advice of counsel to the indemnified party) between the indemnified party and the indemnifying party (in which case the indemnifying party will not have the right to direct the defense of such action on behalf of the indemnified party) or (4) the indemnifying party has not in fact employed counsel to assume the defense of such action within a reasonable time after

---



receiving notice of the commencement of the action, in each of which cases the reasonable fees, disbursements and other charges of counsel will be at the expense of the indemnifying party or parties. It is understood that the indemnifying party or parties shall not, in connection with any proceeding or related proceedings in the same jurisdiction, be liable for the reasonable fees, disbursements and other charges of more than one separate firm admitted to practice in such jurisdiction at any one time for all such indemnified party or parties. All such fees, disbursements and other charges will be reimbursed by the indemnifying party promptly as they are incurred after the indemnifying party receives a written invoice relating to fees, disbursements and other charges in reasonable detail. An indemnifying party will not, in any event, be liable for any settlement of any action or claim effected without its written consent. No indemnifying party shall, without the prior written consent of each indemnified party, settle or compromise or consent to the entry of any judgment in any pending or threatened claim, action or proceeding relating to the matters contemplated by this Section 9 (whether or not any indemnified party is a party thereto), unless such settlement, compromise or consent includes an unconditional release of each indemnified party from all liability arising or that may arise out of such claim, action or proceeding.

(d) Contribution. In order to provide for just and equitable contribution in circumstances in which the indemnification provided for in the foregoing paragraphs of this Section 9 is applicable in accordance with its terms but for any reason is held to be unavailable from the Company or Cowen, the Company and Cowen will contribute to the total losses, claims, liabilities, expenses and damages (including any investigative, legal and other expenses reasonably incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claim asserted, but after deducting any contribution received by the Company from persons other than Cowen, such as persons who control the Company within the meaning of the Securities Act, officers of the Company who signed the Registration Statement and directors of the Company, who also may be liable for contribution) to which the Company and Cowen may be subject in such proportion as shall be appropriate to reflect the relative benefits received by the Company on the one hand and Cowen on the other. The relative benefits received by the Company on the one hand and Cowen on the other hand shall be deemed to be in the same proportion as the total Net Proceeds from the sale of the Placement Shares (before deducting expenses) received by the Company bear to the total compensation received by Cowen from the sale of Placement Shares on behalf of the Company. If, but only if, the allocation provided by the foregoing sentence is not permitted by applicable law, the allocation of contribution shall be made in such proportion as is appropriate to reflect not only the relative benefits referred to in the foregoing sentence but also the relative fault of the Company, on the one hand, and Cowen, on the other, with respect to the statements or omission that resulted in such loss, claim, liability, expense or damage, or action in respect thereof, as well as any other relevant equitable considerations with respect to such offering. Such relative fault shall be determined by reference to, among other things, whether the untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or Cowen, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company and Cowen agree that it would not be just and equitable if contributions pursuant to this Section 9(d) were to be determined by pro rata allocation or by any other method of allocation that does not take into account the equitable considerations referred to herein. The amount paid or payable by an indemnified party as a result of the loss, claim, liability, expense, or damage, or action in respect thereof, referred to above in this Section 9(d) shall be deemed to include, for the purpose of this Section 9(d), any legal or other expenses reasonably incurred by such indemnified

---

party in connection with investigating or defending any such action or claim to the extent consistent with Section 9(c) hereof. Notwithstanding the foregoing provisions of this Section 9(d), Cowen shall not be required to contribute any amount in excess of the commissions received by it under this Agreement and no person found guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) will be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 9(d), any person who controls a party to this Agreement within the meaning of the Securities Act, and any officers, directors, partners, employees or agents of Cowen, will have the same rights to contribution as that party, and each director of the Company and each officer of the Company who signed the Registration Statement will have the same rights to contribution as the Company, subject in each case to the provisions hereof. Any party entitled to contribution, promptly after receipt of notice of commencement of any action against such party in respect of which a claim for contribution may be made under this Section 9(d), will notify any such party or parties from whom contribution may be sought, but the omission to so notify will not relieve that party or parties from whom contribution may be sought from any other obligation it or they may have under this Section 9(d) except to the extent that the failure to so notify such other party materially prejudiced the substantive rights or defenses of the party from whom contribution is sought. Except for a settlement entered into pursuant to the last sentence of Section 9(c) hereof, no party will be liable for contribution with respect to any action or claim settled without its written consent if such consent is required pursuant to Section 9(c) hereof.

10. Representations and Agreements to Survive Delivery. The indemnity and contribution agreements contained in Section 9 of this Agreement and all representations and warranties of the Company herein or in certificates delivered pursuant hereto shall survive, as of their respective dates, regardless of (i) any investigation made by or on behalf of Cowen, any controlling persons, or the Company (or any of their respective officers, directors or controlling persons), (ii) delivery and acceptance of the Placement Shares and payment therefor or (iii) any termination of this Agreement.

11. Termination.

(a) Cowen shall have the right by giving written notice as hereinafter specified at any time to terminate this Agreement if (i) any Material Adverse Effect, or any development that could reasonably be expected to result in a Material Adverse Effect has occurred that, in the reasonable judgment of Cowen, may materially impair the ability of Cowen to sell the Placement Shares hereunder, (ii) the Company shall have failed, refused or been unable to perform any agreement on its part to be performed hereunder; provided, however, in the case of any failure of the Company to deliver (or cause another person to deliver) any certification, opinion, or letter required under Sections 7(m), 7(n) or 7(o), Cowen's right to terminate shall not arise unless such failure to deliver (or cause to be delivered) continues for more than thirty (30) days from the date such delivery was required; (iii) any other condition of Cowen's obligations hereunder is not fulfilled, or (iv) any suspension or limitation of trading in the Placement Shares or in securities generally on Nasdaq shall have occurred. Any such termination shall be without liability of any party to any other party except that the provisions of Section 7(g) (Expenses), Section 9 (Indemnification and Contribution), Section 10 (Representations and Agreements to Survive Delivery), Section 16 (Applicable Law; Consent to Jurisdiction) and Section 17 (Waiver of Jury Trial) hereof shall remain in full force and effect notwithstanding such termination. If Cowen elects to terminate this

---

Agreement as provided in this Section 11(a), Cowen shall provide the required written notice as specified in Section 12 (Notices).

(b) The Company shall have the right, by giving ten (10) days' notice as hereinafter specified to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 7(g), Section 9, Section 10, Section 16 and Section 17 hereof shall remain in full force and effect notwithstanding such termination.

(c) Cowen shall have the right, by giving ten (10) days' notice as hereinafter specified to terminate this Agreement in its sole discretion at any time after the date of this Agreement. Any such termination shall be without liability of any party to any other party except that the provisions of Section 7(g), Section 9, Section 10, Section 16 and Section 17 hereof shall remain in full force and effect notwithstanding such termination.

(d) Unless earlier terminated pursuant to this Section 11, this Agreement shall automatically terminate upon the issuance and sale of all of the Placement Shares through Cowen on the terms and subject to the conditions set forth herein; *provided* that the provisions of Section 7(g), Section 9, Section 10, Section 16 and Section 17 hereof shall remain in full force and effect notwithstanding such termination.

(e) This Agreement shall remain in full force and effect unless terminated pursuant to Sections 11(a), (b), (c), or (d) above or otherwise by mutual agreement of the parties; *provided, however*, that any such termination by mutual agreement shall in all cases be deemed to provide that Section 7(g), Section 9, Section 10, Section 16 and Section 17 shall remain in full force and effect.

(f) Any termination of this Agreement shall be effective on the date specified in such notice of termination; *provided, however*, that such termination shall not be effective until the close of business on the date of receipt of such notice by Cowen or the Company, as the case may be. If such termination shall occur prior to the Settlement Date for any sale of Placement Shares, such Placement Shares shall settle in accordance with the provisions of this Agreement.

12. Notices. All notices or other communications required or permitted to be given by any party to any other party pursuant to the terms of this Agreement shall be in writing, unless otherwise specified in this Agreement, and if sent to Cowen, shall be delivered to Cowen at Cowen and Company, LLC, 599 Lexington Avenue, New York, NY 10022, fax no. 646-562-1130, Attention: General Counsel, email: Bradley.friedman@cowen.com, with a copy to Cooley LLP, fax no. 212-479-6275, attention: Daniel I. Goldberg; or if sent to the Company, shall be delivered to Annexon, Inc., 180 Kimball Way, Suite 200, South San Francisco, California 94080; Attention: Jennifer Lew, Chief Financial Officer (e-mail: jlew@annexonbio.com), with a copy (which shall not constitute notice) to Latham & Watkins LLP, 140 Scott Drive, Menlo Park, California 94025, Attention: Kathleen M. Wells and Brian J. Cuneo (e-mail: kathleen.wells@lw.com and brian.cuneo@lw.com). Each party to this Agreement may change such address for notices by sending to the parties to this Agreement written notice of a new address for such purpose. Each such notice or other communication shall be deemed given (i) when delivered personally or by verifiable facsimile transmission (with an original to follow) on or before 4:30 p.m., New York City time, on a Business Day (as defined below), or, if such day is not a Business Day on the next

---

succeeding Business Day, (ii) on the next Business Day after timely delivery to a nationally-recognized overnight courier and (iii) on the Business Day actually received if deposited in the U.S. mail (certified or registered mail, return receipt requested, postage prepaid). For purposes of this Agreement, "**Business Day**" shall mean any day on which the Nasdaq and commercial banks in the City of New York are open for business.

13. Successors and Assigns. This Agreement shall inure to the benefit of and be binding upon the Company and Cowen and their respective successors and the affiliates, controlling persons, officers and directors referred to in Section 9 hereof. References to any of the parties contained in this Agreement shall be deemed to include the successors and permitted assigns of such party. Nothing in this Agreement, express or implied, is intended to confer upon any party other than the parties hereto or their respective successors and permitted assigns any rights, remedies, obligations or liabilities under or by reason of this Agreement, except as expressly provided in this Agreement. Neither party may assign its rights or obligations under this Agreement without the prior written consent of the other party; *provided, however*, that Cowen may assign its rights and obligations hereunder to an affiliate of Cowen without obtaining the Company's consent.

14. Adjustments for Share Splits. The parties acknowledge and agree that all share-related numbers contained in this Agreement shall be adjusted to take into account any share split, share dividend or similar event effected with respect to the Common Stock.

15. Entire Agreement; Amendment; Severability. This Agreement (including all schedules and exhibits attached hereto and Placement Notices issued pursuant hereto) constitutes the entire agreement and supersedes all other prior and contemporaneous agreements and undertakings, both written and oral, among the parties hereto with regard to the subject matter hereof. Neither this Agreement nor any term hereof may be amended except pursuant to a written instrument executed by the Company and Cowen. In the event that any one or more of the provisions contained herein, or the application thereof in any circumstance, is held invalid, illegal or unenforceable as written by a court of competent jurisdiction, then such provision shall be given full force and effect to the fullest possible extent that it is valid, legal and enforceable, and the remainder of the terms and provisions herein shall be construed as if such invalid, illegal or unenforceable term or provision was not contained herein, but only to the extent that giving effect to such provision and the remainder of the terms and provisions hereof shall be in accordance with the intent of the parties as reflected in this Agreement.

16. Applicable Law; Consent to Jurisdiction. This Agreement shall be governed by, and construed in accordance with, the internal laws of the State of New York without regard to the principles of conflicts of laws. Each party hereby irrevocably submits to the non-exclusive jurisdiction of the state and federal courts sitting in the City of New York, borough of Manhattan, for the adjudication of any dispute hereunder or in connection with any transaction contemplated hereby, and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is brought in an inconvenient forum or that the venue of such suit, action or proceeding is improper. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof (certified or registered mail, return receipt requested) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof.

---

Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law.

17. Waiver of Jury Trial. The Company and Cowen each hereby irrevocably waives any right it may have to a trial by jury in respect of any claim based upon or arising out of this Agreement or any transaction contemplated hereby.

18. Absence of Fiduciary Relationship. The Company acknowledges and agrees that:

(a) Cowen has been retained solely to act as an arm's length contractual counterparty to the Company in connection with the sale of the Placement Shares contemplated hereby and that no fiduciary, advisory or agency relationship between the Company and Cowen has been created in respect of any of the transactions contemplated by this Agreement, irrespective of whether Cowen has advised or is advising the Company on other matters;

(b) the Company is capable of evaluating and understanding and understands and accepts the terms, risks and conditions of the transactions contemplated by this Agreement;

(c) the Company has been advised that Cowen and its affiliates are engaged in a broad range of transactions which may involve interests that differ from those of the Company and that Cowen has no obligation to disclose such interests and transactions to the Company by virtue of any fiduciary, advisory or agency relationship; and

(d) the Company waives, to the fullest extent permitted by law, any claims it may have against Cowen, for breach of fiduciary duty or alleged breach of fiduciary duty and agrees that Cowen shall have no liability (whether direct or indirect) to the Company in respect of such a fiduciary claim or to any person asserting a fiduciary duty claim on behalf of or in right of the Company, including stockholders, partners, employees or creditors of the Company.

19. Counterparts. This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Delivery of an executed Agreement by one party to the other may be made by facsimile or by electronic delivery of a portable document format (PDF) file (including any electronic signature covered by the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act, the Electronic Signatures and Records Act or other applicable law, e.g., [www.docusign.com](http://www.docusign.com)).

**[Remainder of Page Intentionally Blank]**

---

If the foregoing correctly sets forth the understanding between the Company and Cowen, please so indicate in the space provided below for that purpose, whereupon this letter shall constitute a binding agreement between the Company and Cowen.

Very truly yours,

**COWEN AND COMPANY, LLC**

By: /s/ Michael Murphy  
Name: Michael Murphy  
Title: Managing Director

**ACCEPTED as of the date  
first-above written:**

**ANNEXON, INC.**

By: /s/ Douglas Love  
Name: Douglas Love, Esq.  
Title: President and Chief Executive Officer

---

**FORM OF PLACEMENT NOTICE**

From: [ ]  
Cc: [ ]  
To: [ ]  
Subject: Cowen At the Market Offering—Placement Notice

Gentlemen:

Pursuant to the terms and subject to the conditions contained in the Sales Agreement between Annexon, Inc. (the "Company") and Cowen and Company, LLC ("Cowen") dated August 16, 2021 (the "Agreement"), I hereby request on behalf of the Company that Cowen sell up to [ ] shares of the Company's common stock, par value \$0.001 per share, at a minimum market price of \$\_\_\_\_\_ per share. Sales should begin on the date of this Notice and shall continue until [DATE] [all shares are sold].

---

**Notice Parties**

**Company**

Douglas Love, Esq.      Chief Executive Officer

Jennifer Lew      Chief Financial Officer

**Cowen**

Michael J. Murphy      Managing Director

William Follis      Managing Director

---



**Compensation**

Cowen shall be paid compensation up to 3.0% of the gross proceeds from the sales of Common Stock pursuant to the terms of this Agreement.

---

**OFFICER CERTIFICATE**

The undersigned, the duly qualified and elected \_\_\_\_\_, of Annexon, Inc., a Delaware corporation (“**Company**”), does hereby certify in such capacity and on behalf of the Company, pursuant to Section 7(m) of the Sales Agreement dated August 16, 2021 (the “**Sales Agreement**”) between the Company and Cowen and Company, LLC, that to the best of the knowledge of the undersigned.

- (i) The representations and warranties of the Company in Section 6 of the Sales Agreement (A) to the extent such representations and warranties are subject to qualifications and exceptions contained therein relating to materiality or Material Adverse Effect, are true and correct on and as of the date hereof with the same force and effect as if expressly made on and as of the date hereof, except for those representations and warranties that speak solely as of a specific date and which were true and correct as of such date, and (B) to the extent such representations and warranties are not subject to any qualifications or exceptions, are true and correct in all material respects as of the date hereof as if made on and as of the date hereof with the same force and effect as if expressly made on and as of the date hereof except for those representations and warranties that speak solely as of a specific date and which were true and correct as of such date; and
- (ii) The Company has complied with all agreements and satisfied all conditions on its part to be performed or satisfied pursuant to the Sales Agreement at or prior to the date hereof.

By:  
Name:  
Title:

Date:

**CERTIFICATION PURSUANT TO  
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Douglas Love, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Annexon, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) [Reserved];
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 16, 2021

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

**CERTIFICATION PURSUANT TO  
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,  
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Jennifer Lew, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Annexon, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) [Reserved];
  - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 16, 2021

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, 2021 (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: August 16, 2021

/s/ Douglas Love

---

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

/s/ Jennifer Lew

---

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