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

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**FORM 10-Q**

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(Mark One)

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

For the quarterly period ended June 30, 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: 001-40675

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**Immuneering Corporation**

(Exact name of registrant as specified in its charter)

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

26-1976972  
(I.R.S. Employer  
Identification Number)

245 Main St.  
Second Floor  
Cambridge, MA 02142  
(Address of Principal Executive Offices)

(617) 500-8080  
(Registrant's telephone number)

N/A

(Former name, former address and former fiscal year, if changed since last report)

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

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

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

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

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

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

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

<u>Title of Each Class</u>	<u>Trading symbol</u>	<u>Name of Exchange on which registered</u>
Class A common Stock, par value \$0.001 per share	IMRX	The Nasdaq Global Market

As of September 3, 2021, the registrant had 25,938,064 shares of Class A common stock, \$0.001 par value per share, issued and outstanding and 0 shares of Class B common stock, \$0.001 par value per share, issued and outstanding.

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## FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in 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. In some cases, you can identify forward-looking statements by terms such as “may,” “will,” “should,” “expect,” “plan,” “anticipate,” “could,” “intend,” “target,” “project,” “contemplate,” “believe,” “estimate,” “predict,” “potential” or “continue” or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. All statements other than statements of historical fact contained in this Quarterly Report on Form 10-Q, including without limitation statements regarding our plans to develop, manufacture and commercialize our product candidates, the timing or outcome of our ongoing or planned clinical trials for IMM-1-104, any of our other pipeline product candidates and any future product candidates, the clinical utility of our product candidates, the ongoing impact of the pandemic related to COVID-19 and its variants on our business and operations, including manufacturing, research and development, clinical trials and employees, our cash needs and availability, and the plans and objectives of management for future operations, are forward-looking statements.

The forward-looking statements in this Quarterly Report on Form 10-Q are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of known and unknown risks, uncertainties and other important factors that could cause actual results to differ materially from those projected in the forward-looking statements, including, but not limited to, those described in the sections of this Quarterly Report on Form 10-Q entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations”. These risks and uncertainties include, but are not limited to:

- our limited operating history;
- our history of operating losses;
- risks related to the pandemic related to COVID-19 and its variants;
- our ability to raise the substantial additional capital that will be required to finance our operations;
- the difficulty of obtaining regulatory approval for any of our current or future product candidates;
- our ability to file INDs or IND amendments or comparable documents in foreign jurisdictions in order to commence clinical trials on the timelines we expect;
- our limited experience in designing clinical trials;
- the risk of substantial delays in completing, if at all, the development and commercialization of our current or future product candidates;
- risks related to adverse events, toxicities or other undesirable side effects caused by our current or future product candidates;
- the risk of delays or difficulties in the enrollment and/or maintenance of patients in clinical trials;
- our substantial reliance on the successful development of our current and future product candidates, as well as our platform, including our proprietary technologies such as DCT and Fluency;
- risks related to competition in our industry;
- the market opportunity for our product candidates, if approved;

- risks related to manufacturing;
- risks related to our reliance on third parties; and
- risks related to our intellectual property.

Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Unless otherwise stated or the context requires otherwise, references to “Immuneering,” the “Company,” “we,” “us,” and “our,” refer to Immuneering Corporation.

### **Risk Factors Summary**

Our business is subject to numerous risks and uncertainties, including those described in Part II Item 1A. “Risk Factors” in this Quarterly Report on Form 10-Q. You should carefully consider these risks and uncertainties when investing in our Class A common stock. The principal risks and uncertainties affecting our business include the following:

- We have a limited operating history, have not completed any clinical trials and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.
- We have incurred significant net losses for the past several years and we expect to continue to incur significant net losses for the foreseeable future and may never attain profitability.
- We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.
- The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, or to obtain regulatory approval to treat the indications we seek to treat with our product candidates, we will be unable to generate product revenue or the level of planned product revenue and our business will be substantially harmed.
- We may encounter substantial delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA or other comparable foreign regulatory authorities.
- Our current or future product candidates may cause adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could inhibit regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.
- We are early in our development efforts. Our business is substantially dependent on the successful development of our current and future product candidates. If we are unable to advance our current or future product candidates through clinical trials, obtain marketing approval to treat the indications we seek to treat with our product candidates, and ultimately commercialize any product candidates we develop, or experience significant delays in doing so, our business will be materially harmed.
- We are substantially dependent on our platform, including our proprietary technologies such as DCT and Fluency, which are supported by our information technology systems. Any failure of these or other elements of our platform will materially harm our business.
- Our long-term prospects depend in part upon discovering, developing and commercializing product candidates, which may fail in development or suffer delays that adversely affect their commercial viability.
- Our approach to the discovery and development of product candidates is unproven, and we may not be successful in our efforts to use and expand our DCT platform to build a pipeline of product candidates with commercial value.

- We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.
- We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted.
- The COVID-19 pandemic and potential future pandemics could continue to adversely impact our business, including our anticipated clinical trials, supply chain and business development activities.
- We substantially rely, and expect to continue to rely, on third parties, including independent clinical investigators and contract research organizations, or CROs, to conduct certain aspects of our preclinical studies, and in the future, our clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.
- We contract with third parties for the manufacture of our product candidates for preclinical studies, and expect to continue to do so for clinical trials and ultimately, for commercialization of any approved product candidate. This reliance on third parties increases the risk that we will not have sufficient quantities of our product candidates or drugs or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.
- The manufacture of drugs is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.
- If we are unable to obtain and maintain patent and other intellectual property protection for our product candidates and technologies or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our products and technology may be impaired, and we may not be able to compete effectively in our market.

## PART I – FINANCIAL INFORMATION

## Item 1. Financial Statements

IMMUNEERING CORPORATION  
CONDENSED CONSOLIDATED BALANCE SHEETS  
(Unaudited)

	<u>June 30, 2021</u>	<u>December 31, 2020</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 50,245,103	\$ 37,090,151
Accounts receivable	495,105	500,110
Prepays and other current assets	696,684	140,958
Total current assets	51,436,892	37,731,219
Property and equipment, net	82,077	64,363
Right-of-use asset, net	562,770	613,103
Other assets	960,386	14,333
<b>Total assets</b>	<b>\$ 53,042,125</b>	<b>\$ 38,423,018</b>
<b>Liabilities, Convertible Preferred Stock and Stockholders' Deficit</b>		
Current liabilities:		
Accounts payable	\$ 1,432,516	\$ 1,480,537
Accrued expenses	3,318,870	698,992
Lease liability, current	80,605	76,322
Total current liabilities	4,831,991	2,255,851
Long-term liabilities:		
Lease liability, noncurrent	503,213	544,767
Total liabilities	5,335,204	2,800,618
Commitments and contingencies (Note 9)		
Convertible preferred stock:		
Series B preferred stock, \$0.001 par value, 6,032,183 shares authorized, 6,032,145 and 3,619,292 shares issued and outstanding at June 30, 2021 and December 31, 2020	61,772,761	36,983,910
Series A preferred stock, \$0.001 par value, 2,495,933 shares authorized, 2,495,933 shares issued and outstanding at June 30, 2021 and December 31, 2020	21,119,940	21,119,940
Total convertible preferred stock	82,892,701	58,103,850
Stockholders' deficit:		
Class A common stock, \$0.001 par value, 22,026,200 shares authorized, 5,275,936 and 4,950,129 shares issued and outstanding at June 30, 2021 and December 31, 2020	5,276	4,950
Class B common stock, \$0.001 par value, 6,032,183 shares authorized, 0 shares issued and outstanding at June 30, 2021 and December 31, 2020	—	—
Additional paid-in capital	4,763,900	3,251,240
Accumulated deficit	(39,954,956)	(25,737,640)
Total stockholders' deficit	(35,185,780)	(22,481,450)
<b>Total liabilities, convertible preferred stock and stockholders' deficit</b>	<b>\$ 53,042,125</b>	<b>\$ 38,423,018</b>

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

**IMMUNEERING CORPORATION**  
**CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS**  
**(Unaudited)**

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
<b>Revenue</b>	\$ 660,040	\$ 480,835	\$ 1,408,240	\$ 963,885
<b>Cost of revenue</b>	318,601	237,062	727,763	492,089
<b>Gross profit</b>	341,439	243,773	680,477	471,796
<b>Operating expenses</b>				
Research and development	6,991,965	3,221,000	12,382,985	6,044,254
General and administrative	1,340,398	629,403	2,524,422	1,273,412
<b>Total operating expenses</b>	<b>8,332,363</b>	<b>3,850,403</b>	<b>14,907,407</b>	<b>7,317,666</b>
<b>Loss from operations</b>	(7,990,924)	(3,606,630)	(14,226,930)	(6,845,870)
<b>Other income</b>				
Interest income	3,259	2,468	9,614	40,988
<b>Net loss</b>	<b>\$ (7,987,665)</b>	<b>\$ (3,604,162)</b>	<b>\$ (14,217,316)</b>	<b>\$ (6,804,882)</b>
Net loss per share attributable to common stockholders, basic and diluted	\$ (1.61)	\$ (0.73)	\$ (2.87)	\$ (1.37)
Weighted-average common shares outstanding, basic and diluted	4,954,553	4,950,129	4,952,352	4,950,129

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



IMMUNEERING CORPORATION

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT  
(Unaudited)

	Convertible Preferred Stock					Stockholders' Deficit						
	Series B		Series A		Total Convertible Preferred Stock	Class A Common Stock		Class B Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount		Shares	Par Value	Shares	Par Value			
<b>Balance at December 31, 2019</b>	—	\$ —	1,966,043	\$ 16,611,832	\$ 16,611,832	4,950,129	\$ 4,950	—	\$ —	\$ 2,164,471	\$ (8,697,742)	\$ (6,528,321)
Issuance of Series A convertible preferred stock, net of issuance costs	—	—	529,890	4,508,108	4,508,108	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	272,143	—	272,143
Net loss	—	—	—	—	—	—	—	—	—	—	(3,200,720)	(3,200,720)
<b>Balance at March 31, 2020</b>	—	—	2,495,933	21,119,940	21,119,940	4,950,129	4,950	—	—	2,436,614	(11,898,462)	(9,456,898)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	287,554	—	287,554
Net loss	—	—	—	—	—	—	—	—	—	—	(3,604,162)	(3,604,162)
<b>Balance at June 30, 2020</b>	—	\$ —	2,495,933	\$ 21,119,940	\$ 21,119,940	4,950,129	\$ 4,950	—	\$ —	\$ 2,724,168	\$ (15,502,624)	\$ (12,773,506)
	Convertible Preferred Stock					Stockholders' Deficit						
	Series B		Series A		Total Convertible Preferred Stock	Class A Common Stock		Class B Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount		Shares	Par Value	Shares	Par Value			
<b>Balance at December 31, 2020</b>	3,619,292	\$ 36,983,910	2,495,933	\$ 21,119,940	\$ 58,103,850	4,950,129	\$ 4,950	—	\$ —	\$ 3,251,240	\$ (25,737,640)	\$ (22,481,450)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	182,225	—	182,225
Net loss	—	—	—	—	—	—	—	—	—	—	(6,229,651)	(6,229,651)
<b>Balance at March 31, 2021</b>	3,619,292	36,983,910	2,495,933	21,119,940	58,103,850	4,950,129	4,950	—	—	3,433,465	(31,967,291)	(28,528,876)
Issuance of Series B convertible preferred stock, net of issuance costs	2,412,853	24,788,851	—	—	24,788,851	—	—	—	—	—	—	—
Issuance of common stock upon exercise of stock options	—	—	—	—	—	17,499	18	—	—	52,609	—	52,627
Issuance of common stock upon exercise of warrants	—	—	—	—	—	308,308	308	—	—	926,817	—	927,125
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	351,009	—	351,009
Net loss	—	—	—	—	—	—	—	—	—	—	(7,987,665)	(7,987,665)
<b>Balance at June 30, 2021</b>	6,032,145	\$ 61,772,761	2,495,933	\$ 21,119,940	\$ 82,892,701	5,275,936	\$ 5,276	—	\$ —	\$ 4,763,900	\$ (39,954,956)	\$ (35,185,780)

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

**IMMUNEERING CORPORATION**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
**FOR THE SIX MONTHS ENDED JUNE 30, 2021 and 2020**  
**(Unaudited)**

	<u>2021</u>	<u>2020</u>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (14,217,316)	\$ (6,804,882)
Adjustment to reconcile to net loss to net cash used in operating activities:		
Depreciation expense	18,674	11,223
Right-of-use asset amortization	50,333	19,994
Stock based compensation expense	533,234	559,697
Change in assets and liabilities:		
(Increase) decrease in:		
Accounts receivable	5,005	(90,020)
Prepaid expenses and other current assets	(555,726)	(387,506)
Other assets	(946,053)	—
Increase (decrease) in:		
Accounts payable	(48,021)	601,874
Accrued expenses	2,619,878	427,933
Lease liability	(37,271)	(19,994)
Net cash used in operating activities	<u>(12,577,263)</u>	<u>(5,681,681)</u>
<b>Cash flows from investing activities:</b>		
Purchase of property and equipment	(36,388)	(9,754)
Net cash used in investing activities	<u>(36,388)</u>	<u>(9,754)</u>
<b>Cash flows from financing activities:</b>		
Proceeds from the issuance of Series A preferred stock, net of issuance costs	—	998,306
Proceeds from the issuance of Series B preferred stock, net of issuance costs	24,788,851	—
Proceeds from exercise of stock options	52,627	—
Proceeds from exercise of warrants	927,125	—
Net cash provided by financing activities	<u>25,768,603</u>	<u>998,306</u>
<b>Net increase (decrease) in cash and cash equivalents</b>	<b>13,154,952</b>	<b>(4,693,129)</b>
<b>Cash and cash equivalents at beginning of period</b>	<b>37,090,151</b>	<b>13,782,175</b>
<b>Cash and cash equivalents at end of period</b>	<b><u>\$ 50,245,103</u></b>	<b><u>\$ 9,089,046</u></b>
<b>Supplemental disclosures of noncash information:</b>		
Reclassification of liability for Series A preferred stock	\$ —	\$ 3,509,802
Deferred offering costs included in accounts payable and accrued expenses	<u>\$ 875,078</u>	<u>\$ —</u>

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

**IMMUNEERING CORPORATION**  
**NOTES TO UNAUDITED CONDENSED CONSOLIDATED FINANCIAL STATEMENTS**  
**(Unaudited)**

**Note 1 – Organization and Nature of Business**

Immuneering Corporation, a Delaware corporation, (“Immuneering” or the “Company”) was incorporated in 2008. The Company is a biopharmaceutical company with an emerging pipeline focused on improving patient outcomes across a spectrum of debilitating oncologic and neurologic diseases by applying the Company’s deep knowledge of translational bioinformatics to every stage of the drug development process. The Company has more than a decade of experience in translational bioinformatics and generating insights into drug mechanisms of action and patient treatment responses. Building on this experience, the Company developed a disease agnostic platform that enables the Company to utilize human data, novel biology and chemistry, and translational planning to create and advance the Company’s wholly owned pipeline.

On October 30, 2019, Immuneering formed a wholly owned subsidiary, Immuneering Securities Corporation (“ISC”), a Massachusetts securities corporation, for the sole purpose of buying, selling and holding securities on the Company’s behalf. Immuneering and ISC are collectively referred to as “the Company” throughout these consolidated financial statements.

Since inception, the Company has devoted substantially all of its efforts to business planning, service revenue generation, research and development, recruiting management and technical staff, and raising capital. The Company has financed its operations through service revenues, the issuance of convertible debt and the sale of convertible preferred stock and common stock.

The Company is subject to a number of inherent risks associated with any biotechnology company that has substantial expenditures for research and development. These risks include, but are not limited to, the need to obtain adequate additional funding, possible failure of clinical trials or other events demonstrating lack of clinical safety or efficacy of its product candidates, dependence on key personnel, reliance on third-party service providers for manufacturing drug product and conducting clinical trials, the ability to successfully secure its proprietary technology, and risks related to the regulatory approval and commercialization of a product candidate. There can be no assurance that the Company’s research and development program will be successful. In addition, the Company operates in an environment of rapid technological change and is largely dependent on the services of its employees, advisors, and consultants.

On August 3, 2021, the Company completed its initial public offering (“IPO”) pursuant to which it issued and sold 8,625,000 shares of its Class A common stock, inclusive of 1,125,000 shares of its Class A common stock sold pursuant to the full exercise of the underwriters’ option to purchase additional shares. The aggregate net proceeds received by the Company from the IPO were \$120,318,750, after deducting underwriting discounts and commissions, but before deducting offering costs payable by the Company, which are estimated to be \$2,000,000. Upon the closing of the IPO, all 8,528,078 shares of the Company’s convertible preferred stock then outstanding automatically converted into 11,939,281 shares of Class A common stock (see Note 11).

To date, the Company has funded its operations through service revenues, and with proceeds from the sale of its capital stock and convertible notes and, most recently, with proceeds from the IPO. The Company has incurred recurring losses over the past several years and as of June 30, 2021, the Company had an accumulated deficit of \$39,954,956. The Company expects to continue to generate operating losses for the foreseeable future. The future viability of the Company is dependent on its ability to raise additional capital to finance its operations. The Company’s inability to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies. There can be no assurances that additional funding will be available on terms acceptable to the Company, or at all. If the Company is unable to raise additional funds when needed, it may be required to delay, reduce the scope of, or eliminate development programs, which may adversely affect its business and operations. Management considers that there are no conditions or events, in the aggregate, that raise substantial doubt about the entity’s ability to continue as a going concern and estimates that its cash and cash equivalents will be sufficient to fund its operating expenses and capital expenditure requirements for at least 12 months from the issuance date of the interim consolidated financial statements. The full extent to which coronavirus (“COVID-19”) pandemic will directly or indirectly impact the Company’s business, results of operations and

financial condition, including expenses and research and development costs, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and its variants and the actions taken to contain or treat COVID-19 and its variants, as well as the economic impact on local, regional, national and international markets. The Company has considered potential impacts arising from the pandemic related to COVID-19 and its variants and is not presently aware of any events or circumstances that would require the Company to update its estimates, judgements or revise the carrying values of its assets or liabilities.

## **Note 2 - Summary of Significant Accounting Policies**

### **Basis of Presentation**

The consolidated financial statements have been prepared in accordance with accounting standards set by the Financial Accounting Standards Board (“FASB”). The FASB sets generally accepted accounting principles (“GAAP”) to ensure the consolidated financial statements are consistently reported. References to GAAP issued by the FASB in these footnotes are to the FASB Accounting Standards Codifications (“ASC”). The consolidated financial statements include the accounts of the Company and its wholly owned subsidiary. All intercompany balances and transactions have been eliminated in consolidation.

There have been no material changes to the accounting policies of the Company as those set forth in Note 2 to the audited consolidated financial statements contained in the final prospectus, dated July 29, 2021, filed with the SEC on July 30, 2021 pursuant to Rule 424(b) relating to our Registration Statement on Form S-1 (File No. 333-257791) (the “Prospectus”).

### **Unaudited Interim Financial Information**

The unaudited interim consolidated financial statements of the Company have been prepared, without audit, in accordance with GAAP and in accordance with the rules and regulations of the Securities and Exchange Commission (“SEC”) regarding interim financial reporting. Certain information and footnote disclosures normally included in the annual financial statements prepared in accordance with GAAP have been omitted from the unaudited interim consolidated financial statements, as is permitted by such rules and regulations. While we believe that the disclosures presented are adequate in order to make the information not misleading, these unaudited interim consolidated financial statements should be read in conjunction with the Company’s audited consolidated financial statements and notes for the year ended December 31, 2020.

It is management’s opinion that these financial statements include all normal and recurring adjustments necessary for a fair presentation of the Company’s financial position, operating results and cash flows. Revenues and net loss for any interim period are not necessarily indicative of future or annual results.

### **Deferred Offering Costs**

The Company capitalizes certain legal, professional accounting and other third-party fees that are directly associated with in-process equity financings as deferred offering costs until such financings are consummated. After consummation of an equity financing, these costs are recorded as a reduction of the proceeds from the offering, either as a reduction of the carrying value of the preferred stock or in stockholder's equity (deficit) as a reduction of additional paid-in capital generated as a result of the offering. Should the in-process equity financing be abandoned, the deferred offering costs would be expensed immediately as a charge to operating expenses in the statements of operations and comprehensive loss. There were no deferred offering costs as of December 31, 2020. As of June 30, 2021, deferred offering costs of \$946,053 related to the IPO were recorded in the Company's consolidated balance sheets.

### **Stock Split**

On July 23, 2021, the Company approved a one-for-1.4 stock split which was consummated in connection with the Company's IPO. All information in the accompanying financial statements and notes thereto regarding share amounts of common stock, price per share of common stock and the conversion factor for Series A and Series B Preferred Stock into common stock have been adjusted to reflect the application of the stock split on a retroactive basis.

### **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, liabilities, revenues and expenses during the reporting periods. These estimates and assumptions are based on current facts, historical experience and various other factors believe to be reasonable under the circumstances, the results of which form the basis for making judgements about the carrying values of assets liabilities and the recording of expenses that are not readily apparent from other sources. Significant estimates reflected in these consolidated financial statements included but are not limited to, the research and development expenses, determination of fair value of stock-based awards, the valuation of common stock, and the right-to-use assets and operating lease liability. Actual results may differ materially and adversely from these estimates.

### **Recently Issued Accounting Pronouncements**

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. The Company is an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, as amended (Jobs Act). The Jobs Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. The Company elected to avail itself of this extended transition period and, as a result, we will not be required to adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

In June 2016, the FASB issued ASU 2016-13, Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Statements. The new standard, as amended, requires that expected credit losses relating to financial assets measured on an amortized cost basis and available-for-sale debt securities be recorded through an allowance for credit losses. It also limits the amount of credit losses to be recognized for available-for-sale debt securities to the amount by which carrying value exceeds fair value and also requires the reversal of previously recognized credit losses if fair value increases. The targeted transition relief standard allows filers an option to irrevocably elect the fair value option of ASC 825-10, Financial Instruments-Overall, applied on an instrument-by-instrument basis for eligible instruments. ASU No. 2016-13, Financial Instruments - Credit Losses (Topic 326) will become effective for the Company on January 1, 2023. The Company is currently assessing the impact of the adoption of this guidance on its consolidated financial statements.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740): Simplifying the Accounting for Income Taxes, which simplifies the accounting for income taxes by removing certain exceptions to the general principles in the existing guidance for income taxes and making other minor improvements. The amendments are effective for annual

reporting periods beginning after December 15, 2020 with early adoption permitted. The Company is currently assessing the impact of the adoption of this guidance on its consolidated financial statements.

### Note 3 – Property and Equipment, net

Property and equipment, net consisted of the following:

	<u>June 30, 2021</u>	<u>December 31, 2020</u>
Computer equipment	\$ 210,705	\$ 174,317
Furniture and fixtures	18,798	18,798
Total	229,503	193,115
Accumulated depreciation	(147,426)	(128,752)
Property and equipment, net	<u>\$ 82,077</u>	<u>\$ 64,363</u>

Depreciation expense totaled \$9,807 and \$5,916 for the three months ended June 30, 2021 and 2020, respectively. Depreciation expense totaled \$18,674 and \$11,223 for the six months ended June 30, 2021 and 2020, respectively.

### Note 4 – Accrued Expenses

Accrued expenses consisted of the following:

	<u>June 30, 2021</u>	<u>December 31, 2020</u>
Accrued professional services	\$ 1,110,157	\$ 269,302
Accrued employee expenses	1,685,293	163,668
Accrued contract research expenses	523,420	266,022
Total	<u>\$ 3,318,870</u>	<u>\$ 698,992</u>

### Note 5 – Convertible Preferred Stock

#### Series A Preferred Stock

In September 2019, the Company authorized the sale and issuance of up to 1,987,979 shares of Series A Preferred Stock, \$0.001 par value per share, at an original issuance price of \$8.5514 per share. In January 2020, the number of shares authorized for the Series A Preferred Stock was increased to 2,495,933 shares. The Series A Preferred Stock financing was structured to be issued in rolling closes during 2019 and 2020.

On September 20, 2019, the Company issued an additional 1,122,458 shares of Series A Preferred Stock for gross cash proceeds of \$9,598,847 and issued 785,706 shares of Series A Preferred Stock in conjunction with the conversion of the outstanding amount of the Convertible Notes. In 2019, the Company incurred issuance costs of \$200,587 in connection with this offering.

The Company received funds for issuance of an additional 468,315 shares of Series A Preferred Stock for gross cash proceeds of \$4,004,975 through December 31, 2019. Of these shares, 410,436 shares of Series A Preferred Stock for gross cash proceeds of \$3,509,802 exceeded the authorized amount allowed by the articles of incorporation, resulting in a liability of \$3,509,802 and a total of 1,966,043 shares of Series A Preferred Stock outstanding at December 31, 2019. In January 2020, the shares that were previously classified as a liability as of December 31, 2019 were reclassified to temporary equity upon the approved increase to authorized shares of Series A Preferred Stock.

In January 2020, the Company issued 119,454 additional shares of Series A Preferred Stock for gross cash proceeds of \$1,021,413. The Company incurred issuance costs of \$23,610 in connection with the financing in January 2020.

### **Series B Preferred Stock**

In December 2020, the Company authorized the sale and issuance of up to 6,032,183 shares of Series B Preferred Stock, \$0.001 par value per share, at an original issuance price of \$10.2782 per share. The Series B Preferred Stock financing was structured to close in two tranches. The first tranche closed in December 2020 and the Company issued 3,619,292 shares of Series B Preferred Stock for gross cash proceeds of \$37,199,929. The Company incurred issuance costs of \$216,019 in connection with the financing in December 2020.

The Company determined the right of the investors to purchase 2,412,853 shares of Series B Preferred Stock in the second tranche does not meet the definition of a freestanding financial instrument as it is not separable from the Series B Preferred Stock issued in the first tranche. The issuance of the second tranche is subject to the Company meeting certain development milestones or at the election of the holders of at least a majority of the then outstanding shares of Series B Preferred Stock which must include one specific shareholder (the "Requisite Holders"). Each holder of Series B Preferred Stock may elect to purchase their requisite shares of the second tranche at any time. As of March 31, 2021, the Company has not met these development milestones nor did the Requisite Holders elect to purchase the second tranche prior to meeting these milestones and therefore no shares of the second tranche were issued.

In April and May 2021, all 2,412,853 shares of the second tranche of Series B Preferred Stock were issued based on the voluntary election of substantially all of the holders of Series B Preferred Stock. The Company received gross proceeds of \$24,799,786. The Company incurred issuance costs of \$10,935 in connection with the second tranche of Series B Preferred Stock.

As of June 30, 2021, the rights and preferences of the Series A Preferred Stock and Series B Preferred Stock ("Preferred Stock") are as follows:

#### Conversion

Each share of Preferred Stock may be converted at any time, at the option of the holder, into shares of Class A common stock, subject to the applicable conversion rate as determined by dividing the original issue price by the conversion price. The conversion price for the Series A Preferred Stock and Series B Preferred Stock (as may be adjusted for certain customary dilutive events) is \$6.1081 and \$7.3416, respectively. The Preferred Stock automatically convert into shares of Class A common stock at the then effective conversion rate upon the closing of a public offering of the Company's securities with gross proceeds to the Company of at least \$75,000,000 and a share price of at least \$7.3416 or at the election of the holders of the Requisite Holders.

Holders of Series B Preferred Stock that would beneficially own at least 9.9% of any then outstanding class of equity securities may elect to receive a portion of their converted Series B Preferred Stock as Class B common stock upon conversion.

Upon the closing of the IPO on August 3, 2021, all 8,528,078 shares of the Company's convertible preferred stock then outstanding automatically converted into 11,939,281 shares of Class A common stock (see Note 11).

#### Dividends

Preferred Stockholders are entitled to receive per annum dividends of 7% of the original issue price share, payable only when, as and if declared by the Board of Directors. The right to receive these dividends is not cumulative, and therefore, if not declared in any year, the right to receive such dividends shall terminate and not carry forward into the next year. As of June 30, 2021 and December 31, 2020, no dividends had been declared.

### Voting Rights

Preferred Stock and common stock vote together as one class on an as converted basis. Common stock voting rights on certain matters are subject to the powers, preferences, and rights of the Preferred Stock. Preferred Stockholders are entitled to vote on all matters and shall have the number of votes equal to the number of shares of common stock into which the shares of Preferred Stock held by such holder are then convertible. As long as 2,132,029 shares of Preferred Stock are outstanding, certain actions such as mergers, acquisition, liquidation, dissolution, wind up of business, and deemed liquidation events, must be approved by the holders of at least a majority of the then-outstanding shares of Preferred Stock.

### Liquidation Preference

Upon liquidation, dissolution, or winding up of business, holders of Preferred Stock are entitled to receive a liquidation preference in priority to holders of common stock at the original respective Preferred Stock issue price for such series. If assets available for distribution are insufficient to satisfy the liquidation payment to holders of Preferred Stock in full, assets available for distribution will be allocated among holders of Preferred Stock on a pari passu basis at an amount per share equal to the greater of the respective original Preferred Stock issue price for such series plus any declared but unpaid dividends or such amount had all shares been converted to common stock.

When holders of Preferred Stock are satisfied in full, any excess assets available for distribution will be allocated ratably among common stock holders based on their pro rata shareholdings. Upon a deemed liquidation event, as defined in the articles of incorporation, holders have the option to redeem their shares at the liquidation payment amounts summarized above.

### Redemption

Other than described above, the shares of Preferred Stock are not redeemable.

### **Note 6 - Common Stock**

As of June 30, 2021 and December 31, 2020, the Company has 22,026,200 authorized shares of Class A common stock, \$0.001 par value per share, of which 5,275,936 and 4,950,129 are issued and outstanding, respectively. The holders of Class A common stock are entitled one vote for each share of common stock. Dividends may be paid when, and if declared by the Board of Directors, subject to the limitations, powers and preferences granted to the Preferred Stockholders and on a proportionate basis with holders of Class B common stock.

As of June 30, 2021 and December 31, 2020, the following number of shares of Class A common stock have been reserved:

	<u>June 30, 2021</u>	<u>December 31, 2020</u>
Conversion of Series A Preferred	3,494,284	3,494,284
Conversion of Series B Preferred	8,444,997	5,066,995
Exercise of common stock warrants	—	308,308
Exercise of common stock options	2,668,327	1,801,263
	<u>14,607,608</u>	<u>10,670,850</u>

As of June 30, 2021 and December 31, 2020, the Company has 6,032,183 authorized shares of Class B common stock, \$0.001 par value per share, of which no shares have been issued nor are outstanding. The holders of Class B common stock have no voting rights. Dividends may be paid when, and if, declared by the Board of Directors, subject to the limitations, powers and preferences granted to the preferred stockholders and on a proportionate basis with holders of Class A common stock.



## Common Stock Warrants

During 2019, the Company issued warrants to purchase an aggregate of 308,308 shares of Class A common stock at an exercise price of \$3.01 per share to several advisors, including 200,984 shares to entities related to members of the Board of Directors of the Company, in lieu of cash payments. These warrants vested immediately upon issuance, became exercisable on January 9, 2021 and have a 10-year term set to expire on January 9, 2030. The Company evaluated the terms of these warrants and determined that equity classification was appropriate. As of December 31, 2020, no warrants had been exercised. During June 2021, all warrant holders exercised their warrants to purchase an aggregate of 308,308 shares of common stock. As of June 30, 2021, there were no warrants outstanding.

## Note 7 - Net Loss Per Share Attributable to Common Stockholders

Net loss per share of common stock is computed using the two-class method required for multiple classes of common stock and participating securities based upon their respective rights to receive dividends as if all income for the period has been distributed. The rights, including the liquidation and dividend rights and sharing of losses, of the Class A and Class B common stock are identical, other than voting rights. As the liquidation and dividend rights and sharing of losses are identical, the undistributed earnings are allocated on a proportionate basis and the resulting net loss per share attributed to common stockholders is therefore the same for Class A and Class B common stock on an individual or combined basis.

The Company's participating securities include the Company's Preferred Stock, as the holders are entitled to receive noncumulative dividends in the event that a dividend is paid on common stock. The holders of Preferred Stock do not have a contractual obligation to share in losses of the Company, and therefore during periods of loss there is no allocation required under the two-class method.

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 during the period, adjusted for outstanding shares that are subject to repurchase.

Diluted net loss per share is computed by giving effect to all potentially dilutive securities outstanding for the period using the treasury stock method or the if-converted method based on the nature of such securities. The Company has reported net losses for all periods presented, therefore diluted net loss per common share attributable to common stockholders is the same as basic net loss per common share attributable to common stockholders, because potentially dilutive common shares are not assumed to have been issued if their effect is anti-dilutive.

Basic and diluted net loss per share attributable to common stockholders was calculated at June 30, 2021 and 2020 as follows:

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2021</u>	<u>2020</u>	<u>2021</u>	<u>2020</u>
<b>Numerator:</b>				
Net loss	\$ (7,987,665)	\$ (3,604,162)	\$ (14,217,316)	\$ (6,804,882)
<b>Denominator - basic and diluted:</b>				
Weighted-average common shares outstanding, basic and diluted	4,954,553	4,950,129	4,952,352	4,950,129
Net loss per share - basic and diluted	<u>\$ (1.61)</u>	<u>\$ (0.73)</u>	<u>\$ (2.87)</u>	<u>\$ (1.37)</u>

The following table sets forth the potentially dilutive securities that have been excluded from the calculation of diluted net loss per share because to include them would be anti-dilutive (in common stock equivalent shares) at June 30, 2021 and 2020:

	<u>2021</u>	<u>2020</u>
Series A Preferred	3,494,284	3,494,306
Series B Preferred	8,444,997	—
Warrants to purchase common stock	—	308,308
Options to purchase common stock	2,668,327	1,766,234
Total shares of common stock equivalents	<u>14,607,608</u>	<u>5,568,848</u>

#### Note 8 – Stock-Based Compensation

During 2015, the Company established the Long Term Incentive Plan (“Incentive Plan”), under which incentive stock options, nonqualified stock options, restricted stock or other awards may be awarded to employees, directors or consultants of the Company. The options typically vest over a four-year period. As of June 30, 2021, the maximum number of shares available for issuance under the Incentive Plan was 2,825,173 shares. As of June 30, 2021, the number of shares available for future grants under the Incentive Plan was 137,947 shares. However, from and after the effectiveness of the Company’s 2021 Incentive Award Plan, no additional awards will be granted under the Incentive Plan.

During the three and six months ended June 30, 2021, the Company recognized stock-based compensation expense of \$351,009 and \$533,234, respectively. During the three and six months ended June 30, 2020, the Company recognized stock-based compensation expense of \$287,554 and \$559,697, respectively. As of June 30, 2021, compensation expense remaining to be recognized for outstanding stock options was \$6,765,850 and to be recognized over a weighted-average period of 2.4 years.

The fair value of options granted is calculated on the grant date using the Black-Scholes option valuation model. For the six months ended June 30, 2021, the Company granted 1,160,894 shares of stock options at a weighted-average grant date fair value of \$8.66. For the six months ended June 30, 2020, the Company granted 285,740 shares at a weighted-average grant date fair value of \$3.01.

The Company used the following assumptions in its application of the Black-Scholes option pricing model for grants during the six months ended June 30, 2021 and 2020:

	<u>Six Months Ended June 30,</u>	
	<u>2021</u>	<u>2020</u>
Weighted-average risk-free interest rate	1.04% - 1.71%	1.21%
Expected term (in years)	5.83 - 10 years	6.01 years
Expected dividend yield	0%	0%
Expected volatility	68.92% - 80.99%	67.30%

The following table summarizes the stock option activity during the six months ended June 30, 2021 under the Plan:

	Number of Options	Weighted- Average Exercise Price per Share	Weighted Average Remaining Contractual Term (in Years)	Aggregate Intrinsic Value
Outstanding at of December 31, 2020	1,801,263	\$ 3.01	8.37	
Granted	1,160,894	\$ 8.66		
Exercised	(17,499)	\$ 3.01		
Cancelled	(276,331)	\$ 3.58		
Outstanding at June 30, 2021	2,668,327	\$ 5.41	8.61	\$ 11,548,289
Vested and exercisable at June 30, 2021	1,059,428	\$ 3.01	7.51	\$ 7,128,724
Vested and expected to vest at June 30, 2021	2,668,327	\$ 5.41	8.61	\$ 11,548,289

For the three and six months ended June 30, 2021 and 2020, the Company recognized share-based compensation expense recognized on the accompanying condensed consolidated statements of operations as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Cost of revenue	\$ 22,367	\$ 27,641	\$ 44,882	\$ 52,558
Research and development	168,725	131,182	222,732	262,364
General and administrative	159,917	128,731	265,620	244,775
Total	\$ 351,009	\$ 287,554	\$ 533,234	\$ 559,697

## Note 9 – Commitments and Contingencies

### Operating Leases

The Company leases office space in Cambridge, Massachusetts, New York, New York and as of July 2021, San Francisco, California, pursuant to short-term arrangements. The Cambridge and San Francisco leases are on a month-to-month basis, requiring one month’s notice before termination. The New York lease is renewable on a quarterly basis and the last renewal was on June 15, 2021 which extended the lease term until September 30, 2021. These lease agreements include payments for lease and non-lease components and the Company has elected to not separate such components and these payments were recognized as rent expense.

As of June 30, 2021, total future minimum lease payments for its short-term leases in Cambridge, Massachusetts, New York, New York and San Francisco, California was \$26,040 due in 2021 and \$11,040 due in 2022. The Company leases storage space for its electronic data equipment in Somerville, Massachusetts. This lease is renewable on an annual basis effective every March 1st. Prior to June 30, 2021, the Company renewed the lease through March 31, 2022. As of June 30, 2021, total future minimum lease payments for this lease were \$10,708 due in 2021 and \$3,569 due in 2022.

In July 2019, the Company entered into an office lease in San Diego, California (“2019 San Diego Lease”) with a lease term of 24 months with no escalations and variable costs based on additional number of employees using the facility. This lease was cancelable upon a 30-day notice period. Upon adoption of ASC 842 on January 1, 2020, a right-to-use asset and lease liability based on the fixed costs was recognized by the Company for \$61,822. Effective September 20, 2020, the lease was terminated, and the remaining right-of-use asset and lease liability were derecognized. No gain or loss was recognized for the termination of this lease.

In October 2020, the Company entered into an office lease in San Diego, California (“2020 San Diego Lease”) with a lease term of 67 months. At the lease commencement date, a right-to-use asset and lease liability was recognized by the Company for \$637,863.

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Maturities of the lease liabilities due under the Company's 2020 San Diego Lease as of June 30, 2021 are as follows:

	<u>Amount</u>
Remainder of 2021	\$ 56,087
2022	115,430
2023	125,741
2024	161,498
2025	167,150
2026	57,332
Total future lease payments	683,238
Less: Imputed interest	(99,420)
Total lease liabilities	<u>\$ 583,818</u>
Current portion lease liability	\$ 80,605
Lease liability, noncurrent	503,213
Total lease liability	<u>\$ 583,818</u>

Quantitative information regarding the Company's leases for the six months ended June 30, 2021 and 2020 is as follows:

	<u>June 30, 2021</u>	<u>June 30, 2020</u>
Lease costs:		
Operating lease cost	\$ 68,502	\$ 21,600
Short-term lease cost	117,352	138,995
Variable lease cost	—	8,200
Total lease costs	<u>\$ 185,854</u>	<u>\$ 168,795</u>
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	\$ 55,440	\$ 21,600
Operating cash flows from short-term leases	117,352	138,995
	<u>\$ 172,792</u>	<u>\$ 160,595</u>
Weighted-average remaining lease term - operating leases	4.83 years	5.83 years
Weighted-average discount rate - operating leases	6.0 %	6.0 %

As the Company's leases typically do not provide an implicit rate, the Company uses an estimate of its incremental borrowing rate based on the information available at the lease commencement date in determining the present value of lease payments.

#### Litigation

From time to time, the Company may have certain contingent liabilities that arise in the ordinary course of its business activities and may be exposed to litigation in connection with its products and operations. The Company's policy is to assess the likelihood of any adverse judgments or outcomes related to legal matters, as well as ranges of probable losses. When it is probable that future expenditures will be made and can be reasonably estimated the Company will accrue a liability for such matters. Significant judgement is required to determine both probability and estimated amount. The Company is not aware of any material legal matters.

#### Clinical Research Contracts

The Company may enter into contracts in the normal course of business with clinical research organizations for clinical trials, with contract manufacturing organizations for clinical supplies, and with other vendors for preclinical studies, supplies and other services for our operating purposes. These contracts generally provide for termination with a 30-day notice.

#### **Note 10 – Related Party Transactions**

An officer of the Company is a board member of a contract research organization (“CRO”) that provides contract services to the Company. Research and development expenses in the accompanying condensed consolidated statement of operations include the cost of services provided by the CRO to the Company which amounted to \$2,096,425 and \$1,212,433 for the six months ended June 30, 2021 and 2020, respectively. As of June 30, 2021 and December 31, 2020, \$352,642 and \$279,153, respectively, was owed to the CRO and is included in accounts payable or accrued contract research expenses in the accompanying consolidated balance sheets.

#### **Note 11 – Subsequent Events**

##### ***Initial Public Offering***

On August 3, 2021, the Company completed its IPO, pursuant to which it issued and sold 8,625,000 shares of its Class A common stock, inclusive of 1,125,000 shares of its Class A common stock sold pursuant to the full exercise of the underwriters’ option to purchase additional shares. The aggregate net proceeds received by the Company from the IPO were approximately \$120,318,750, after deducting underwriting discounts and commissions, but before deducting offering costs payable by the Company, which are estimated to be \$2,000,000. Upon the closing of the IPO, all of the 8,528,078 shares of the Company’s convertible preferred stock then outstanding automatically converted into 11,939,281 shares of Class A common stock. Upon the conversion of the convertible preferred stock, the Company reclassified the carrying value of the convertible preferred stock to common stock (at par value) and additional paid-in capital.

##### ***Increase in Authorized Number of Shares of Common Stock and Changes in Authorized Preferred Stock***

On July 23, 2021, in connection with the closing of the IPO, the Company filed a restated certificate of incorporation, which amended and restated the Company’s certificate of incorporation to, among other things: (i) increase the number of authorized shares of common stock to 200,000,000 shares of Class A common stock, 20,000,000 shares of Class B common stock, par value \$0.001 per share (the “Class B Common Stock”), and (ii) authorize 10,000,000 shares of Preferred Stock; and (iii) authorize the Board to establish the rights, preferences and restrictions on any unissued series of Preferred Stock.

##### ***2021 Incentive Award Plan***

On July 23, 2021, the Company’s board of directors adopted, and on July 23, 2021 its stockholders approved, the 2021 Incentive Award Plan (the “2021 Plan”), which became effective on July 29, 2021. The 2021 Plan provides for the grant of incentive stock options, stock appreciation rights, restricted stock awards, restricted stock units, and other stock-based awards. The number of shares reserved for issuance under the 2021 Plan is initially equal to 2,590,000 plus an annual increase on the first day of each calendar year, beginning on January 1, 2022 and ending on and including January 1, 2031, equal to the lesser of (i) 4% of the aggregate number of shares of Class A common stock outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares of Class A common stock as determined by the Board of Directors. No more than 15,350,000 shares of Class A common stock may be issued under the 2021 Plan upon the exercise of incentive stock options. Shares issued under the 2021 Plan may be authorized but unissued shares, shares purchased on the open market or treasury shares. If an award under the 2021 Plan expires, lapses or is terminated, exchanged for or settled in cash, surrendered, repurchased, cancelled without having been fully exercised/settled or forfeited, any unused shares subject to the award will, as applicable, become or again be available for new grants under the 2021 Plan. In addition, shares subject to stock options issued under the Incentive Plan may become available for issuance under the 2021 Plan to the extent such stock options are canceled, forfeited, exchanged, settled in cash or otherwise terminated.

##### ***2021 Employee Stock Purchase Plan***

On July 23, 2021, the Company’s board of directors adopted, and on July 23, 2021 its stockholders approved, the 2021 Employee Stock Purchase Plan (the “2021 ESPP”), which became effective on July 29, 2021. A total of 250,000

shares of Class A common stock were initially reserved for issuance under this plan. The number of shares of Class A common stock that may be issued under the 2021 ESPP will automatically increase on the first day of each calendar year, beginning on January 1, 2022 and ending on and including January 1, 2031, equal to the lesser of (i) 1% of the shares of Class A common stock outstanding on the final day of the immediately preceding calendar year and (ii) such smaller number of shares of Class A common stock as determined by the board of directors, provided that not more than 3,340,000 shares of Class A common stock may be issued under the 2021 ESPP.

## MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our final prospectus for our initial public offering filed pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, or the Securities Act, with the Securities and Exchange Commission, or SEC, on July 30, 2021 (the "Prospectus"). Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.*

### Overview

We are a biopharmaceutical company with an emerging pipeline focused on improving patient outcomes across a spectrum of debilitating oncologic and neurologic diseases by applying our deep knowledge of translational bioinformatics to every stage of the drug development process. We have more than a decade of experience in translational bioinformatics and generating insights into drug mechanisms of action and patient treatment responses. Building on this experience, we developed a disease agnostic platform that enables us to utilize human data, novel biology and chemistry, and translational planning to create and advance our wholly owned pipeline. Our current development programs in oncology are focused on providing treatments for patients with solid tumors caused by mutations of the RAS/RAF/MEK/ERK pathway and other oncologic signaling pathways. Our lead product candidate, IMM-1-104, is designed to be a highly selective dual-MEK inhibitor that further disrupts the kinase suppressor of RAS 1 and 2 for the treatment of advanced solid tumors in patients harboring RAS mutant tumors. We plan to submit an Investigational New Drug, or IND, for IMM-1-104 to the U.S. Food and Drug Administration, or the FDA, in the first quarter of 2022. In addition, we anticipate filing at least two additional INDs for our other oncology programs, one in each of 2023 and 2024.

For the period from inception through 2017, we devoted substantially all of our efforts to business planning, service revenue generation, developing tools to aid in drug discovery, and recruiting management and technical staff. Since 2018, we have also focused significant effort on our own internal research and development programs. We have financed our operations through service revenues, the issuance of convertible debt and the sale of convertible preferred stock and common stock.

Our operations have been financed primarily by service revenues and aggregate net proceeds of approximately \$81.4 million from the issuance of convertible notes payable, convertible preferred stock including gross proceeds of approximately \$24.8 million from the issuance of shares in the second tranche of Series B Preferred in April and May 2021, common stock, exercise of stock options and most recently, with proceeds from our completed initial public offering ("IPO"). On August 3, 2021, we completed our IPO pursuant to which we issued and sold 8,625,000 shares of Class A common stock, inclusive of 1,125,000 shares sold by us pursuant to the full exercise of the underwriters' option to purchase additional shares. We received aggregate net proceeds of approximately \$120.3 million from the IPO, after deducting underwriting discounts and commissions, but before deducting offering costs payable by us, which are estimated to be \$2.0 million.

Since inception, we have had significant annual operating losses. Our net loss was approximately \$14.2 million, for the six months ended June 30, 2021 and \$17 million for the year ended December 31, 2020. As of June 30, 2021, we had an accumulated deficit of approximately \$40.0 million and approximately \$50.2 million in cash and cash equivalents.

Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, as reflected in the change in our accounts payable and accrued expenses. We expect to continue to incur net losses for the foreseeable future, and we expect our research and development expenses, general and administrative expenses, and capital expenditures will continue to increase. In particular, we expect our expenses to increase as we continue our development of, and seek regulatory approvals for, our internally developed product candidates as well as add operational, financial and management

informational systems and personnel to support our product development as well as support our transition to a public company. In addition, if and when we seek and obtain regulatory approval to commercialize any product candidate, we will also incur increased expenses in connection with commercialization and marketing of any such product. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of our clinical trials and our expenditures on other research and development activities.

Based upon our current business plans, we believe that our existing cash and cash equivalents, inclusive of the net proceeds from the IPO, will be sufficient to fund our development activities and other operations into 2024. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. To finance our operations beyond that point we will need to raise additional capital, which cannot be assured.

We have not had any internally developed products approved for sale. We do not expect to generate any product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our internally developed product candidates. If we obtain regulatory approval for any of our internally developed product candidates, we expect to incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution. As a result, until such time, if ever, that we can generate substantial product revenue, we expect to finance our cash needs through service revenue, equity offerings, debt financings or other capital sources, including collaborations, licenses or similar arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed or on favorable terms, if at all. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies, including our research and development activities. If we are unable to raise capital, we will need to delay, reduce or terminate planned activities to reduce costs.

In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic. In particular, the ongoing pandemic related to COVID-19 and its variants has resulted in federal, state and local governments and private entities mandating various restrictions, including travel restrictions, access restrictions, restrictions on public gatherings, and stay at home orders. The effect of these orders, government imposed quarantines and measures we have taken, such as implementing work-at-home policies, may negatively impact productivity, disrupt our business and/or could adversely affect our development plans and results. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions, but if we or any of the third parties with whom we engage, including personnel at third-party manufacturing facilities and other third parties with whom we conduct business, were to experience shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timeline presently planned could be materially and adversely impacted. It is unknown how long these conditions will last and what the complete effect will be on us. While to date we have been able to continue to execute our overall business plan, some of our business activities have been slowed and taken longer to complete, particularly with respect to our process for recruiting new employees, and we continue to adjust to the challenges of operating in a largely remote setting with our employees. Overall, we recognize the challenges the pandemic may pose to our business, will continue to closely monitor events as they develop and plan for alternative and mitigating measures that we can implement if needed.

## **Components of Our Results of Operations**

### **Revenue**

Our revenue is generated by providing computational biology professional services to pharmaceutical and biotechnology companies. We charge an agreed upon rate per hour based on the aggregate level of personnel assigned to work on the project or a fixed fee for a defined scope of work. Our contracts specify the period of time over which these professional services will be provided. We recognize revenue over time by measuring the progress toward complete satisfaction of the performance obligation using a single method of measuring progress, which depicts the performance in transferring control of the associated services to the customer. We use input methods to measure the progress toward the complete satisfaction of performance obligations and evaluate the measure of progress each reporting period and, if necessary, adjust the measure of performance and related revenue recognition. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenue and net loss in the period of adjustment.



We expect revenue to remain similar to prior years in the near-term as we continue to provide services to our existing customers and these revenues could decrease as we have deprioritized new services work in order to focus on developing our wholly owned pipeline.

### **Cost of Revenue**

Our cost of revenue expenses consists primarily of costs related to providing professional services to our customers. These costs include salaries, bonuses, benefits, and equity-based compensation expense, depreciation, facilities, and other outside services.

### **Operating Expenses**

Our operating expenses consist of (i) research and development expenses and (ii) general and administrative expenses.

### **Research and Development**

Research and development expenses account for a significant portion of our operating expenses. Our research and development expenses consist primarily of direct and indirect costs incurred in connection with the development of our research platform, product candidates, discovery efforts and preclinical studies related to our program pipeline.

Our direct costs include:

- expenses incurred under agreements with CROs and other vendors that conduct our preclinical activities on our behalf; including laboratory expenses related to the execution of preclinical studies on our behalf;
- expenses associated with the manufacturing of our product candidates and preclinical material, including fees paid to contract manufacturers; and
- consulting fees and expenses related to preparation of initiation of clinical trials

Our indirect costs include:

- personnel-related expenses, consisting of employee salaries, bonuses, benefits and equity-based compensation expense and recruiting costs for personnel engaged in research and development activities; and
- facility and equipment related expenses, consisting of indirect and allocated expenses for rent, depreciation, maintenance of facilities, insurance, and other supplies.

We expense research and development costs as incurred. Our direct research and development expenses are not currently tracked on a program-by-program basis, but we anticipate tracking costs on a program-by-program basis at the time IMM-1-104 enters clinical trials, which we expect to occur in the first half of 2022. We use our personnel and infrastructure resources across multiple research and development programs directed toward identifying and developing product candidates.

Due to the inherently unpredictable nature and numerous risks and uncertainties associated with product development and the current stage of development of our product candidates and programs, we cannot reasonably estimate or know the nature, timing and estimated costs necessary to complete the remainder of the development of our product candidates or programs. We are also unable to predict if, when, or to what extent we will obtain approval and generate revenues from the commercialization and sale of any of our product candidates.

The duration, costs and timing of preclinical studies and clinical trials and development of our product candidates will depend on a variety of factors, such as:

- successful completion of preclinical studies and initiation of clinical trials for future product candidates;
- successful enrollment and completion of clinical trials for our current product candidates;

- data from our clinical programs that support an acceptable risk-benefit profile of our product candidates in the intended patient populations;
- acceptance by the FDA or other applicable regulatory agencies of IND applications, clinical trial applications and/or other regulatory filings for our product candidates;
- expansion and maintenance of a workforce of experienced scientists and others to continue to develop our product candidates;
- successful application for and receipt of marketing approvals from applicable regulatory authorities;
- obtainment and maintenance of intellectual property protection and regulatory exclusivity for our product candidates;
- making of arrangements with contract manufacturing organizations for, or establishment of, commercial manufacturing capabilities;
- establishment of sales, marketing and distribution capabilities and successful launch of commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of our product candidates, if and when approved, by patients, the medical community and third-party payors;
- effective competition with other therapies;
- obtainment and maintenance of coverage, adequate pricing and adequate reimbursement from third-party payors, including government payors;
- maintenance, enforcement, defense and protection of our rights in our intellectual property portfolio;
- avoidance of infringement, misappropriation or other violations with respect to others' intellectual property or proprietary rights; and
- maintenance of a continued acceptable safety profile of our products following receipt of any marketing approvals.

A change in the outcome of any of these variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate.

The process of conducting the necessary preclinical and clinical research to obtain regulatory approval is costly and time-consuming. The actual probability of success for our product candidates may be affected by a variety of factors.

We may never succeed in achieving regulatory approval for any of our product candidates. Further, a number of factors, including those outside of our control, could adversely impact the timing and duration of our product candidates' development, which could increase our research and development expense. We may obtain unexpected results from our preclinical studies and clinical trials. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. A change in the outcome of any of these factors could mean a significant change in the costs and timing associated with the development of our current and future preclinical and clinical product candidates. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development, or if we experience significant delays in execution of or enrollment in any of our preclinical studies or clinical trials, we could be required to expend significant additional financial resources and time on the completion of preclinical and clinical development.

We expect that our research and development expenses will substantially increase for the foreseeable future as we continue to implement our business strategy, which includes advancing our product candidates through clinical development, expanding our research and development efforts, including hiring additional personnel to support our research and development efforts, and seeking regulatory approvals for our product candidates that successfully complete clinical trials. In addition, product candidates in later stages of clinical development generally incur higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect our research and development expenses to increase as our product candidates advance into later stages of clinical development. As of the date of this prospectus, we cannot reasonably determine or accurately project total program-specific expenses through commercialization. There are numerous factors associated with the successful commercialization of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development.

## General and Administrative

Our general and administrative expenses consist primarily of personnel-related expenses, including employee salaries, bonuses, benefits, equity-based compensation, and recruiting costs for personnel in executive, finance, and other administrative functions. Other significant general and administrative expenses include legal fees relating to intellectual property and corporate matters, professional fees for accounting, tax and consulting services, insurance costs, travel expenses and facility related expenses not otherwise included in research and development expenses.

We expect our general and administrative expenses will substantially increase for the foreseeable future as we continue to increase our general and administrative headcount to support our continued research and development activities and, if any product candidates receive marketing approval, commercialization activities, as well as to support our operations generally. As we expand our operations, we also expect to incur increased expenses associated with operating as a public company, including costs related to accounting, audit, legal, regulatory, and tax-related services associated with maintaining compliance with exchange listing and rules and regulations of the SEC, Sarbanes-Oxley Act, director and officer insurance costs, and investor and public relations costs.

## Other Income (Expense), Net

Other income (expense), net consists primarily of interest income earned on our cash and cash equivalents carried at fair value, and interest expense related to the conversion of notes payable and a loss on the extinguishment of the convertible note.

## Results of Operations

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

The following table summarizes our results of operations for the periods indicated:

	<u>Three Months Ended June 30,</u>		<u>Change</u>	
	<u>2021</u>	<u>2020</u>	<u>\$</u>	<u>%</u>
	<u>(in thousands, except percentages)</u>			
<b>Revenue</b>	\$ 660	\$ 481	\$ 179	37 %
<b>Cost of revenue</b>	319	237	82	35 %
<b>Gross profit</b>	<u>341</u>	<u>244</u>	98	40 %
<b>Operating expenses</b>				
Research and development	6,992	3,221	3,771	117 %
General and administrative	1,340	629	711	113 %
Total operating expenses	<u>8,332</u>	<u>3,850</u>	4,482	116 %
<b>Loss from operations</b>	(7,991)	(3,607)	(4,384)	122 %
<b>Other income</b>				
Interest income	3	2	1	50 %
Net loss	<u>\$ (7,988)</u>	<u>\$ (3,604)</u>		

## Revenue

The following table summarizes the revenue recognized for the periods indicated:

	<u>Three Months Ended June 30,</u>		<u>Change</u>	
	<u>2021</u>	<u>2020</u>	<u>\$</u>	<u>%</u>
	<u>(in thousands, except percentages)</u>			
<b>Revenue</b>	<u>\$ 660</u>	<u>\$ 481</u>	<u>\$ 179</u>	37 %

Revenue increased by approximately \$0.2 million, or 37%, to approximately \$0.7 million for the three months ended June 30, 2021 compared to approximately \$0.5 million for the three months ended June 30, 2020. The increase in revenue was due to an increase of approximately \$0.3 million of revenue from new customers in 2021 and, growth in existing customers of \$0.1 million which was partially offset by approximately \$0.2 million decrease due to customer agreements that were completed in 2020.

### Cost of Revenue

The following table summarizes the components of cost of revenue expenses for the periods indicated:

	Three Months Ended June 30,		Change	
	2021	2020	\$	%
	(in thousands, except percentages)			
Employee related costs	\$ 285	\$ 194	\$ 91	46.9 %
Equity-based compensation expense	22	28	(6)	(21.4)%
Facilities and other allocated expenses	11	14	(3)	(21.4)%
Depreciation	1	1	—	— %
Total cost of revenue	<u>\$ 319</u>	<u>\$ 237</u>	<u>\$ 82</u>	34.6 %

Cost of revenue increased by approximately \$0.1 million, or 34.6%, to approximately \$0.3 million for the three months ended June 30, 2021 compared to approximately \$0.2 million for the three months June 30, 2020. The increase was primarily due to increased employee related costs of approximately \$0.1 million, partially offset by a decrease in equity-based compensation and facilities.

### Research and Development

The following table summarizes the components of our research and development expenses for the periods indicated:

	Three Months Ended June 30,		Change	
	2021	2020	\$	%
	(in thousands, except percentages)			
Employee related costs	\$ 2,053	\$ 1,237	\$ 816	66.0 %
Equity-based compensation expense	160	129	31	24.0 %
Outside contract research services	4,658	1,775	2,883	162.4 %
Facilities and other allocated expenses	112	75	37	49.3 %
Depreciation	9	5	4	80.0 %
Total research and development	<u>\$ 6,992</u>	<u>\$ 3,221</u>	<u>\$ 3,771</u>	117.1 %

Research and development expenses increased by approximately \$3.8 million, or 117.0%, to approximately \$7.0 million for the three months ended June 30, 2021 as compared to approximately \$3.2 million for the three months ended June 30, 2020. The increase of approximately \$3.8 million was primarily due to approximately \$2.9 million of outside contract research services for our preclinical candidates due to an increased number of discovery programs and increased spending on later stage preclinical efforts. The increase also includes approximately \$0.8 million of additional employee related costs, primarily due to an increase in headcount.

## General and Administrative

The following table summarizes the components of our general and administrative expenses for the periods indicated:

	<b>Three Months Ended June 30,</b>		<b>Change</b>	
	<b>2021</b>	<b>2020</b>	<b>\$</b>	<b>%</b>
	(in thousands, except percentages)			
Employee related costs	\$ 565	\$ 227	\$ 338	148.9 %
Equity-based compensation expense	169	131	38	29.0 %
Professional fees	474	205	269	131.2 %
Public relations	99	49	50	102.0 %
Outside consultants	8	5	3	60.0 %
Facilities and other allocated expenses	11	10	1	10.0 %
Other	14	2	12	600.0 %
<b>Total general and administrative</b>	<b>\$ 1,340</b>	<b>\$ 629</b>	<b>\$ 711</b>	<b>113.0 %</b>

General and administrative expenses increased by approximately \$0.7 million, or 113%, to approximately \$1.3 million for the three months ended June 30, 2021 compared to approximately \$0.6 million for the three months ended June 30, 2020. The increase of approximately \$0.7 million was primarily due to increased employee related costs of approximately \$0.3 million, increased professional fees incurred for accounting, auditing, legal, public relations and tax services of approximately \$0.3 million.

## Other Income, Net

Other income decreased by approximately \$1,000, or 50% due to a decrease in interest rates earned from our cash and cash equivalents balances due to changes in interest rates.

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

The following table summarizes our results of operations for the periods indicated:

	<b>Six Months Ended June 30,</b>		<b>Change</b>	
	<b>2021</b>	<b>2020</b>	<b>\$</b>	<b>%</b>
	(in thousands, except percentages)			
<b>Revenue</b>	\$ 1,408	\$ 964	\$ 444	46 %
<b>Cost of revenue</b>	728	492	236	48 %
<b>Gross profit</b>	680	472	209	44 %
<b>Operating expenses</b>				
Research and development	12,383	6,044	6,339	105 %
General and administrative	2,524	1,273	1,251	98 %
<b>Total operating expenses</b>	<b>14,907</b>	<b>7,318</b>	<b>7,590</b>	<b>104 %</b>
<b>Loss from operations</b>	(14,227)	(6,846)	(7,381)	108 %
<b>Other income</b>				
Interest income	10	41	(31)	(77)%
<b>Net loss</b>	<b>\$ (14,217)</b>	<b>\$ (6,805)</b>		

## Revenue

The following table summarizes the revenue recognized for the periods indicated:

	<u>Six Months Ended June 30,</u>		<u>Change</u>	
	<u>2021</u>	<u>2020</u>	<u>\$</u>	<u>%</u>
	(in thousands, except percentages)			
Revenue	\$ 1,408	\$ 964	\$ 444	46 %

Revenue increased by approximately \$0.4 million, or 46%, to approximately \$1.4 million for the six months ended June 30, 2021 compared to approximately \$1.0 million for the six months ended June 30, 2020. The increase in revenue was due to an increase by approximately \$0.4 million from new customers during 2021 and, a \$0.2 million increase in existing customers partially offset by an approximately \$0.2 million decrease due to customer agreements that were completed in 2020.

## Costs of Revenue

The following table summarizes the components of cost of revenue expenses for the periods indicated:

	<u>Six Months Ended June 30,</u>		<u>Change</u>	
	<u>2021</u>	<u>2020</u>	<u>\$</u>	<u>%</u>
	(in thousands, except percentages)			
Employee related costs	\$ 655	\$ 404	\$ 251	62.1 %
Equity-based compensation expense	45	53	(8)	(15.1)%
Facilities and other allocated expenses	25	33	(8)	(24.2)%
Depreciation	3	2	1	50.0 %
Total cost of revenue	\$ 728	\$ 492	\$ 236	48.0 %

Cost of revenue increased by approximately \$0.2 million, or 48%, to approximately \$0.7 million for the six months ended June 30, 2021 compared to approximately \$0.5 million for the six months ended June 30, 2020. The increase was primarily due to increased employee related costs of approximately \$0.3 million, partially offset by decreases in equity-based compensation, facilities, depreciation, and outside contract research services.

## Research and Development

The following table summarizes the components of research and development expenses for the periods indicated:

	<u>Six Months Ended June 30,</u>		<u>Change</u>	
	<u>2021</u>	<u>2020</u>	<u>\$</u>	<u>%</u>
	(in thousands, except percentages)			
Employee related costs	\$ 3,817	\$ 2,330	\$ 1,487	63.8 %
Equity-based compensation expense	266	245	21	8.6 %
Outside contract research services	8,071	3,304	4,767	144.3 %
Facilities and other allocated expenses	213	156	57	36.5 %
Depreciation	16	9	7	77.8 %
Total research and development	\$ 12,383	\$ 6,044	\$ 6,339	104.9 %

Research and development expenses increased by approximately \$6.3 million, or 104.9%, to approximately \$12.4 million for the six months ended June 30, 2021 as compared to approximately \$6.0 million for the year ended June 30, 2020. The increase of approximately \$6.3 million was primarily due to approximately \$4.8 million of outside contract research

services for our preclinical candidates due to an increased number of discovery programs and increased spending on later stage preclinical efforts. The increase also includes approximately \$1.5 million of additional employee related costs, primarily due to higher headcount and increased equity-based compensation and facilities and other allocated expense of approximately \$0.1 million.

### General and Administrative

The following table summarizes the components of general and administrative expenses for the periods indicated:

	Six Months Ended June 30,		Change	
	2021	2020	\$	%
	(in thousands, except percentages)			
Employee related costs	\$ 1,142	\$ 503	\$ 639	127.0 %
Equity-based compensation expense	223	262	(39)	(14.9)%
Professional fees	916	363	553	152.3 %
Public relations	197	114	83	72.8 %
Outside consultants	11	9	2	22.2 %
Facilities and other allocated expenses	20	20	—	— %
Other	15	2	13	650.0 %
<b>Total general and administrative</b>	<b>\$ 2,524</b>	<b>\$ 1,273</b>	<b>\$ 1,251</b>	<b>98.3 %</b>

General and administrative expenses increased by approximately \$1.3 million, or 98.3%, to approximately \$2.5 million for the six months ended June 30, 2021 compared to approximately \$1.3 million for the six months ended June 30, 2020. The increase of approximately \$1.3 million was primarily due to increased employee related costs of approximately \$0.6 million, increased professional fees incurred for accounting, auditing, legal, and tax services of approximately \$0.6 million, increased public relation costs of approximately \$0.1 million, partially offset by a decrease in equity-based compensation expense..

### Other Income (Expense), Net

Other income decreased by approximately \$31,000, or 77% due to a decrease in interest rates earned from our cash and cash equivalents balances due to changes in interest rates.

### Liquidity and Capital Resources

#### Sources of Liquidity

Since our inception, we have financed our operations through service revenues, the issuance of convertible notes payable, convertible preferred stock, common stock, and the exercise of stock options. As of June 30, 2021, we had an accumulated deficit of \$40.0 million and \$50.2 million in cash and cash equivalents. Cash and cash equivalents are comprised of deposits at major financial banking institutions and highly liquid investments with an original maturity of three months or less at the date of purchase. Our primary use of cash is to fund operating expenses, which consist primarily of research and development expenditures, and to a lesser extent, general and administrative expenditures. Cash used to fund operating expenses is impacted by the timing of when we pay these expenses, reflected in the change in our outstanding accounts payable and accrued expenses.

Since our inception, we have incurred significant operating losses. We have not yet commercialized any of our product candidates and we do not expect to generate revenue from sales of any product candidates for the next several years, if at all. To date, our operations have been financed primarily by service revenues and aggregate net proceeds of approximately \$81.4 million from the issuance of convertible notes payable, convertible preferred stock including gross proceeds of approximately \$24.8 million from the issuance of shares in the second tranche of Series B Preferred in April and May 2021, common stock, the exercise of stock options and most recently, the proceeds from our IPO. In August, 2021,

we completed our IPO pursuant to which we issued and sold 8,625,000 shares of Class A common stock, inclusive of 1,150,000 shares sold by us pursuant to the full exercise of the underwriters' option to purchase additional shares. We received aggregate net proceeds of approximately \$120.3 million from the IPO, after deducting underwriting discounts and commissions, but before deducting offering costs payable by us, which are estimated to be \$2.0 million.

### Cash Flows

The following table summarizes our sources and uses of cash for the periods indicated:

	<b>Six Months Ended June 30,</b>	
	<b>2021</b>	<b>2020</b>
	<b>(in thousands)</b>	
Net cash (used in) provided by:		
Operating activities	\$ (12,577)	\$ (5,682)
Investing activities	(36)	(10)
Financing activities	25,769	998
Net increase (decrease) in cash and cash equivalents	<u>\$ 13,155</u>	<u>\$ (4,693)</u>

### Net Cash Used in Operating Activities

During the six months ended June 30, 2021, operating activities used approximately \$12.6 million of cash, primarily resulting from our net loss of approximately \$14.2 million and cash provided by changes in our operating assets and liabilities of approximately \$1.0 million, partially offset by equity-based compensation expense of approximately \$0.5 million.

During the six months ended June 30, 2020, operating activities used approximately \$5.7 million of cash, primarily resulting from our net loss of approximately \$6.8 million, partially offset by equity-based compensation expense of approximately \$0.6 million and cash provided by changes in our operating assets and liabilities of approximately \$0.6 million.

### Net Cash Used in Investing Activities

During the six months ended June 30, 2021 and 2020, investing activities used approximately \$36,388, and \$9,754 respectively, for the purchase of property and equipment.

### Net Cash Provided by Financing Activities

During the six months ended June 30, 2021, net cash provided by financing activities was approximately \$25.8 million, consisting primarily of approximately \$24.8 million in net proceeds received from the issuance of Series B preferred stock and approximately \$1.0 million in net proceeds from the exercise of warrants and approximately \$52,625 from the exercise of stock options.

During the six months ended June 30, 2020, net cash provided by financing activities was approximately \$1.0 million, consisting primarily of proceeds received from the issuance of Series A preferred stock, net of issuance costs.

### Future Funding Requirements

We expect that our expenses will increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials for our product candidates in development. The timing and amount of our operating and capital expenditures will depend largely on:

- the impacts of the pandemic related to COVID-19 and its variants and potential future pandemics;
- the costs and results of our potential future clinical trials for our other product candidates;



- the scope, progress, results and costs of discovery research, preclinical development, laboratory testing and clinical trials for our other product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- our ability to enter into contract manufacturing arrangements for supply of active pharmaceutical ingredient, or API, and manufacture of our product candidates and the terms of such arrangements;
- the payment or receipt of milestones and receipt of other collaboration-based revenues, if any;
- the costs and timing of any future commercialization activities, including product manufacturing, sales, marketing and distribution, for any of our product candidates for which we may receive marketing approval;
- the amount and timing of revenue, if any, received from commercial sales of our product candidates for which we receive marketing approval;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property and proprietary rights and defending any intellectual property related claims;
- the extent to which we acquire or in-license other products, product candidates, technologies or data referencing rights;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- our ability to access the private and public capital markets or to obtain financing at commercially reasonable rate;
- the ability to receive additional non-dilutive funding, including grants from organizations and foundations; and
- the costs of operating as a public company.

We believe that our existing cash, cash equivalents and marketable securities, including the net proceeds from our IPO, will enable us to fund our operating expenses and capital expenditure requirements into 2024. 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.

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

There have been no material changes from the contractual commitments and obligations previously disclosed in the Prospectus.

Our financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our financial statements and related disclosures requires us to make estimates, assumptions and judgments that affect the reported amount of assets, liabilities, revenue, costs and expenses, and related disclosures. Our critical accounting policies are described under the heading “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Policies and Significant Judgments and Estimates” in our Prospectus. If actual results or events differ materially from the estimates, judgments and assumptions used by us in applying these policies, our reported financial condition and results of operations could be materially affected. There have been no significant changes to our critical accounting policies from those described in the Prospectus.

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

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in Note 2 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

#### **Off-balance Sheet Arrangements**

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

### **Emerging Growth Company Status**

As an emerging growth company, or EGC, under the Jumpstart Our Business Startups Act of 2012, or JOBS Act, we may delay the adoption of certain accounting standards until such time as those standards apply to private companies. Other exemptions and reduced reporting requirements under the JOBS Act for EGCs include presentation of only two years of audited consolidated financial statements in a registration statement for an IPO, an exemption from the requirement to provide an auditor's report on internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board, and less extensive disclosure about our executive compensation arrangements.

In addition, the JOBS Act provides that an EGC can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an EGC to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have elected to use this extended transition period for complying 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 consolidated financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We may remain classified as an EGC until the end of the fiscal year following the fifth anniversary of this offering, although if the market value of our common stock that is held by non-affiliates exceeds \$700 million as of June 30 of any year before that time, or if we have annual gross revenues of \$1.07 billion or more in any fiscal year, we would cease to be an EGC as of December 31 of the applicable year. We also would cease to be an EGC if we issue more than \$1.0 billion of non-convertible debt over a three-year period.

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

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

As of June 30, 2021, our cash and cash equivalent consists of cash held as deposits at a major financial banking institution and highly liquid investments with an original maturity of three months or less at the date of purchase. As a result, the fair value of our portfolio is relatively insensitive to interest rate changes. As of June 30, 2021, we had no variable-rate debt outstanding and are therefore not exposed to interest rate risk with respect to debt. We believe a hypothetical 100 basis point increase or decrease in interest rates during the period presented would not have had a material impact on our financial results.

#### ***Foreign Currency Exchange Risk***

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates. Our operations may be subject to fluctuations in foreign currency exchange rates in the future.

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

We do not believe that inflation has had a material effect on our business, financial condition or results of operations. Our operations may be subject to inflation in the future.

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

#### **Limitations on Effectiveness of Controls and Procedures**

Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

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

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of June 30, 2021. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of June 30, 2021, our disclosure controls and procedures were effective at the reasonable assurance level.

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

No change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three months ended June 30, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

## **PART II — OTHER INFORMATION**

### **Item 1. Legal Proceedings**

We are not currently party to any material legal proceedings

### **Item 1A. Risk Factors**

*Our future operating results could differ materially from the results described in this Quarterly Report on Form 10-Q due to the risks and uncertainties described below. You should consider carefully the following information about risks below in evaluating our business. If any of the following risks actually occur, our business, financial conditions, results of operations and future growth prospects would likely be materially and adversely affected. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. In these circumstances, the market price of our Class A common stock would likely decline. In addition, we cannot assure investors that our assumptions and expectations will prove to be correct. Important factors could cause our actual results to differ materially from those indicated or implied by forward-looking statements. See “Forward Looking Statements” for a discussion of some of the forward-looking statements that are qualified by these risk factors. Factors that could cause or contribute to such differences include those factors discussed below.*

### **Risks Related to Our Financial Condition and Capital Requirements**

***We have a limited operating history in developing pharmaceutical products, have not completed any clinical trials and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and predict our future success and viability.***

Pharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. We are a biopharmaceutical company with a limited operating history in developing pharmaceutical products which makes it difficult to evaluate our business and prospects in future product development. We have no products approved for commercial sale and have not generated any revenue from product sales. To date, we have devoted substantially all of our resources and efforts to providing computational biology services to pharmaceutical and biotechnology companies, organizing and staffing our company, business planning, executing partnerships, raising capital, discovering, identifying and developing potential product candidates, securing related intellectual property rights and undertaking research and preclinical studies of our product candidates, including the anticipated Phase 1 clinical trial of IMM-1-104 for the treatment of advanced solid tumors in patients harboring RAS mutant tumors. We have not yet demonstrated our ability to successfully initiate any clinical trials, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult for you to accurately predict our future success or viability to develop new pharmaceutical products than it could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by biopharmaceutical companies developing products in rapidly evolving fields. We also may need to transition from a company with a research focus to a company capable of supporting commercial activities. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

***We have incurred significant net losses for the past several years and we expect to continue to incur significant net losses for the foreseeable future and may never obtain profitability.***

We have incurred net losses in each reporting period for the past several years, have not generated any revenue from product sales to date and have financed our operations principally through our computational biology services to pharmaceutical and biotechnology companies, the issuance of convertible debt and the sale of our convertible preferred stock and Class A common stock. We have incurred net losses of approximately \$17.0 million and \$7.7 million for the years ended December 31, 2020 and 2019, respectively, and net loss of approximately \$14.2 million for the six months ended June 30, 2021. As of June 30, 2021, we had an accumulated deficit of approximately \$40.0 million. Our losses have resulted principally from expenses incurred in research and development of our product candidates, from management and administrative costs and other expenses that we have incurred while building our business infrastructure. Our lead product candidate, IMM-1-104, is undergoing IND-enabling studies and we expect to submit an IND to the FDA in the first quarter of 2022. We intend to initiate a Phase 1 clinical trial of IMM-1-104 in the first half of 2022 for the treatment of advanced solid tumors in patients harboring RAS mutant tumors, if our IND for IMM-1-104 is accepted. Our other product candidates are in earlier stages of drug development. As a result, we expect that it will be several years, if ever, before we have a commercialized product and generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses as we discover, develop and market additional potential product candidates. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase substantially if and as we:

- advance the development of our lead product candidate, IMM-1-104, and our other product candidates through preclinical and clinical development, and, if approved by the FDA or other comparable foreign regulatory authorities, commercialization;
- incur manufacturing costs for our product candidates;
- seek regulatory approvals for any of our product candidates that successfully complete clinical trials;
- increase our research and development activities to identify and develop new product candidates;
- hire additional personnel;
- expand our operational, financial and management systems;
- invest in measures to protect and expand our intellectual property;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval and intend to commercialize;
- expand our manufacturing and develop our commercialization efforts; and
- operate as a public company.

The net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our working capital and our ability to achieve and maintain profitability.

***We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.***

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase in connection with our ongoing activities, particularly as we initiate and conduct clinical trials of, and seek marketing approval for our current and any future product candidates. Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with commercializing any approved product candidate. Our expenses could increase beyond expectations if we are required by the FDA or other comparable foreign regulatory authorities to perform clinical trials or preclinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to drug sales, marketing, manufacturing and distribution. Because the design and outcome of our anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we develop. We also expect to incur additional costs associated with operating as a public company. Accordingly, it is likely that we will need to obtain substantial additional funding in order to maintain our continuing operations in the future.

As of June 30, 2021, we had approximately \$50.2 million in cash and cash equivalents. Based on our current business plans, we believe that our existing cash and cash equivalents, including the net proceeds from our IPO, will be sufficient to fund our operating expenses and capital expenditures requirements into 2024. Our estimate as to how long we expect our existing cash and cash equivalents to be able to continue to fund our operating expenses and capital expenditures requirements is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

Our future funding requirements will depend on many factors, including, but not limited to:

- the initiation, progress, timeline, cost and results of our clinical trials for our product candidates;
- the initiation, progress, timeline, cost and results of additional research and preclinical studies related to pipeline development and other research programs we initiate in the future;
- the cost and timing of manufacturing activities as we advance our product candidates through preclinical and clinical development, and commercialization;
- the potential expansion of our current development programs to seek new indications;
- the continued negative impact of the COVID-19 pandemic or future pandemics on our business;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;

- the cost of filing, prosecuting, defending and enforcing patent claims and other intellectual property rights, licensed or otherwise;
- the effect of competing technological and market developments;
- the payment of licensing fees, potential royalty payments and potential milestone payments;
- the cost of general operating expenses;
- the cost and timing of completion of commercial-scale manufacturing activities;
- the cost of establishing sales, marketing, and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own; and
- the cost of operating as a public company.

Advancing the development of our product candidates will require a significant amount of capital. Our existing cash and cash equivalents will not be sufficient to fund all of the activities that are necessary to complete the development of our product candidates.

We will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, which may dilute our stockholders or restrict our operating activities. We do not have any committed external source of funds. Adequate additional financing may not be available to us on acceptable terms, or at all. Additionally, the impact of the pandemic related to COVID-19 and its variants on the capital markets may affect the availability, amount and type of financing available to us in the future. Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research-stage programs, clinical trials or future commercialization efforts.

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

We may seek additional capital through a variety of means, including through public or private equity offering, debt financings or other sources, including up-front payments and milestone payments from strategic collaborations. To the extent that we raise additional capital through the sale of equity or convertible debt or equity securities, your ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Such financing may result in dilution to stockholders, imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through up-front payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. 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 ability to use our net operating losses and other tax attributes may be limited.***

As of December 31, 2020, we had approximately \$22.0 million of federal and \$14.3 million of state net operating loss carryforwards, or NOLs, available to offset future taxable income. Under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an “ownership change,” generally defined as a greater than 50% change by value in its equity ownership over a three-year period is subject to limitations on its ability to utilize its pre-change NOLs and other tax attributes such as research tax credits to offset future taxable income. We have not performed an analysis to determine whether our past issuances of stock and other changes in our stock ownership may have resulted in other ownership changes. If it is determined that we have in the past experienced other ownership changes, or if we undergo one or more ownership changes as a result

of future transactions in our stock, which may be outside our control, then our ability to utilize NOLs and other pre-change tax attributes could be further limited by Sections 382 and 383 of the Code, and certain of our NOLs and other pre-change tax attributes may expire unused. As a result, if or when we earn net taxable income, our ability to use our pre-change NOLs or other tax attributes to offset such taxable income or otherwise reduce any liability for income taxes may be subject to limitations, which could adversely affect our future cash flows.

### **Risks Related to Development, Regulatory Approval and Commercialization**

***The regulatory approval processes of the FDA and other comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are ultimately unable to obtain regulatory approval for our product candidates, or to obtain regulatory approval to treat the indications we seek to treat with our product candidates, we will be unable to generate product revenue or the level of planned product revenue and our business will be substantially harmed.***

We are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining marketing approval from the FDA. Foreign regulatory authorities impose similar requirements. The time required to obtain approval by the FDA and other comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. In addition, approval policies, regulations or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. Even if we eventually complete clinical testing and receive approval of any regulatory filing for our product candidates, the FDA and other comparable foreign regulatory authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested. We have not submitted for, or obtained, regulatory approval for any product candidate, and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval.

Further, development of our product candidates and/or regulatory approval may be delayed for reasons beyond our control. For example, a U.S. federal government shutdown or budget sequestration, such as ones that occurred during 2013, 2018 and 2019, may result in significant reductions to the FDA's budget, employees and operations, which may lead to slower response times and longer review periods, potentially affecting our ability to progress development of our product candidates or obtain regulatory approval for our product candidates.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or other comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA or other comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- the FDA or other comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;

- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a New Drug Application, or NDA, or other submission or to obtain regulatory approval in the United States or elsewhere;
- we may be unable to demonstrate to the FDA or other comparable foreign regulatory authorities that a product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA or other comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA or other comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

This lengthy approval process, as well as the unpredictability of the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects. In addition, the FDA or comparable foreign regulatory authorities may change their policies, adopt additional regulations or revise existing regulations or take other actions, which may prevent or delay approval of our future product candidates under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained.

In addition, even if we obtain approval of our product candidates, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may impose significant limitations in the form of narrow indications, warnings, or a Risk Evaluation and Mitigation Strategy, or REMS. Regulatory authorities may not approve the price we intend to charge for products we may develop, may grant approval contingent on the performance of costly post-marketing clinical trials, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could seriously harm our business.

***We may not be able to file INDs or IND amendments or comparable documents in foreign jurisdictions to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA may not permit us to proceed.***

While we plan to submit INDs or comparable documents for our potential product candidates, we may not be able to file such INDs or comparable documents on the timeline we expect. For example, we may experience manufacturing delays or other delays with IND-enabling studies. Moreover, we cannot be sure that submission of an IND or comparable document will result in the FDA or other comparable foreign regulatory authorities allowing further clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND. Any failure to file INDs on the timelines we expect or to obtain regulatory approvals for our trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all.

***Our company has limited experience in designing clinical trials and may experience delays or unexpected difficulties in obtaining regulatory approval for our current and future product candidates.***

We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. We cannot be certain that our planned clinical trials or any future clinical trials will be successful. It is possible that the FDA may refuse to accept any or all of our planned NDAs for substantive review or may conclude after review of our data that our application is insufficient to obtain regulatory approval for any product candidates. If the FDA does not approve any of our planned NDAs, it may require that we conduct additional costly clinical trials, preclinical studies or manufacturing validation studies before it will reconsider our applications.



Depending on the extent of these or any other FDA-required studies, approval of any NDA or other application that we submit may be significantly delayed, possibly for several years, or may require us to expend more resources than we have available. Any failure or delay in obtaining regulatory approvals would prevent us from commercializing our product candidates, generating revenues and achieving and sustaining profitability. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve any NDA or other application that we submit. If any of these outcomes occur, we may be forced to abandon the development of our product candidates, which would materially adversely affect our business and could potentially cause us to cease operations. We face similar risks for our applications in foreign jurisdictions.

***We may encounter substantial delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.***

Before obtaining marketing approval from the FDA or other comparable foreign regulatory authorities for the sale of our product candidates, we must complete preclinical development and extensive clinical trials to demonstrate the safety and efficacy of our product candidates. Clinical testing is expensive, difficult to design and implement, can take many years to complete and its ultimate outcome is uncertain. A failure of one or more clinical trials can occur at any stage of the process. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials.

In addition, we are substantially dependent on preclinical, clinical and quality data generated by CROs and other third parties for regulatory submissions for our product candidates. While we have or will have agreements governing these third parties' services, we have limited influence over their actual performance. If these third parties do not make data available to us, or, if applicable, make regulatory submissions in a timely manner, in each case pursuant to our agreements with them, our development programs may be significantly delayed, and we may need to conduct additional studies or collect additional data independently. In either case, our development costs would increase, perhaps substantially.

We do not know whether our future clinical trials will begin on time or enroll patients on time, or whether our future clinical trials will be completed on schedule or at all. Clinical trials can be delayed for a variety of reasons, including delays related to:

- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical studies;
- obtaining regulatory authorizations to commence a trial or reaching a consensus with regulatory authorities on trial design;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval from one or more institutional review boards, or IRBs;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- delays in enrollment due to travel or quarantine policies, or other factors related to COVID-19 and its variants, other pandemics or other events outside our control;
- changes to clinical trial protocol;

- clinical sites deviating from trial protocol or dropping out of a trial;
- manufacturing sufficient quantities of product candidates or obtaining sufficient quantities of combination therapies for use in clinical trials;
- subjects failing to enroll or remain in our trial at the rate we expect, or failing to return for post-treatment follow-up;
- subjects choosing an alternative treatment for the indication for which we are developing our product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected drug-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies;
- selection of clinical end points that require prolonged periods of clinical observation or analysis of the resulting data;
- a facility manufacturing our product candidates or any of their components being ordered by the FDA or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of current good manufacturing practice, or cGMP, regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, good clinical practices, or GCP, or other regulatory requirements;
- third-party contractors not performing data collection or analysis in a timely or accurate manner; or
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications.

For instance, the ongoing pandemic related to COVID-19 and its variants and the measures taken by the governmental authorities could disrupt the supply chain and the manufacture or shipment of drug substances and finished drug products for our product candidates for use in our research and clinical trials, delay, limit or prevent our employees and CROs from continuing research and development activities, impede the ability of patients to enroll or continue in clinical trials, or impede testing, monitoring, data collection and analysis or other related activities, any of which could delay our clinical trials and increase our development costs, and have a material adverse effect on our business, financial condition and results of operations.

We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a Data Safety Monitoring Board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical

protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign 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. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, conducting clinical trials in foreign countries, as we may do for 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, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

Additionally, if the results of our clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our product candidates, we may:

- be delayed in obtaining marketing approval, if at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings
- be subject to additional post-marketing testing requirements;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- have regulatory authorities withdraw, or suspend, their approval of the drug or impose restrictions on its distribution in the form of a modified REMS;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

Our development costs will also increase if we experience delays in testing or obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, need to be restructured or be completed on schedule, if at all. Any delay in, or termination of, our clinical trials will delay the submission of an NDA to the FDA or similar applications with comparable foreign regulatory authorities and, ultimately, our ability to commercialize our product candidates, if approved, and generate product revenue. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our claims for differentiation or the effectiveness or safety of our product candidate. The FDA has substantial discretion in the review and approval process and may disagree that our data support the claims we propose.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authorities may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval,

or rejection, of our marketing applications by the FDA or comparable foreign regulatory authorities, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues.

In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition and prospects significantly.

***The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA or other comparable foreign regulatory authorities.***

Before obtaining regulatory approvals for the commercial sale of any of our product candidates, we will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for their intended uses. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. Success in preclinical studies and early-stage clinical trials does not mean that future clinical trials will be successful. We do not know whether any of our product candidates will perform in current or future clinical trials as they have performed in preclinical studies. Product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA or other comparable foreign regulatory authorities despite having progressed through preclinical studies and early-stage clinical trials.

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments and may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to our product candidate. As a result, assessments of efficacy can vary widely for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes. We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market our product candidates. Most product candidates that begin clinical trials are never approved by regulatory authorities for commercialization.

We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval. We cannot be certain that our planned clinical trials or any other future clinical trials will be successful. Additionally, any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could seriously harm our business.

Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials nonetheless failed to obtain FDA or comparable foreign regulatory authority approval. We cannot guarantee that the FDA or comparable foreign regulatory authorities will interpret trial results as we do, and more trials could be required before we are able to submit applications seeking approval of our product candidates. To the extent that the results of the trials are not satisfactory to the FDA or comparable foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to

conduct additional trials in support of potential approval of our product candidates. Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the scope and use of our product candidate, which may also limit its commercial potential. Furthermore, the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval, which may lead to the FDA or comparable foreign regulatory authorities delaying, limiting or denying approval of our product candidates.

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

From time to time, we may publicly disclose preliminary or top-line data from our preclinical studies and clinical trials, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary 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. Top-line and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the top-line or preliminary data we previously published. As a result, top-line and preliminary data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. 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 or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the trading price of our Class A common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If the interim, top-line, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, results of operations, prospects or financial condition. Moreover, such disclosure could adversely affect the trading price of our Class A common stock.

***Our current or future product candidates may cause adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could inhibit regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.***

As is the case with pharmaceuticals generally, it is likely that there may be side effects and adverse events associated with the use of our product candidates. Results of our preclinical studies and clinical trials could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics. 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. The drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

If our product candidates are associated with undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with approved or other investigational products we may need to interrupt, delay or abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial, or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may harm our business, financial condition and prospects significantly.

Patients in our clinical trials may in the future suffer significant adverse events or other side effects not observed in our preclinical studies or previous clinical trials. Some of our product candidates may be used as chronic therapies or be used in pediatric populations, for which safety concerns may be particularly scrutinized by regulatory agencies. In addition, if our product candidates are used in combination with other therapies, our product candidates may exacerbate adverse events associated with the therapy. Patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments, which can cause side effects or adverse events that are unrelated to our product candidate, but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses.

If significant adverse events or other side effects are observed in any of our future clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, other comparable regulatory authorities or an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects.

Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result. For example, the FDA could require us to adopt a REMS to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and costlier than what is typical for the industry. We or our collaborators may also be required to adopt a REMS or engage in similar actions, such as patient education, certification of health care professionals or specific monitoring, if we or others later identify undesirable side effects caused by any product that we develop alone or with collaborators. Other potentially significant negative consequences include that:

- we may be forced to suspend marketing of that product, or be forced to or decide to remove the product from the marketplace;
- regulatory authorities may withdraw or change their approvals of that product in one or more countries;
- regulatory authorities may require additional warnings on the label or limit access of that product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment;
- we may be required to create a medication guide outlining the risks of the product for patients, or to conduct post-marketing studies;

- we may be required to change the way the product is administered;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or to be sued and held liable for harm caused to subjects or patients; and
- the product may become less competitive, and our reputation may suffer.

Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of the affected product candidate, if approved by applicable regulatory authorities.

***If we experience delays or difficulties in the enrollment and/or maintenance of patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected.***

Patient enrollment is a significant factor in the timing of clinical trials, and the timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to such trial's conclusion as required by the FDA or other comparable foreign regulatory authorities. Additionally, our clinical trials will compete with other clinical trials for product candidates that focusing on the same therapeutic targets (e.g., evaluating patients harboring RAS mutant tumors) as our current and potential future product candidates, which may further limit enrollment of eligible patients or may result in slower enrollment than we anticipate. The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants.

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

- size and nature of the patient population;
- severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- patient eligibility criteria for the trial in question as defined in the protocol;
- perceived risks and benefits of the product candidate under study;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- efforts to facilitate timely enrollment in clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients;
- continued enrollment of prospective patients by clinical trial sites;

- the risk that patients enrolled in clinical trials will drop out of the trials before completion or, because they may be late-stage cancer patients, will not survive the full terms of the clinical trials; and
- delays or difficulties in enrollment and completion of studies due to the pandemic related to COVID-19 and its variants or any future pandemic.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain marketing approval for the sale of our product candidates. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining enrollment of such patients in our clinical trials.

***Even if approved, our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.***

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, healthcare payors and others in the medical community. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which the product candidate is approved;
- restrictions on the use of our product candidates, such as boxed warnings or contraindications in labeling, or a REMS, if any, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of product candidates over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement, as well as pricing, by third-party payors, including government authorities;
- the availability of the approved product candidate for use as a combination therapy;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the effectiveness of sales and marketing efforts;
- unfavorable publicity relating to our products or product candidates or similar approved products or product candidates in development by third parties; and
- the approval of other new therapies for the same indications.

If any of our product candidates is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate or derive sufficient revenue from that product candidate and our financial results could be negatively impacted.



***We may be unable to obtain U.S. or foreign regulatory approvals and, as a result, may be unable to commercialize our product candidates.***

Our product candidates are subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution of drugs. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process must be successfully completed in the United States and in many foreign jurisdictions before a new drug can be marketed. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. We cannot provide any assurance that any product candidate we may develop will progress through required clinical testing and obtain the regulatory approvals necessary for us to begin selling them.

We have not conducted, managed or completed large-scale or pivotal clinical trials nor managed the regulatory approval process with the FDA or any other regulatory authority. The time required to obtain approvals from the FDA and other regulatory authorities is unpredictable, and requires successful completion of extensive clinical trials which typically takes many years, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when evaluating clinical trial data can and often changes during drug development, which makes it difficult to predict with any certainty how they will be applied. We may also encounter unexpected delays or increased costs due to new government regulations, including future legislation or administrative action, or changes in FDA policy during the period of drug development, clinical trials and FDA regulatory review.

Any delay or failure in seeking or obtaining required approvals would have a material and adverse effect on our ability to generate revenue from the particular product candidate for which we are developing and seeking approval. Furthermore, any regulatory approval to market a drug may be subject to significant limitations on the approved uses or indications for which we may market the drug or the labeling or other restrictions. In addition, the FDA has the authority to require a REMS as part of approving a NDA, or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. These requirements or restrictions might include limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may significantly limit the size of the market for the drug and affect reimbursement by third-party payors.

We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries, and generally includes all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval.

***Our approach to the discovery and development of product candidates is unproven, and we may not be successful in our efforts to use and expand our DCT platform to build a pipeline of product candidates with commercial value.***

A key element of our strategy is to use and expand our DCT platform to build a pipeline of product candidates and progress these product candidates through clinical development for the treatment of various cancers. Although our research and development efforts to date have resulted in our discovery and preclinical development of IMM-1-104, it and other product candidates may not be safe or effective for the indications for which we study them in clinical trials, and we may not be able to develop any other product candidates. Our DCT platform is evolving and may not reach a state at which building a pipeline of product candidates is possible.

We have not commenced clinical trials for any product candidates developed with our DCT platform. The scientific research that forms the basis of our efforts to develop product candidates with our platforms is still ongoing. Further, the scientific evidence to support the feasibility of developing therapeutic treatments based on our DCT platform is both preliminary and limited. As a result, we are exposed to a number of unforeseen risks and it is difficult to predict

the types of challenges and risks that we may encounter during development of our product candidates. For example, we have not tested any of the product candidates being developed using our DCT platform in humans, and our current data is limited to animal models and preclinical cell lines, the results of which may not translate into humans. As a result, it is possible that safety events or concerns could negatively affect the development of our product candidates, including adversely affecting patient enrollment among the patient populations that we intend to treat.

Given the novelty of our technologies, we intend to work closely with the FDA and comparable foreign regulatory authorities to perform the requisite scientific analyses and evaluation of our methods to obtain regulatory approval for our product candidates; however, due to a lack of comparable experiences, the regulatory pathway with the FDA and comparable regulatory authorities may be more complex and time-consuming relative to other more well-known therapeutics. Even if we obtain human data to support our product candidates, the FDA or comparable foreign regulatory agencies may lack experience in evaluating the safety and efficacy of our product candidates developed using our platforms, which could result in a longer than expected regulatory review process, increase our expected development costs, and delay or prevent commercialization of our product candidates. The validation process takes time and resources, may require independent third-party analyses, and may not be accepted or approved by the FDA and comparable foreign regulatory authorities. We cannot be certain that our approach will lead to the development of approvable or marketable products, alone or in combination with other therapies.

Additionally, a key element of our strategy is to use and expand our platforms to build a pipeline of product candidates and progress those product candidates through clinical development for the treatment of a variety of different types of diseases. Although our research and development efforts to date have been focused on identifying a pipeline of product candidates directed at various disease types, we may not be able to develop product candidates that are safe and effective. Even if we are successful in building our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to be approvable or marketable products that will receive marketing approval and achieve market acceptance. If we do not continue to successfully develop, get approval for and begin to commercialize any product candidates, we will face difficulty in obtaining product revenue in future periods, which could result in significant harm to our financial position and adversely affect our share price.

Even if we are successful in building our pipeline of product candidates, the potential product candidates that we identify may not be suitable for clinical development or generate acceptable clinical data, including as a result of being shown to have unacceptable toxicity or other characteristics that indicate that they are unlikely to be products that will receive marketing approval from the FDA or other regulatory authorities or achieve market acceptance. If we do not successfully develop and commercialize product candidates, we will not be able to generate product revenue in the future, which likely would result in significant harm to our financial position and adversely affect our stock price.

***We may develop our current and future product candidates in combination with other therapies, which exposes us to additional risks.***

We may also develop certain product candidates as biologic/drug combination products. Additional time may be required to obtain regulatory approval for our product candidates if they are combination products. Our product candidates that may be biologic/drug combination products will require coordination within the FDA and other comparable foreign regulatory authorities for review of their biologic and drug components. Although the FDA and other comparable foreign regulatory authorities have systems in place for the review and approval of combination products, we may experience delays in the development and commercialization of our product candidates that may be combination products due to regulatory timing constraints and uncertainties in the product development and approval process.

In addition, even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or

comparable foreign regulatory authorities outside of the United States could revoke approval of the therapy used in combination with our product or that safety, efficacy, manufacturing or supply issues could arise with any of those existing therapies. If the therapies we use in combination with our product candidates are replaced as the standard of care for the indications we choose for any of our product candidates, the FDA or comparable foreign regulatory authorities may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially.

We also may choose to evaluate our current product candidates or any other future product candidates in combination with one or more cancer therapies that have not yet been approved for marketing by the FDA or comparable foreign regulatory authorities. We will not be able to market and sell our product candidates we develop in combination with an unapproved cancer therapy for a combination indication if that unapproved therapy does not ultimately obtain marketing approval either alone or in combination with our product. In addition, unapproved cancer therapies face the same risks described with respect to our product candidates currently in development and clinical trials, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA approval.

If the FDA or comparable foreign regulatory authorities do not approve these other drugs or revoke their approval of, or if safety, efficacy, quality, manufacturing or supply issues arise with, the drugs we choose to evaluate in combination with our product candidate we develop, we may be unable to obtain approval of or market such combination therapy.

***If we successfully develop our product candidates, we may seek approval from the FDA through the use of accelerated approval pathways. If we are unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we initially contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw accelerated approval.***

We may in the future seek an accelerated approval for one or more of our product candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit, the FDA may withdraw its approval of the drug.

Prior to seeking accelerated approval for any of our product candidates, we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA feedback we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or receive an expedited regulatory designation (e.g., breakthrough therapy designation) for our product candidates, there can be no assurance that such submission or application will be

accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer time period to commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

***We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success.***

Because we have limited financial and managerial resources, we focus on research programs, therapeutic platforms and product candidates that we identify for specific indications. As a result, we may forego or delay pursuit of opportunities with other therapeutic platforms or product candidates or for other indications that later prove to have greater commercial potential or a greater likelihood of success than our product candidates. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future research and development programs, therapeutic platforms and product candidates for specific indications may not yield any commercially viable products.

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

***We are early in our development efforts. Our business is substantially dependent on the successful development of our current and future product candidates. If we are unable to advance our current or future product candidates through clinical trials, obtain marketing approval to treat the indications we seek to treat with our product candidates, and ultimately commercialize any product candidates we develop, or experience significant delays in doing so, our business will be materially harmed.***

We are early in our development efforts and we have not yet completed our IND-enabling studies for our lead product candidate, IMM-1-104. Our other product candidates are in earlier stages of drug development. We have invested substantially all of our efforts and financial resources in the identification of targets and preclinical development of small molecules targeting the MAPK and mTOR pathways in cancer therapy and small molecules targeting central nervous system disorders, including AD.

The success of our business, including our ability to finance our company and generate revenue from products in the future, which we do not expect will occur for several years, if ever, will depend heavily on the successful development and eventual commercialization of the product candidates we develop, which may never occur. Our current product candidates, and any future product candidates we develop, will require additional preclinical and clinical development, management of clinical, preclinical and manufacturing activities, marketing approval in the United States and other markets, demonstrating effectiveness to pricing and reimbursement authorities, obtaining sufficient manufacturing supply for both clinical development and commercial production, building of a commercial organization, and substantial investment and significant marketing efforts before we generate any revenues from product sales.

The success of our current and future product candidates will depend on several factors, including the following:

- the successful and timely completion of additional preclinical studies;
- the successful initiation, patient enrollment and completion of our anticipated clinical trials on a timely basis, including any delays arising out of the pandemic related to COVID-19 and its variants or any future pandemic;
- maintaining and establishing relationships with CROs and clinical sites for clinical development, both in the United States and internationally;
- the frequency and severity of adverse events in the clinical trials;

- the efficacy, safety and tolerability profiles that are satisfactory to the FDA or any comparable foreign regulatory authority for marketing approval;
- the timely receipt of marketing approvals from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- the maintenance of existing or the establishment of new supply arrangements with third-party drug product suppliers and manufacturers for clinical development;
- the maintenance of existing, or the establishment of new, scaled production arrangements with third-party manufacturers to obtain finished products that are appropriate for commercial sale of our product candidates, if approved;
- obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- the protection of our rights in our intellectual property portfolio;
- the successful launch of commercial sales following any marketing approval;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by patients, the medical community and third-party payors; and
- our ability to compete with other therapies.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize the product candidates we develop, which would materially harm our business. If we do not receive marketing approvals for IMM-1-104, or any other product candidate we develop, we may not be able to continue our operations.

***We are substantially dependent on our platform, including our proprietary technologies such as DCT and Fluency, which are supported by our information technology systems. Any failure of these or other elements of our platform will materially harm our business.***

We are substantially dependent on our platform, including our proprietary technologies such as DCT and Fluency, which are supported by our information technology systems, for significant elements of our drug discovery process, bioinformatics and computational biology software systems, database of information relating to our product candidates and their role in the targeted disease process, amongst others. Although we invest substantially in the backup/restore, high-availability architecture, monitoring and reporting, documentation and preventive security controls of our systems and proprietary technologies, these elements of our platform are still vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious or inadvertent human acts, and natural disasters. Our information technology systems and proprietary technologies are potentially also vulnerable to physical or electronic break-ins, employee errors, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our information technology systems and proprietary technologies, failures or significant downtime of these systems could prevent us from conducting research and development activities for our current and future product candidates,

and ultimately delay our drug discovery process. Any failure of our information technology systems and proprietary technologies will materially harm our business.

***Our long-term prospects depend in part upon discovering, developing and commercializing product candidates, which may fail in development or suffer delays that adversely affect their commercial viability.***

Our future results of operations are dependent on our ability to successfully discover, develop, obtain regulatory approval for and commercialize product candidates beyond those we currently have in preclinical studies and early stage development. A product candidate can unexpectedly fail at any stage of preclinical and clinical development. The historical failure rate for product candidates is high due to risks relating to safety, efficacy, clinical execution, changing standards of medical care and other unpredictable variables. The results from preclinical studies or early clinical trials of a product candidate may not be predictive of the results that will be obtained in later stage clinical trials of the product candidate.

The success of the product candidates we have or may develop will depend on many factors, including the following:

- the success of our research methodology in identifying potential indications or product candidates;
- generating sufficient data to support the initiation or continuation of clinical trials;
- obtaining regulatory permission to initiate clinical trials;
- contracting with the necessary parties to conduct clinical trials;
- successful enrollment of patients in, and the completion of, clinical trials on a timely basis;
- the timely manufacture of sufficient quantities of the product candidate for use in clinical trials;
- adverse events in the clinical trials; and
- any potential interruptions or delays resulting from factors related to the pandemic related to COVID-19 and its variants or any future pandemic.

Even if we successfully advance any other product candidates into clinical development, their success will be subject to all of the clinical, regulatory and commercial risks described elsewhere in this “Risk Factors” section. Accordingly, we cannot assure you that we will ever be able to discover, develop, obtain regulatory approval of, commercialize or generate significant revenue from our other product candidates.

***We have never commercialized a product candidate before and may lack the necessary expertise, personnel and resources to successfully commercialize any products on our own or together with suitable collaborators.***

We have never commercialized a product candidate, and we currently have no sales force, marketing or distribution capabilities. We will have to develop our own sales, marketing and supply organization or outsource these activities to a third party to commercialize our products. If we decide to license our product candidate to others, we may need to rely on the marketing assistance and guidance of those collaborators.

Factors that may affect our ability to commercialize our product candidates on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or persuading adequate numbers of physicians to prescribe our product candidates and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization will be expensive and time-consuming and could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization. If we are unable to build our own distribution and marketing capabilities or to find

suitable partners for the commercialization of our product candidates, we may not generate revenues from them or be able to reach or sustain profitability.

***We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than the product candidates we develop, our commercial opportunities will be negatively impacted.***

The pharmaceutical and biotechnology industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. Our competitors have developed, are developing or may develop products, product candidates and processes competitive with our product candidates. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we may attempt to develop product candidates. In addition, our products may need to compete with off-label drugs used by physicians to treat the indications for which we seek approval. This may make it difficult for us to replace existing therapies with our products.

In particular, there is intense competition in the fields of oncology we are pursuing. We have competitors both in the United States and internationally, including major multinational biopharmaceutical companies, established biotechnology companies, specialty biopharmaceutical companies, emerging and start-up companies, universities and other research institutions. For example, our product candidates and programs for oncology and neuroscience will compete with products or programs being advanced by certain pharmaceutical and biotechnology companies. We also compete with these organizations to recruit management, scientists and clinical development personnel, which could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites, enrolling subjects for clinical trials and in identifying and in-licensing new product candidates.

We have chosen to initially address well-validated biochemical targets, and therefore expect to face competition from existing products and products in development for each of our product candidates. There are a large number of companies developing or marketing treatments for cancer, including many major pharmaceutical and biotechnology companies. Many of these current and potential competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources and commercial expertise than we do. Large pharmaceutical and biotechnology companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing biotechnology products. These companies also have significantly greater research and marketing capabilities and experience than we do and may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical and biotechnology companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result of all of these factors, our competitors may succeed in obtaining approval from the FDA or other comparable foreign regulatory authorities or in discovering, developing and commercializing products in our field before we do.

Our commercial opportunities could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe effects, are more convenient, have a broader label, are marketed more effectively, are reimbursed or are less expensive than any products that we may develop. Our competitors also may obtain marketing approval from the FDA or other comparable foreign regulatory authorities for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Even if the product candidates we develop achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected.

***If the market opportunity for any product candidate that we develop is smaller than we believe, our revenue may be adversely affected and our business may suffer.***

We intend to initially focus our product candidate development on treatments for various oncology indications. Our projections of addressable patient populations that may benefit from treatment with our product candidates are based on our estimates. These estimates, which have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations and market research, may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these cancers. Additionally, the potentially addressable patient population for our product candidates may not ultimately be amenable to treatment with our product candidates. Our market opportunity may also be limited by future competitor treatments that enter the market. If any of our estimates prove to be inaccurate, the market opportunity for any product candidate that we develop could be significantly diminished and have an adverse material impact on our business.

***We have never obtained marketing approval for a product candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any product candidate.***

We have never obtained marketing approval for a product candidate. It is possible that the FDA may refuse to accept for substantive review any NDAs that we submit for our product candidates or may conclude after review of our data that our applications are insufficient to obtain marketing approval of our product candidates. We believe our approach of treating conditions or diseases through neuroregeneration is novel and, as a result, the process for, and the outcome of, FDA approval is especially uncertain. If the FDA does not accept or approve our NDAs for our product candidates, it may require that we conduct additional clinical, preclinical, or manufacturing validation studies and submit that data before it will reconsider our applications. Depending on the extent of these or any other FDA-required studies, approval of any NDA that we submit may be delayed or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA to approve our NDAs.

Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing our product candidates, generating revenues, and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to abandon our development efforts for our product candidates, which could significantly harm our business.

***The COVID-19 pandemic and potential future pandemics could continue to adversely impact our business, including our anticipated clinical trials, supply chain and business development activities.***

In December 2019, SARS-CoV-2, a novel strain of coronavirus, was first reported in Wuhan, China and has since become a global pandemic. The President of the United States declared the COVID-19 pandemic a national emergency and many states and municipalities in the United States have announced aggressive actions to reduce the spread of the disease, including limiting non-essential gatherings of people, ceasing all non-essential travel, ordering certain businesses and government agencies to cease non-essential operations at physical locations and issuing “shelter-in-place” orders which direct individuals to shelter at their places of residence (subject to limited exceptions). We may experience limitations on employee resources in the future, including because of sickness of employees or their families. The effects of government actions and our own policies and those of third parties to reduce the spread of COVID-19 and its variants may negatively impact productivity and slow down or delay our future clinical trials, preclinical studies and research and development activities, and may cause disruptions to our supply chain and impair our ability to execute our business development strategy. In the event that government authorities were to enhance current restrictions, our employees who currently are not telecommuting may no longer be able to access our facilities, and our operations may be further limited or curtailed.

As COVID-19 and its variants continues to spread, we may experience ongoing disruptions that could severely impact our business, preclinical studies and clinical trials, including:



- interruption or delays in our operations, which may impact our ability to conduct and produce preclinical results required for submission of an IND;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials;
- changes in local regulations as part of a response to the pandemic related to COVID-19 and its variants which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- 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;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events; and
- refusal of the FDA to accept data from clinical trials in affected geographies.

These and other disruptions in our operations and the global economy could negatively impact our business, results of operations and financial condition.

Our future clinical trials may be affected by the pandemic related to COVID-19 and its variants or any future pandemic. For example, some clinical trial sites have slowed down or stopped further enrollment of new patients in clinical trials, denied access to site monitors and otherwise curtailed certain operations. Similarly, our ability to recruit and retain principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 and its variants, may be adversely impacted. Our planned clinical trials may also be impacted by interruptions or delays in the operations of the FDA and comparable foreign regulatory agencies. We and our CROs will act in accordance with the guidance issued by the FDA in our future clinical trials to ensure the monitoring and safety of patients and minimize risks to trial integrity during the pandemic related to COVID-19 and its variants. This may have unforeseen effects on the enrollment, progress and completion of these trials and the findings. These events could delay our clinical trials, increase the cost of completing our clinical trials and negatively impact the integrity, reliability or robustness of the data from our clinical trials.

In addition, quarantines, shelter-in-place and similar government orders, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 and its variants or other infectious diseases could impact personnel at third-party manufacturing facilities upon which we may rely in the future, or the availability or cost of materials, which could disrupt the supply chain for our product

candidates. To the extent our future suppliers and service providers are unable to comply with their obligations under our future agreements with them or they are otherwise unable to deliver or are delayed in delivering goods and services to us due to the pandemic related to COVID-19 and its variants, our future ability to continue meeting clinical supply demand for our product candidates or otherwise advancing development of our product candidates may become impaired.

The spread of COVID-19 and its variants and actions taken to reduce its spread may also materially affect us economically. While the potential economic impact brought by, and the duration of, the pandemic related to COVID-19 and its variants may be difficult to assess or predict, there could be a significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity and financial position. In addition, the trading prices for other biopharmaceutical companies have been highly volatile as a result of the pandemic related to COVID-19 and its variants. As a result, we may face difficulties raising capital through sales of our Class A common stock or such sales may be on unfavorable terms.

COVID-19 and its variants and actions taken to reduce their spread continue to rapidly evolve. The extent to which COVID-19 and its variants may impede the development of our product candidates, reduce the productivity of our employees, disrupt our supply chains, delay our clinical trials, reduce our access to capital or limit our business development activities, will depend on future developments, which are highly uncertain and cannot be predicted with confidence. To the extent the pandemic related to COVID-19 and its variants adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this “Risk Factors” section, such as those relating to the timing and results of our clinical trials and our financing needs

***We may fail to adequately meet the requirements under our computational biology service contracts to pharmaceutical and biotechnology companies, which may harm our reputation, growth opportunities and prospects, possibly resulting in related losses.***

Over a decade ago, we began to offer computational biology services to pharmaceutical and biotechnology companies. We have deprioritized this business and plan to gradually wind down our computational biology services to pharmaceutical and biotechnology companies in the future. However, we are currently servicing several companies and in doing so, we must:

- accurately assess and meet the customer’s needs;
- ensure our computational biology services meet industry standards and practices for performance of similar services;
- retain the proper personnel to fulfill these service contracts; and
- compete effectively with other computational biology service providers performing similar services.

If we fail to adequately meet the requirements under our computational biology service contracts to our typical high standards, our reputation, growth opportunities and prospects could be adversely affected, possibly resulting in related losses. In addition, as is typical for contracts of this nature, there are inherent legal risks and potential liabilities associated with our work under each of our past, present and future contracts.

### **Risks Relating to Our Dependence on Third Parties**

***We substantially rely, and expect to continue to rely, on third parties, including independent clinical investigators and CROs, to conduct certain aspects of our preclinical studies, and in the future, our clinical trials. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.***

We substantially rely, and expect to continue to rely, on third parties, including independent clinical investigators and third-party CROs, to conduct certain aspects of our preclinical studies and to monitor and manage data for our ongoing preclinical programs. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies and trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We, our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for all of our products candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be adversely affected if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws. Further, there is no guarantee that any such CROs, investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. These risks are heightened as a result of the efforts of government agencies and the CROs themselves to limit the spread of COVID-19 and its variants, including quarantines and shelter-in-place orders. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed or precluded entirely.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach. In addition, some of our CROs have an ability to terminate their respective agreements with us if it can be reasonably demonstrated that the safety of the subjects participating in our clinical trials warrants such termination, if we make a general assignment for the benefit of our creditors or if we are liquidated.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Additionally, CROs may lack the capacity to absorb higher workloads or take on additional capacity to support our needs. Though we carefully manage our relationships with our CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

***We rely on, and in the future may rely on, third-party datasets and collaborations with third parties to inform patient selection, drug target identification and other bioinformatic and computational biology analyses for our existing product candidates and any future product candidates and for the supply of biomarker companion diagnostics.***

We are using bioinformatics, including data analytics, biostatistics and computational biology, throughout our drug discovery and development process, including to identify new target and biomarker opportunities. As part of this approach, we interrogate public and proprietary datasets, including, but not limited to, human tumor genetic information and specific cancer-target dependency networks. We rely on these datasets and data analytics for multiple analyses, including identifying or validating some of our biomarker-target relationships and access to these databases may not continue to be available publicly or through a proprietary subscription on acceptable terms. Our past, present and future use of such datasets could also create potential liabilities for us if the data provided to us contains inherent errors, inaccuracies or artifacts, or if we improperly analyze, handle, store or utilize the data.

Many of our product candidates also rely on the availability and use of commercially available tumor diagnostics panels or data on the prevalence of our target patient population to inform the patient selection and drug target identification for our product candidates. In cases where such biomarker diagnostic is not already commercially available, we expect to establish strategic collaborations for the clinical supply and development of companion diagnostics. If these diagnostics are not able to be developed, or if commercial tumor profiling panels are not able to be updated to include additional tumor-associated genes, or if clinical oncologists do not incorporate molecular or genetic sequencing into their clinical practice, we may not be successful in developing our existing product candidates or any future product candidates.

***If we decide to establish new collaborations in the future, but are not able to establish those collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.***

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may seek to selectively form collaborations to expand our capabilities, potentially accelerate research and development activities and provide for commercialization activities by third parties. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business.

We may face significant competition in seeking appropriate collaborators and the related negotiation process is time-consuming and complex. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of intellectual property and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidate. Further, we may not be successful in our efforts to establish a collaboration or other alternative arrangements for future product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

In addition, there have been a significant number of recent business combinations among large biopharmaceutical companies that have resulted in a reduced number of potential future collaborators. Even if we are successful in entering into a collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements on certain terms with potential collaborators.

If and when we seek to enter into collaborations, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its

potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate product revenue.

***We may enter into collaborations in the future with third parties for the development and commercialization of product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates.***

We may seek third-party collaborators in the future for the development and commercialization of one or more of our product candidates. Our likely collaborators for any future collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies.

We will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations involving our product candidates could pose numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations and may not perform their obligations as expected;
- collaborators may deemphasize or 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 the collaborators' strategic focus, including as a result of a sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or 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 product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products;
- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;

- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all; and
- if a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our drug development or commercialization program could be delayed, diminished or terminated.

***Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.***

We are exposed to the risk that our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities. Misconduct by these parties could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with federal and state health care fraud and abuse and compliance laws and regulations, accurately report financial information or data or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, submission of false claims, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting/rebating, marketing and promotion, consulting, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter misconduct by these parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations.

#### **Risks Related to Manufacturing**

***The manufacture of drugs is complex and our third-party manufacturers may encounter difficulties in production. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.***

Manufacturing drugs, especially in large quantities, is complex and may require the use of innovative technologies. Each lot of an approved drug product must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing drugs requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our manufacturer, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. The use of biologically derived ingredients can also lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization as a result of these challenges, or otherwise, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

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

We do not currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of our product candidates for preclinical studies and clinical trials under the guidance of members of our organization. We do not have long-term supply agreements. Furthermore, the raw materials for our product candidates may be sourced, in some cases, from a single-source supplier. If we were to experience an unexpected loss of supply of any of our product candidates or any of our future product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials.

We expect to continue to rely on third-party manufacturers for the commercial supply of any of our product candidates for which we obtain marketing approval. We may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third party to manufacture our product candidates according to our schedule, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the reduction or termination of production or deliveries by suppliers, or the raising of prices or renegotiation of terms;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements;
- the failure of the third party to manufacture our product candidates according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing both active drug substances and finished drug products. Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we do not have 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 does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing

approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations.

In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, including due to the impact of the pandemic related to COVID-19 and its variants, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third-party, which we may not be able to do on commercially reasonable terms, if at all. In particular, any replacement of our manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such skills or technology to another third-party and a feasible alternative may not exist. In addition, certain of our product candidates and our own proprietary methods have never been produced or implemented outside of our company, and we may therefore experience delays to our development programs if and when we attempt to establish new third-party manufacturing arrangements for these product candidates or methods. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to have another third-party manufacture our product candidates. If we are required to or voluntarily change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines and that the product produced is equivalent to that produced in a prior facility. The delays associated with the verification of a new manufacturer and equivalent product could negatively affect our ability to develop product candidates in a timely manner or within budget.

Our or a third-party's failure to execute on our manufacturing requirements, do so on commercially reasonable terms and timelines and comply with cGMP requirements could adversely affect our business in a number of ways, including:

- inability to meet our product specifications and quality requirements consistently;
- inability to initiate or continue clinical trials of our product candidates under development;
- delays in submitting regulatory applications, or receiving marketing approvals, for our product candidates, if at all;
- inability to commercialize any product candidates that receive marketing approval on a timely basis;
- loss of the cooperation of future collaborators;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease development or to recall batches of our product candidates;
- in the event of approval to market and commercialize our product candidates, an inability to meet commercial demands for our product or any other future product candidates; and
- our future profit margins.



***Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.***

As product candidates progress through preclinical and clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates, if approved, and generate revenue.

**Risks Related to Legal and Regulatory Compliance Matters**

***Our relationships with healthcare professionals, clinical investigators, CROs and third party payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws, which could expose us to, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.***

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, clinical investigators, CROs, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include, among others, the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid. The term “remuneration” has been broadly interpreted to include anything of value. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation;
- the federal false claims laws, including the civil False Claims Act, which can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalties laws, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government, with potential liability including mandatory treble damages and significant per claim penalties per false claim or statement. In addition, the government may assert that a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act;
- the federal Criminal Statute on False Statements Relating to Healthcare Matters, which makes it a crime to knowingly and willfully falsify, conceal, or cover up a material fact, make any materially false, fictitious, or fraudulent statements or representations, or make or use any materially false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items, or services;

- the federal Civil Monetary Penalties Law, which authorizes the imposition of substantial civil monetary penalties against an entity, such as a pharmaceutical manufacturer, that engages in activities including, among others (1) knowingly presenting, or causing to be presented, a claim for services not provided as claimed or that is otherwise false or fraudulent in any way; (2) arranging for or contracting with an individual or entity that is excluded from participation in federal healthcare programs to provide items or services reimbursable by a federal healthcare program; (3) violations of the federal Anti-Kickback Statute; or (4) failing to report and return a known overpayment;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program, with specific exceptions, to annually report to the Centers for Medicare and Medicaid Services, or CMS, information regarding payments and other transfers of value to physicians (as defined by statute), certain other healthcare providers starting in 2022 and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members. The information reported is publicly available on a searchable website, with disclosure required annually;
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws require biotechnology companies to comply with the biotechnology industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; and
- some state laws require biotechnology companies to report information to state agencies and/or commercial purchasers on the pricing of certain drug products that exceed a certain level as identified in the relevant statute. Some of these laws and regulations contain ambiguous requirements that government officials have not yet clarified. Given the lack of clarity in the laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent federal and state laws and regulations.

State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. For instance, the collection and use of health data in the European Union is governed by the General Data Protection Regulation, or the GDPR, which extends the geographical scope of European Union data protection law to non-European Union entities under certain conditions, tightens existing European Union data protection principles, creates new obligations for companies and new rights for individuals. Failure to comply with the GDPR may result in substantial fines and other administrative penalties. The GDPR may increase our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the GDPR. This may be onerous, and if our efforts to comply with GDPR or other applicable European Union laws and regulations are not successful, it could adversely affect our business in the European Union. Moreover, the United Kingdom leaving the EU could also lead to further legislative and regulatory changes. It remains unclear how the United Kingdom data protection laws or regulations will develop in the medium to longer term and how data transfer to the United Kingdom from the EU will be regulated, especially

following the United Kingdom's departure from the EU on January 31, 2020 without a deal. However, the United Kingdom has transposed the GDPR into domestic law with the Data Protection Act 2018, which remains in force following the United Kingdom's departure from the EU. In addition, on June 28, 2018, the State of California enacted the California Consumer Privacy Act, or CCPA, which went into effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. The CCPA may increase our compliance costs and potential liability, and similar laws have been proposed at the federal level and in other states.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve on-going substantial costs. It is possible that governmental authorities will conclude that our business practices, including our arrangements with physicians, some of whom have ownership interests in us, may not comply with current or future statutes, regulations 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 these laws or any other governmental regulations that may apply to us, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

***Our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage such inability could have an adverse effect on our business and financial condition.***

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA or other regulatory authority investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs. FDA or other regulatory authority investigations could potentially lead to a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources and substantial monetary awards to trial participants or patients. We currently have insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to marketing any of our product candidates, if approved. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have an adverse effect on our business and financial condition.

***Any product candidates we develop may become subject to unfavorable third-party coverage and reimbursement practices, as well as pricing regulations.***

The availability and extent of coverage and adequate reimbursement by third-party payors, including government health administration authorities, private health coverage insurers, managed care organizations and other third-party payors is essential for most patients to be able to afford expensive treatments. Sales of any of our product candidates that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of our product candidates will be covered and reimbursed by third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us

to establish or maintain pricing sufficient to realize an adequate return on our investment. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement levels for products can differ significantly from payor to payor. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs and biologics. However, one third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific and clinical support for the use of our products to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmacoeconomic studies to demonstrate the medical necessity and cost effectiveness of our products. Nonetheless, our product candidates may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be.

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, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the European Union, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing approval. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for products, but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

If we are unable to establish or sustain coverage and adequate reimbursement for any future product candidates from third-party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

***We face potential liability related to the privacy of health information we obtain from clinical trials sponsored by us.***

Most healthcare providers, including research institutions from which we obtain patient health information, are subject to privacy and security regulations promulgated under HIPAA, as amended by the HITECH. We are not currently classified as a covered entity or business associate under HIPAA and thus are not directly subject to its requirements or penalties. However, any person may be prosecuted under HIPAA's criminal provisions either

directly or under aiding-and-abetting or conspiracy principles. Consequently, depending on the facts and circumstances, we could face substantial criminal penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider or research institution that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, we may maintain sensitive personally identifiable information, including health information, that we receive throughout the clinical trial process, in the course of our research collaborations, and directly from individuals (or their healthcare providers) who enroll in our patient assistance programs. As such, we may be subject to state laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA.

Furthermore, certain health privacy laws, data breach notification laws, consumer protection laws and genetic testing laws may apply directly to our operations and/or those of our collaborators and may impose restrictions on our collection, use and dissemination of individuals' health information. Patients about whom we or our collaborators obtain health information, as well as the providers who share this information with us, may have statutory or contractual rights that limit our ability to use and disclose the information. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws. Claims that we have violated individuals' privacy rights or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend and could result in adverse publicity that could harm our business. If we or third-party contract manufacturing organizations, or CMOs, CROs or other contractors or consultants fail to comply with applicable federal, state or local regulatory requirements, we could be subject to a range of regulatory actions that could affect our or our contractors' ability to develop and commercialize our product candidates and could harm or prevent sales of any affected products that we are able to commercialize, or could substantially increase the costs and expenses of developing, commercializing and marketing our products. Any threatened or actual government enforcement action could also generate adverse publicity and require that we devote substantial resources that could otherwise be used in other aspects of our business. Increasing use of social media could give rise to liability, breaches of data security or reputational damage.

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

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

Although we will maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the potential use of hazardous materials in the future, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of hazardous and flammable materials, including chemicals and biological materials.

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

***The FDA or other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.***

We may choose to conduct international clinical trials in the future. The acceptance of study data by the FDA or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. 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 (1) the data are applicable to the United States population and United States medical practice; (2) the trials are performed by clinical investigators of recognized competence; and (3) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, such foreign trials would be 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 other comparable foreign regulatory authority will accept data from trials conducted outside of its applicable jurisdiction. If the FDA or any other 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 our product candidates not receiving approval for commercialization in the applicable jurisdiction.

***Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of our product candidates in other jurisdictions.***

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion and reimbursement of the product candidate in those countries. However, a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be harmed.

***Even if our product candidates receive regulatory approval, they will be subject to significant post-marketing regulatory requirements and oversight.***

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and surveillance to monitor the safety and efficacy of the product candidate, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS in order to approve our product candidates, which could entail requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or foreign regulatory authorities approve our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as on-going compliance with cGMPs and GCP for any clinical trials that we conduct post-approval. In addition, manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities

where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. In addition, failure to comply with FDA and other comparable foreign regulatory authority requirements may subject our company to administrative or judicially imposed sanctions, including:

- delays in or the rejection of product approvals;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning or untitled letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production; and
- imposition of restrictions on operations, including costly new manufacturing requirements.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

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

We also 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. We currently have a limited set of compliance policies and personnel, and intend to develop our compliance infrastructure in the future, as our clinical development programs progress. Developing a compliance infrastructure is costly and time-consuming, and even a well-designed and implemented compliance program cannot necessarily prevent all violations of relevant laws. 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 product candidates, if approved. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected.

***The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.***

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. If we receive marketing approval for a product candidate, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The government has also required companies to enter into consent decrees or imposed permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

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

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

Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, including in 2018 and 2019, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, as a public company, future government shutdowns could impact our ability to further access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. 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. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its 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 where direct inspection is otherwise limited by travel restrictions, but where the FDA determines that remote evaluation would still be appropriate. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the pandemic related to COVID-19 and its variants. 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 may face difficulties from changes to current regulations and future legislation.***

Existing regulatory policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, collectively referred to as the ACA, was passed, which substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things, subjected biologic products to potential competition by lower-cost biosimilars; increased the minimum level of Medicaid rebates payable by manufacturers of brand name drugs from 15.1% to 23.1% of the average manufacturer price; required collection of rebates for drugs paid by Medicaid managed care organizations; imposed a non-deductible annual fee on pharmaceutical manufacturers or importers who sell certain “branded prescription drugs” to specified federal government programs; implemented 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; expanded eligibility criteria for Medicaid programs; required reporting of certain financial arrangements between manufacturers of biologics, physicians and teaching hospitals under the federal Physician Payments Sunshine Act; expanded the types of entities eligible for the 340B Drug Pricing Program; created 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 established a Center for Medicare & Medicaid Innovation at 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, executive and Congressional challenges to certain aspects of the ACA. By way of example, the Tax Cuts and Jobs Act, or the Tax Act, was signed into law, which included a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate”. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the “individual mandate” was eliminated by Congress as part of the Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5<sup>th</sup> Circuit affirmed the District Court’s ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the mandate could be severed from the ACA (i.e., whether the remaining provisions of the ACA are unconstitutional as well). The U.S. Supreme Court is currently reviewing this case. The case is expected to be decided in 2021, although it is unclear how the Supreme Court will rule. It is also unclear how 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 ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of 2% per fiscal year, effective April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through December 31, 2021 due to the coronavirus pandemic, unless additional congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations.

Moreover, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing,

review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. The likelihood of success of these and other measures initiated by the former Trump administration is uncertain, particularly in light of the new Biden administration. Since the Presidential inauguration, the Biden administration has taken several recent executive actions that signal changes in policy from the prior administration. For example, on January 20, 2021, the Biden administration directed all federal departments and agencies to consider taking steps to withdraw or delay certain regulations and guidance issued by the Trump administration that had not become effective as of January 20, 2021 to permit the Biden administration to review such actions for questions of fact, law, and policy. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Further, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Beilina Right to Try Act of 2017, or the Right to Try Act, was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new product candidates that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its products available to eligible patients as a result of the Right to Try Act.

We expect that other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates. Further, it is possible that additional governmental action is taken in response to the pandemic related to COVID-19 and its variants.

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

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

***If we are unable to obtain and maintain patent and other intellectual property protection for our product candidates and technologies or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our ability to successfully commercialize our products and technology may be impaired, and we may not be able to compete effectively in our market.***

We rely upon a combination of patents, trademarks, trade secret protection and confidentiality agreements to protect the intellectual property related to our products and technologies and to prevent third parties from copying and surpassing our achievements, thus eroding our competitive position in our market. Our commercial success depends in part on our ability to obtain and maintain patent, trade secret or other intellectual property protection for our product candidates, proprietary technologies and their uses as well as our ability to operate without infringing the proprietary rights of others. If we are unable to protect our intellectual property rights or if our intellectual property rights are inadequate for our technology or our product candidates, our competitive position could be harmed. We generally seek to protect our proprietary position by filing patent applications in the United States and, in some cases, abroad related to our product candidates, technology platforms and their uses that are important to our business.

As of June 30, 2021, we owned pending patent applications, in the United States only, related to our platform technologies, as well as pending patent applications related to our product candidates. We currently do not have any issued patents related to our product candidates or platform technologies. Further, patent prosecution with respect to our pending patent applications related to our product candidates is in the early stages and, as such, no patent examiner has yet scrutinized the merits of such pending patent applications. Our patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology and such third parties practice the technology in countries where such patents have issued. With respect to our patent applications related to our platform technology, we filed those applications only in the U.S., so it is possible that a competitor may practice outside the U.S. the aspects of our platform technology disclosed in those patent applications. We maintain other aspects of our platform technology as trade secrets, which were not disclosed in those patent applications. There can be no assurance that any of our current and future patent applications, if any, owned by us or our future in-licensed patent applications will result in patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents if issued will not be infringed, designed around, invalidated or rendered unenforceable by third parties, or would effectively prevent others from commercializing competitive products or technologies. Composition of matter patents for biological and pharmaceutical product candidates often provide a strong form of intellectual property protection for those types of products, as such patents may provide protection without regard to any method of use. We cannot be certain that the claims in our pending patent applications related to composition of matter of our product candidates will be considered patentable by the United States Patent and Trademark Office, or USPTO, or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the existence, issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain.

Although we may obtain licenses to issued patents in the United States and foreign countries in the future, we cannot be certain that the claims in future in-licensed U.S. pending patent applications, if any, corresponding international patent applications and patent applications in certain foreign countries will be considered patentable by the USPTO, courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in future in-licensed issued patents will not be found invalid or unenforceable if challenged.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or our licensors or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we or our potential licensors do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or block our ability to make, use and sell our product candidates;

- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than the patent law typically applied by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing products.

The patent prosecution process is also expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. In addition, we may decide to abandon national and regional patent applications before they are granted. The examination of each national or regional patent application is an independent proceeding. As a result, patent applications in the same family may issue as patents in some jurisdictions, such as in the United States, but may issue as patents with claims of different scope or may be refused in other jurisdictions. It is also quite common that depending on the country, the scope of patent protection may vary for the same product or technology. For example, certain jurisdictions do not allow for patent protection with respect to method of treatment. Moreover, the scope of claims in a patent application can be significantly reduced before any claims in a patent are issued, and claim scope can be reinterpreted after issuance. Even if our current or future patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Consequently, we do not know whether our product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner, which could materially adversely affect our business, financial condition, results of operations and prospects.

It is also possible that we may not identify patentable aspects of our research and development output before it is too late to obtain patent protection. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. In addition, the USPTO might require that the term of a patent issuing from a pending patent application to be disclaimed and limited to the term of another patent that is commonly owned or names a common inventor. Moreover, in some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, directed to technology that we license, including those from our licensors, if any, and from third parties. We also may require the cooperation of our potential future licensors in order to enforce the licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business. We cannot be certain that patent prosecution and maintenance activities by our potential future licensors have been or will be conducted in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such applications. If they fail to do so, this could cause us to lose rights in any applicable intellectual property that we may in-license, and as a result our ability to develop and commercialize products or product candidates may be adversely affected and we may be unable to prevent competitors from making, using and selling competing products.

Even if our current or future patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or potential future in-licensed patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and any future in-licensed patents may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant review, or PGR, and inter partes review, or IPR, or other similar proceedings in the USPTO or foreign patent offices challenging our patent rights. The outcome following legal assertions of invalidity and

unenforceability is unpredictable. With respect to validity of our patents, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found. There is also no assurance that there is no prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, allow third parties to commercialize our product candidates and compete directly with us, without payment to us. Such loss of patent rights, loss of exclusivity or our patent claims being narrowed, invalidated or held unenforceable could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable or trade secret aspects of our technology platforms and research and development output, such as our employees, outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors, licensors, and other third parties, any of these parties may breach such agreements and disclose such aspects or output before a patent application is filed, thereby jeopardizing our ability to seek patent protection or maintain the trade secret status of our technology platforms or research and development output.

As referenced above, we have filed patent applications directed to our platform technologies that involve certain of our proprietary software modules. Moreover, while software and other of our proprietary works may be protected under copyright law, we have chosen not to register any copyrights in these works, and instead, rely on the above-referenced patent applications for protection of certain modules and trade secret protection for other of our software modules. In order to bring a copyright infringement lawsuit in the United States, the copyright must be registered. Accordingly, the remedies and damages available to us for unauthorized use of our software may be limited.

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

In the future, we may enter into license agreements under which we are granted rights to intellectual property that may be important to our business. We expect that any future license agreements where we in-license intellectual property would impose on us various development, regulatory and/or commercial diligence obligations, payment of milestones and/or royalties and other obligations. If we fail to comply with our obligations under these agreements (including as a result of COVID-19 and its variants impacting our operations), or we use the licensed intellectual property in an unauthorized manner or are subject to bankruptcy-related proceedings, the licensors may have the right to materially modify the terms of the licenses, such as by rendering currently exclusive licenses non-exclusive, or terminate the licenses, in which event we would not be able to market products covered by the licenses. We may also in the future enter into license agreements with third parties under which we are a sublicensee. If our sublicensor fails to comply with its obligations under its upstream license agreement with its licensor, the licensor may have the right to terminate the upstream license, which may terminate our sublicense. If this were to occur, we would no longer have rights to the applicable intellectual property unless we are able to secure our own direct license with the owner of the relevant rights, which we may not be able to do on reasonable terms, or at all, which may impact our ability to continue to develop and commercialize our product candidates incorporating the relevant intellectual property.

We may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates or platform, and we cannot provide any assurances that third-party patents do not exist that might be

enforced against our product candidates or platform in the absence of such a license. For example, our programs may involve additional product candidates that may require the use of additional proprietary rights held by third parties. Our product candidates may also require specific formulations to work effectively and efficiently. These formulations may be covered by intellectual property rights held by others. We may be unable to acquire or in-license any relevant third-party intellectual property rights that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses on commercially reasonable terms, if at all. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights, and may need to seek to develop alternative approaches that do not infringe such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. 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 for commercializing 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.

In addition, disputes may arise between us and any future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted and obligations imposed under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations;
- the amounts, if any, we owe to a potential licensor in respect of sublicense fees or income or in respect of backup product;
- our right to transfer or assign the license; and
  
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and its affiliates and sublicensees and by us and our partners and sublicensees.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our future licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize the affected product candidates, which would have a material adverse effect on our business.

In addition, certain of our agreements may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities. For example, we may in the future enter into license agreements that are not assignable or transferable, or that require the licensor's express consent in order for an assignment or transfer to take place.

***The patent protection and patent prosecution for some of our product candidates may be dependent on our future licensors and third parties.***

We or our future potential licensors may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. It is possible that defects as to form in the preparation or filing of our potential future in-licensed patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our future potential licensors fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our future potential licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our future potential in-licensed patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

As a future potential licensee of third parties, we would rely on third parties to file and prosecute patent applications and maintain patents and otherwise protect the licensed intellectual property under some of our future license agreements. We would not have primary control over these activities for certain of our patents or patent applications and other intellectual property rights. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents or other intellectual property rights. Future potential licensors may have the right to control enforcement of our future potential licensed patents or defense of any claims asserting the invalidity of these patents and even if we are permitted to pursue such enforcement or defense, we will require the cooperation of our future licensors. We cannot be certain that our future licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. If any of our future potential licensors or future collaborators fail to appropriately prosecute and maintain patent protection for patents directed to any of our product candidates, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products.

In addition, even where we have the right to control patent prosecution of patents and patent applications we have acquired or licensed from third parties in the future, we may still be adversely affected or prejudiced by actions or inactions of our potential licensors and their counsel that took place prior to us assuming control over patent prosecution.

Technology we may acquire or license from various third parties in the future may be subject to retained rights. Our future licensors may retain certain rights under their agreements with us, including the right to use the underlying technology for use in fields other than the fields licensed to us or for use in noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It may be difficult to monitor whether our future licensors may limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

***Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Claims by third parties that we infringe or misappropriate their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.***

Our commercial success depends in part on avoiding infringement or misappropriation of the patents and other proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Because the intellectual property landscape in the industry in which we participate is rapidly evolving and interdisciplinary, it is difficult to conclusively assess our ability to freely make, use, and sell our

products without infringing third party rights. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidates and products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, oppositions, reexaminations, IPR proceedings and PGR proceedings before the USPTO and/or foreign patent offices. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates, as well as related to our platform.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates or platform may be subject to claims of infringement of the patent rights of third parties. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published we may be unaware of third-party patents that may be infringed by commercialization of any of our product candidates, and we cannot be certain that others have not filed patent applications for a product candidate or technology covered by our pending patent applications, or that we were the first to file a patent application related to a product candidate or technology. Our competitors may have filed, and may in the future file, patent applications covering our products or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could require us to obtain rights to issued patents relating to such technologies. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe.

In addition, identification of third-party patent rights that may be relevant to our product candidates or platform is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction. 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. For example, we may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our products.

Further, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Any claims of patent infringement asserted by third parties would be time-consuming and could:

- result in costly litigation that may cause negative publicity;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing any of our product candidates until the asserted patent expires or is held finally invalid or unenforceable or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- subject us to significant liability to third parties; or



- require us to enter into royalty or licensing agreements, that may not be available on commercially reasonable terms, or at all, or that might be non-exclusive, which could result in our competitors gaining access to the same technology.

Although no third party has asserted a claim of patent infringement against us as of the date of this prospectus, others may hold proprietary rights that could prevent our product candidates from being marketed. Any patent-related legal action against us claiming damages and seeking to enjoin activities relating to our product candidates or processes could subject us to potential liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or develop our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially acceptable terms, if at all. Moreover, even if we or our future strategic partners were able to obtain a license, the rights may be non-exclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign our product candidates or processes to avoid infringement, if necessary.

Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing our product candidates, which could harm our business, financial condition and results of operations.

Parties making claims against us may be able to sustain the costs of complex patent or trade secret litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Moreover, if our product candidates or platform are found to infringe the intellectual property rights of third parties, these third parties may assert infringement claims against our future licensees and other parties with whom we have business relationships, and we may be required to indemnify those parties for any damages they suffer as a result of these claims. The claims may require us to initiate or defend protracted and costly litigation on behalf of such licensees and other parties regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of those parties or may be required to obtain licenses for the products they use.

***We may be involved in lawsuits to protect or enforce our patents or the patents of our future licensors, which could be expensive, time-consuming and unsuccessful. Further, our future in-licensed issued patents could be found invalid or unenforceable if challenged in court.***

Competitors may infringe or otherwise violate our, or our future licensors', patents, trademarks or other intellectual property. To prevent infringement or other violations, we and/or our future licensors may be required to file claims, which can be expensive and time-consuming. Further, our future licensors may need to file such claims, but elect not to file them. In addition, in a patent infringement proceeding, a court may decide that a patent we own or license is not valid, is unenforceable and/or is not infringed. If we or any of our future licensors or potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of our product candidates, the defendant could counterclaim that our patent is invalid and/or unenforceable in whole or in part. In patent litigation, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty or written description, non-patentable subject matter (laws of nature, natural phenomena, or abstract idea), obviousness or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent intentionally withheld material information from the USPTO or the applicable foreign counterpart, or made a misleading statement, during prosecution. A litigant or the USPTO itself

could challenge our patents on this basis even if we believe that we have conducted our patent prosecution in accordance with the duty of candor to the USPTO and in good faith. The outcome following such a challenge is unpredictable. With respect to challenges to the validity of our patents, there might be invalidating prior art, of which we and the patent examiner were unaware during prosecution.

If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. In addition, if the breadth or strength of protection provided by our patents and patent applications or those of our future licensors is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates. Such a loss of patent protection would have a material adverse impact on our business. Even if a defendant does not prevail on a legal assertion of invalidity and/or unenforceability, our patent claims may be construed in a manner that would limit our ability to enforce such claims against the defendant and others.

Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights, particularly those in a foreign jurisdiction, may cause us to incur significant expenses, and could distract our technical and management personnel from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. Enforcing our intellectual property rights against third parties may also cause such third parties to file other counterclaims against us, which could be costly to defend, particularly in a foreign jurisdiction, and could require us to pay substantial damages, cease the sale of certain products or enter into a license agreement and pay royalties (which may not be possible on commercially reasonable terms or at all). We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

***Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common shares to decline.***

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs or intellectual property could be diminished. Accordingly, the market price of shares of our Class A common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

***Derivation or interference proceedings may be necessary to determine priority of inventions, and an unfavorable outcome may require us to cease using the related technology or to attempt to license rights from the prevailing party.***

Derivation or interference proceedings provoked by third parties or brought by us or our future licensors, or declared by the USPTO or similar proceedings in foreign patent offices may be necessary to determine the priority of inventions with respect to our or our potential future licensors' patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our or our licensors' defense of such proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with such proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our product candidates to market.

***Patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents.***

In 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a “first inventor to file” system in which, assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether a third party was first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013 but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This requires us to be cognizant of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either (1) file any patent application related to our product candidates or (2) invent any of the inventions claimed in our patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date or the other party benefits from a compulsory license.

The Leahy-Smith Act also includes a number of significant changes that (i) affect the way patent applications are prosecuted, (ii) redefine prior art, and (iii) provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including PGR, IPR, and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would have been insufficient to invalidate the claim if presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation increase the uncertainties and costs surrounding the prosecution of our or our future licensors’ patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

***Changes in U.S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.***

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves a high degree of technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Further, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. We cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents.

In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us. For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope

of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our or our future licensors' ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our or our licensors' ability to obtain new patents or to enforce our existing patents and patents we might obtain in the future.

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

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

Our future licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the U.S. government, such that our future licensors are not the sole and exclusive owners of any patents we may in-license. If other third parties have ownership rights or other rights to our 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.

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. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the term of a patent, and the protection it affords, is limited. Even if patents directed to our product candidates are obtained, once the patent term has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of product candidates, patents directed to our product candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one or more of our U.S. patents may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. A maximum of one patent may be extended per FDA-approved product as

compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval of our product candidates. However, we or our licensors may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we or our licensors are unable to obtain patent term extension or restoration or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

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

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

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our or our licensors' patents or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our or our potential future licensors' 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 or our potential future licensors' patents at risk of being invalidated or interpreted narrowly and our or our potential future licensors' patent applications at risk of not issuing and could provoke third parties to assert claims against us. We or our licensors may not prevail in any lawsuits that we or our potential future licensors initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our or our potential future licensors' 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 in-license.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

***Obtaining and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by regulations and governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.***

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our

patents and/or applications. We have systems in place to remind us to pay these fees, and we rely on third parties to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply, and in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. While an inadvertent lapse, including due to the effect of the pandemic related to COVID-19 and its variants, our patent maintenance vendors or law firms, can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications relating to our product candidates, our competitive position would be adversely affected.

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

In addition to seeking patent protection for some of our technology and product candidates, we rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position, especially with respect to our technology platform. Any disclosure, either intentional or unintentional, by our employees or third-party consultants and vendors that we engage to perform research, clinical trials or manufacturing activities, or misappropriation by third parties (such as through a cybersecurity breach) of our trade secrets or proprietary information could enable competitors to duplicate or surpass our technological achievements, thus eroding our competitive position in our market. Because we expect to rely on third parties in the development and manufacture of our product candidates, we must, at times, share trade secrets with them. Our reliance on third parties may require us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into non-disclosure and confidentiality agreements with third parties who are given access to them, such as our corporate collaborators, outside scientific collaborators, contract research organizations, contract manufacturers, consultants, advisors and other third parties. With our consultants, contractors and outside scientific collaborators, these agreements typically include invention assignment obligations. We cannot guarantee that we have entered into such agreements with each party that may have or has had access to our trade secrets or proprietary technology and processes. Further, we cannot provide any assurances that all such agreements have been duly executed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. In addition, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. We may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors.

Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position would be harmed. If we or our licensors do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have

confidence in these individuals, organizations and systems, agreements or security measures may be breached, and we may not have adequate remedies for any breach.

***We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information or alleged trade secrets of third parties or competitors or are in breach of non-competition or non-solicitation agreements with our competitors or their former employers.***

As is common in the pharmaceutical and biotechnology industries, we employ individuals and engage the services of consultants who previously worked for other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information, trade secrets or other proprietary information of their former employers, or that our consultants have used or disclosed trade secrets or other proprietary information of their former or current clients. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

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

We use and will continue to use registered and/or unregistered trademarks or trade names to brand and market ourselves and our products. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names.

Moreover, any name we have proposed to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA (or an equivalent administrative body in a foreign jurisdiction) objects to any of our proposed proprietary product names, it 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. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

***We use third-party open source software, which could negatively affect our ability to offer our solutions and subject us to litigation or other actions.***

We use open source software licensed to us by third-party authors under “open source” licenses in our platform and solutions and expect to continue to use such open source software in the future. Use and distribution of open source software may entail greater risks than use of third-party commercial software, as open source licensors generally do not provide support, warranties, indemnification or other contractual protections regarding infringement claims or

the quality of the code. To the extent that our platform depends upon the successful operation of open source software, any undetected errors or defects in this open source software could prevent the deployment or impair the functionality of our platform, delay introductions of new solutions, result in a failure of our platform, and injure our reputation. For example, undetected errors or defects in open source software could render it vulnerable to breaches or security attacks, and, as a result, possibly make our systems more vulnerable to data breaches. In addition, the public availability of such software may make it easier for others to compromise our platform.

Further, there are uncertainties regarding the proper interpretation of and compliance with open source licenses, and there is a risk that such licenses could be construed in a manner that imposes unanticipated conditions or restrictions on our ability to use such open source software, and consequently to provide or distribute our platform and solutions. Some open source licenses contain express requirements that we make available source code for modifications or derivative works we create based upon the type of open source software we use, or grant other licenses to our intellectual property. If we combine our proprietary software with open source software in a certain manner, we could, under certain open source licenses, be required to release the source code of our proprietary software to the public. This would allow our competitors to create similar offerings with lower development effort and time and ultimately could result in a loss of our competitive advantages. Alternatively, to avoid the public release of the affected portions of our source code, we could be required to expend substantial time and resources to re-engineer some or all of our software.

Despite our efforts to monitor our use of open source software to avoid subjecting our platform to conditions we do not intend, there is a risk that open source licenses could be construed in a way that could impose unanticipated conditions or restrictions on our ability to provide or distribute our platform. Additionally, we may from time to time face claims from third parties claiming ownership of, or seeking to enforce the terms of, an open source license, including by demanding release of source code for the open source software, derivative works or our proprietary source code that was developed using, or that is distributed with, such open source software. These claims could also result in litigation and could require us to make our proprietary software source code freely available, devote additional research and development resources to re-engineer our platform, seek costly licenses from third parties, pay monetary damages to the owner of the copyright in the relevant open source software or otherwise incur additional costs and expenses, any of which could result in reputational harm and would have a negative effect on our business and results of operations. In addition, if the license terms for the open source software we utilize change, we may be forced to re-engineer our platform, incur additional costs to comply with the changed license terms or replace the affected open source software. Although we have implemented policies to regulate the use and incorporation of open source software into our platform and solutions, we cannot be certain that that such policies will be effective and that we have not incorporated open source software in our platform and solutions in a manner that is inconsistent with such policies.

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

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

- others may be able to develop products that are similar to our product candidates but that are not covered by the claims of the patents that we may own or license;
- we or our potential future licensors might not have been the first to make the inventions covered by the issued patents or patent application that we may own or license;
- we or our potential future licensors might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;



- it is possible that our or our future licensors' pending patent applications will not lead to issued patents;
- future issued patents that we own or license may be held invalid or unenforceable, as a result of legal challenges by our competitors;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

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

#### **Risks Related to Employee Matters and Managing our Growth**

***If we are unable to establish sales or marketing capabilities or enter into agreements with third parties to sell or market our product candidates, we may not be able to successfully sell or market our product candidates that obtain regulatory approval.***

We currently do not have and have never had a marketing or sales team. In order to commercialize any product candidates, if approved, we must build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services for each of the territories in which we may have approval to sell or market our product candidates. We may not be successful in accomplishing these required tasks.

Establishing an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates will be expensive and time-consuming, and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could adversely impact the commercialization of any of our product candidates that we obtain approval to market, if we do not have arrangements in place with third parties to provide such services on our behalf. Alternatively, if we choose to collaborate, either globally or on a territory-by-territory basis, 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, we will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration. If we are unable to enter into such arrangements when needed, on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval or any such commercialization may experience delays or limitations. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

***Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.***

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel, and we face significant competition for experienced personnel. We are highly dependent on the principal members of our management and scientific and medical staff. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our results of operations. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the biotechnology field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary, including bioinformatics and computational biologist specialists, for the future

success of our business. We could in the future have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can discover, develop and commercialize our product candidates will be limited and the potential for successfully growing our business will be harmed.

***In order to successfully implement our plans and strategies, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.***

As of June 30, 2021, we have 34 full-time employees, including 29 employees engaged in research and development. In order to successfully implement our development and commercialization plans and strategies, and as we transition into operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical, FDA and other comparable foreign regulatory agencies' review process of IMM-1-104 and any other product candidate we develop, while complying with any contractual obligations to contractors and other third parties we may have; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to successfully develop and, if approved, commercialize IMM-1-104 and any other product candidate will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including key aspects of clinical development and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third party service providers is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of any current or future product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing third party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and/or engaging additional third party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize IMM-1-104 and any other current or future product candidates and, accordingly, may not achieve our research, development and commercialization goals.

#### **Risks Related to Ownership of Our Class A Common Stock**

***We do not know whether an active, liquid and orderly trading market will develop for our Class A common stock or what the market price of our Class A common stock will be and as a result it may be difficult for you to sell your shares of our Class A common stock.***

An active trading market for our Class A common stock may never develop or be sustained. The market value of our Class A common stock may decrease from the initial public offering price and you may be unable to resell your shares of our Class A common stock at or above the initial public offering price. 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. The lack of an active market may also reduce the fair market value of your shares. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our Class A common stock and may impair our ability to enter into strategic collaborations or acquire companies, technologies or other assets by using our shares of Class A common stock as consideration.

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

The trading price of our Class A common stock is likely to be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. The stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. The trading prices for common stock of other pharmaceutical and biotechnology companies have also been highly volatile as a result of the pandemic related to COVID-19 and its variants.

Broad market and industry factors may negatively affect the market price of our Class A common stock, regardless of our actual operating performance. In addition to the factors discussed in this “Risk Factors” section and elsewhere in this Quarterly Report on Form 10-Q, these factors include:

- the timing and results of preclinical studies and clinical trials of our product candidates or those of our competitors;
- the success of competitive products or announcements by potential competitors of their product development efforts;
- regulatory actions with respect to our products or our competitors’ products;
- actual or anticipated changes in our growth rate relative to our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- market conditions in the pharmaceutical and biotechnology sector;
- changes in the structure of healthcare payment systems;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;

- announcement or expectation of additional financing efforts;
- sales of our Class A common stock by us, our insiders or our other stockholders;
- expiration of market stand-off or lock-up agreements;
- the ongoing and future impact of the pandemic related to COVID-19 and its variants, or any future pandemics, and actions taken to slow their spread; and
- general economic, industry and market conditions.

The realization of any of the above risks or any of a broad range of other risks, including those described in this “Risk Factors” section, could have a dramatic and adverse impact on the market price of our Class A common stock.

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

The trading market for our Class A common stock will be influenced by the research and reports that securities or industry analysts publish about us, our business or our market. We do not currently have and may never obtain research coverage by securities or industry analysts. If no or few securities or industry analysts commence coverage of us, the stock price would be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue adverse or misleading research or reports regarding us, our business model, our intellectual property, our stock performance or our market, or if our results of operations 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.

***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 September 3, 2021, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 60% of our voting stock and these stockholders will be able 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 Class A common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their Class A common stock, and might affect the prevailing market price for our Class A common stock.

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

Our Class A common stock price could decline as a result of sales of a large number of shares of Class A and/or Class B common stock (collectively, including Class A common stock shares issuable upon conversion of the Class B common stock, the “common stock”) or the perception that these sales could occur. These sales, or the possibility that these sales may occur, might also make it more difficult for us to sell equity securities in the future at a time and price that we deem appropriate.

All shares of Class A common stock sold in our IPO are freely tradable without restriction or further registration under the Securities Act of 1933, as amended, or the Securities Act, unless held by our “affiliates” as defined in Rule 144 under the Securities Act. The resale of the remaining 16,889,410 shares, or approximately 65.1% of our outstanding shares of common stock, is currently prohibited or otherwise restricted as a result of securities law provisions, market standoff

agreements entered into by certain of our stockholders with us or lock-up agreements entered into by our stockholders with the underwriters in connection with the IPO. However, subject to applicable securities law restrictions, these shares will be able to be sold in the public market beginning 181 days after the date of the Prospectus. Shares issued upon the exercise of stock options and warrants outstanding under our equity incentive plans or pursuant to future awards granted under those plans will become available for sale in the public market to the extent permitted by the provisions of applicable vesting schedules, market stand-off agreements and/or lock-up agreements, as well as Rules 144 and 701 under the Securities Act.

The holders of approximately 11,939,281 shares, or approximately 46.0% of our outstanding shares of our common stock have rights, subject to some conditions, to require us to file registration statements covering the sale of their shares or to include their shares in registration statements that we may file for ourselves or our other stockholders. Once we register the offer and sale of shares for the holders of registration rights, these shares will be able to be sold in the public market upon issuance, subject to the lock-up agreements described above.

In addition, in the future, we may issue additional shares of Class A common stock, or other equity or debt securities convertible into Class A common stock, in connection with a financing, acquisition, employee arrangement or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and could cause the price of our Class A common stock to decline.

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

We have never declared or paid any cash dividends on our equity securities. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to any appreciation in the value of our Class A common stock, which is not certain.

***Provisions in our certificate of incorporation and bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our Class A common stock.***

Our certificate of incorporation and bylaws contain provisions that could depress the market price of our Class A common stock by acting to discourage, delay or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things:

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- provide that directors may only be removed “for cause” and only with the approval of two-thirds of our stockholders;
- authorize the issuance of “blank check” preferred stock that our board could use to implement a stockholder rights plan (also known as a “poison pill”);
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting;

- authorize our board of directors to amend the bylaws;
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings; and
- require a super-majority vote of stockholders to amend some provisions described above.

In addition, Section 203 of the General Corporation Law of the State of Delaware, or the DGCL, prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Any provision of our certificate of incorporation, bylaws or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our Class A common stock.

***Our amended and restated certificate of incorporation and amended and restated bylaws provides for an exclusive forum in the Court of Chancery of the State of Delaware 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 DGCL, 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 is the exclusive forum for the resolution of any complaint asserting a cause or causes of action against any defendant arising under the Securities Act. Such provision is intended to benefit and may be enforced by us, our officers and directors, employees and agents, including the underwriters and any other professional or entity who has prepared or certified any part of this prospectus. Nothing in our amended and restated certificate of incorporation or 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.

We believe these provisions may benefit us by providing increased consistency in the application of Delaware law and federal securities laws by chancellors and judges, as applicable, particularly experienced in resolving corporate disputes, efficient administration of cases on a more expedited schedule relative to other forums and protection against the burdens of multi-forum litigation. 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 or make such lawsuits more costly for stockholders, 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.

## General Risks

***Our internal computer systems, or those of any of our CROs, manufacturers, other contractors, consultants, collaborators or potential future collaborators, may fail or suffer security or data privacy breaches or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data, or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations.***

Despite the implementation of security measures, our internal computer systems and those of our current and any future CROs and other contractors, consultants, collaborators and third-party service providers, are vulnerable to damage from computer viruses, cybersecurity threats, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failure. If such an event were to occur and cause interruptions in our operations or result in the unauthorized acquisition of or access to personally identifiable information or individually identifiable health information (violating certain privacy laws such as HIPAA, HITECH and GDPR), it could result in a material disruption of our drug discovery and development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions. Some of the federal, state and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships. Notifications and follow-up actions related to a security breach could impact our reputation, cause us to incur significant costs, including legal expenses and remediation costs. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. We also rely on third parties to manufacture our product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data, or inappropriate disclosure of confidential or proprietary information, we could be exposed to litigation and governmental investigations, the further development and commercialization of our product candidates could be delayed, and we could be subject to significant fines or penalties for any noncompliance with certain state, federal and/or international privacy and security laws.

Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption, failure or security breach. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

***Our operations are vulnerable to interruption by fire, severe weather conditions, power loss, telecommunications failure, terrorist activity, future pandemics and other events beyond our control, which could harm our business.***

Our facilities are located in regions which experience severe weather from time to time. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major tornado, flood, fire, earthquake, power loss, terrorist activity, future pandemics or other disasters and do not have a recovery plan for such disasters. In addition, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

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

We are an “emerging growth company,” as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we intend to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced “Management’s Discussion and Analysis of Financial Condition and Results of Operations” disclosure in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor’s report on financial statements;
- reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements; and
- exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our Class A common stock less attractive because we may rely on these exemptions. If some investors find our Class A common stock less attractive as a result, there may be a less active trading market for our Class A common stock and our stock price may be more volatile.

We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which we have more than \$1.07 billion in annual revenue; (2) the date we qualify as a “large accelerated filer,” with at least \$700 million of equity securities held by non-affiliates; (3) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We intend to take advantage of the extended transition period for adopting new or revised accounting standards under the JOBS Act as an emerging growth company. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates.

***The requirements of being a public company may strain our resources, result in more litigation and divert management’s attention.***

As a public company, we are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, or the Dodd-Frank Act, the listing requirements of Nasdaq and other applicable securities rules and regulations. Complying with these rules and regulations has increased and will increase our legal and financial compliance costs, make some activities more difficult, time consuming or costly and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and results of operations. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. We are required to disclose changes made in our internal control and procedures on a quarterly basis. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management’s attention may be diverted from other business concerns, which could adversely affect our business and results of operations. We may also need to hire additional employees or engage outside consultants to comply with these requirements, which will increase our costs and expenses.



In addition, changing laws, regulations and standards relating to corporate governance and public disclosure are creating uncertainty for public companies, increasing legal and financial compliance costs and making some activities more time consuming. These laws, regulations and standards are subject to varying interpretations, in many cases due to their lack of specificity and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to their application and practice, regulatory authorities may initiate legal proceedings against us and our business may be adversely affected.

These new rules and regulations may make it more expensive for us to obtain director and officer liability insurance and, in the future, we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our board of directors, particularly to serve on our audit committee and compensation committee, and qualified executive officers.

By disclosing information in this Quarterly Report on Form 10-Q and in future filings required of a public company, our business and financial condition will become more visible, which we believe may result in threatened or actual litigation, including by competitors and other third parties. If those claims are successful, our business could be seriously harmed. Even if the claims do not result in litigation or are resolved in our favor, the time and resources needed to resolve them could divert our management's resources and seriously harm our business.

***If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our Class A common stock.***

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to 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. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our stock.

We will be required to disclose changes made in our internal controls and procedures on a quarterly basis and our management will be required to assess the effectiveness of these controls annually. However, for as long as we are a smaller reporting company, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404. An independent assessment of the effectiveness of our internal controls over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal controls over financial reporting could lead to restatements of our financial statements and require us to incur the expense of remediation.

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

The market price of our Class A common stock may be volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

***New tax legislation may impact our results of operations and financial condition.***

The U.S. government may enact significant changes to the taxation of business entities including, among others, an increase in the corporate income tax rate, an increase in the tax rate applicable to the global intangible low-taxed income and elimination of certain exemptions, and the imposition of minimum taxes or surtaxes on certain types of income. No specific United States tax legislation has been proposed at this time and the likelihood of these changes being enacted or implemented is unclear. We are currently unable to predict whether such changes will occur. If such changes are enacted or implemented, we are currently unable to predict the ultimate impact on our business.

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

***Unregistered Sales of Equity Securities***

In April and May 2021, we issued 2,412,853 shares of our Series B Preferred Stock, upon the voluntary election of substantially all of the holders of Series B Preferred Stock, pursuant to the terms of such Series B Preferred Stock. We received gross proceeds of \$24,799,786 in connection with this issuance, and incurred issuance costs of \$10,935.

In June 2021, all warrant holders exercised their warrants, resulting in the purchase of an aggregate of 308,308 shares of our Class A common stock. We received total proceeds from the warrant exercises of \$927,125.

In June 2021, we issued 17,499 shares of Class A common stock upon the exercise of stock options. We received total proceeds from the exercises of stock options of \$52,127.

***Use of Proceeds***

On August 3, 2021, we completed the IPO, in which we issued and sold 8,625,000 shares of our Class A common stock, inclusive of 1,125,000 shares we sold pursuant to the full exercise of the underwriters' option to purchase additional shares, at a price to the public of \$15.00 per share.

The offer and sale of all of the shares of our Class A common stock in the IPO were registered under the Securities Act pursuant to a registration statement on Form S-1, as amended (File No. 333-257791), which was declared effective by the SEC on July 29, 2021, and a registration statement on Form S-1 MEF (File No. 333-257791), which was automatically effective upon filing with the SEC on July 29, 2021. Morgan Stanley & Co. LLC, Jefferies LLC and Cowen and Company, LLC acted as representatives of the underwriters for the offering. Following the sale of all of the shares offered in connection with the closing of our IPO, the offering terminated.

We received aggregate gross proceeds from our IPO of \$129.4 million, or aggregate net proceeds of \$118.3 million after deducting underwriting discounts and commissions and other estimated offering expenses. No payments for such expenses were made directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities or (iii) any of our affiliates. There has been no material change in the planned use of IPO proceeds from that described in the Prospectus.

***Issuer Purchases of Equity Securities***

None.

**Item 3. Defaults Upon Senior Securities**

None.

**Item 4. Mine Safety Disclosures**

Not applicable

**Item 5. Other Information**

None.

**Item 6. Exhibits**

**EXHIBIT INDEX**

Exhibit Number	Exhibit Description	Incorporated by Reference				Filed/ Furnished Herewith
		Form	File No.	Exhibit	Filing Date	
3.1	<a href="#">Amended and Restated Certificate of Incorporation of Immuneering Corporation</a>					*
3.2	<a href="#">Amended and Restated Bylaws of Immuneering Corporation</a>					*
4.1	<a href="#">Specimen Stock Certificate</a>	S-1/A	333-257791	4.1	07/26/2021	
4.2	<a href="#">Amended and Restated Investors' Rights Agreement, as amended, dated December 21, 2020, by and among Immuneering Corporation and the other parties thereto</a>	S-1/A	333-257791	4.2	07/26/2021	
31.1	<a href="#">Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a).</a>					*
31.2	<a href="#">Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a).</a>					*
32.1	<a href="#">Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350.</a>					**
32.2	<a href="#">Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350.</a>					**
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.					*
101.SCH	Inline XBRL Taxonomy Extension Schema Document.					*
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document.					*
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document.					*
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document.					*
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document.					*
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)					*
*	Filed herewith.					
**	Furnished herewith.					

**SIGNATURES**

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

**IMMUNEERING CORPORATION**

Date: September 9, 2021

By: /s/ Benjamin J. Zeskind  
Name: Benjamin J. Zeskind, Ph.D.  
Title: Co-Founder, President, Chief Executive Officer and Director  
(Principal Executive Officer)

Date: September 9, 2021

By: /s/ Biren Amin  
Name: Biren Amin  
Title: Chief Financial Officer and Treasurer  
(Principal Financial Officer and Principal Accounting Officer)

**AMENDED AND RESTATED CERTIFICATE OF INCORPORATION  
OF  
IMMUNEERING CORPORATION**

Immuneering Corporation (the "Corporation"), a corporation organized and existing under the General Corporation Law of the State of Delaware (the "DGCL"), does hereby certify as follows:

1. The name of the Corporation is Immuneering Corporation. The Corporation was incorporated under the name Immuneering Corporation by the filing of its original Certificate of Incorporation with the Secretary of State of the State of Delaware on February 14, 2008.

2. This Amended and Restated Certificate of Incorporation (the "Restated Certificate"), which amends, restates and further integrates the certificate of incorporation of the Corporation as heretofore in effect, has been approved by the Board of Directors of the Corporation (the "Board of Directors") in accordance with Sections 242 and 245 of the DGCL, and has been adopted by the written consent of the stockholders of the Corporation in accordance with Section 228 of the DGCL.

3. The text of the certificate of incorporation of the Corporation, as heretofore amended, is hereby amended and restated by this Restated Certificate to read in its entirety as set forth in EXHIBIT A attached hereto.

IN WITNESS WHEREOF, Immuneering Corporation has caused this Amended and Restated Certificate of Incorporation to be signed by a duly authorized officer of the Corporation, on August 3, 2021.

**Immuneering Corporation**, a Delaware corporation

By:   /s/ Benjamin J. Zeskind    
Name: Benjamin J. Zeskind, Ph.D.  
Title: President and Chief Executive Officer

[Signature Page to Certificate of Incorporation]

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## **EXHIBIT A**

### **ARTICLE I**

The name of the corporation is Immuneering Corporation (the "Corporation").

### **ARTICLE II**

The address of the Corporation's registered office in the State of Delaware is 1209 Orange Street, in the City of Wilmington, County of New Castle, 19801, and the name of its registered agent at such address is The Corporation Trust Company.

### **ARTICLE III**

The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware (the "DGCL") as it now exists or may hereafter be amended and supplemented.

### **ARTICLE IV**

The Corporation is authorized to issue three classes of stock to be designated, respectively, "Class A Common Stock," "Class B Common Stock," and "Preferred Stock." The total number of shares of all classes of capital stock which the Corporation shall have authority to issue is 230 million (230,000,000), consisting of 200 million (200,000,000) shares of Class A Common Stock, having a par value of \$0.001 per share, 20 million (20,000,000) shares of Class B Common Stock, having a par value of \$0.001 per share, and ten million (10,000,000) shares of Preferred Stock, having a par value of \$0.001 per share. Any references to "Common Stock" in this Amended and Restated Certificate of Incorporation shall mean Class A Common Stock or Class B Common Stock unless specifically stated otherwise.

### **ARTICLE V**

The designations and the powers, privileges and rights, and the qualifications, limitations or restrictions thereof in respect of each class of capital stock of the Corporation are as follows:

#### **A. COMMON STOCK.**

1. General. The voting, dividend, liquidation, and other rights and powers of the Class A Common Stock and Class B Common Stock are subject to and qualified by the rights, powers and preferences of any series of Preferred Stock as may be designated by the Board of Directors of the Corporation (the "Board of Directors") and outstanding from time to time.

2. Voting. Except as otherwise provided herein or expressly required by law, each holder of Class A Common Stock, as such, shall be entitled to vote on each matter submitted to a vote of stockholders and shall be entitled to one (1) vote for each share of Class A Common Stock held of record by such holder as of the record date for determining stockholders entitled to vote on such matter. Except as otherwise required by law, holders of Class A

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Common Stock, as such, shall not be entitled to vote on any amendment to this Amended and Restated Certificate of Incorporation (including any Certificate of Designation (as defined below)) that relates solely to the rights, powers, preferences (or the qualifications, limitations or restrictions thereof) or other terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together with the holders of one or more other such series, to vote thereon pursuant to this Restated Certificate (including any Certificate of Designation) or pursuant to the DGCL.

Except as otherwise required by law, holders of Class B Common Stock shall not be entitled to vote on any matter on which the holders of Class A Common Stock or Preferred Stock shall be entitled to vote, and shares of Class B Common Stock shall not be included in determining the number of shares of common stock voting or entitled to vote on any such matters. Shares of Class B Common Stock shall not be certificated, but shall instead be held in book-entry form on the books and records of the Corporation.

Subject to the rights of any holders of any outstanding series of Preferred Stock, the number of authorized shares of Class A Common Stock and/or Class B Common Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the stock of the Corporation entitled to vote, irrespective of the provisions of Section 242(b)(2) of the DGCL.

Except as expressly set forth in this Article V with respect to voting rights only, the Class B Common Stock shall have the same rights and powers of, rank equally to, share ratably with and be identical in all respects and as to all matters to Class A Common Stock. If the Corporation in any manner subdivides or combines the shares of Class A Common Stock, then the shares of Class B Common Stock will be subdivided or combined in the same proportion and manner, and if the Corporation in any manner subdivides or combines the shares of Class B Common Stock, then the outstanding shares of Class A Common Stock will be subdivided or combined in the same proportion and manner.

3. Dividends. Subject to applicable law and the rights and preferences of any holders of any outstanding series of Preferred Stock, the holders of Common Stock, as such, shall be entitled to the payment of dividends on the Common Stock when, as and if declared by the Board of Directors in accordance with applicable law.

4. Liquidation. Subject to the rights and preferences of any holders of any shares of any outstanding series of Preferred Stock, in the event of any liquidation, dissolution or winding up of the Corporation, whether voluntary or involuntary, the funds and assets of the Corporation that may be legally distributed to the Corporation's stockholders shall be distributed among the holders of the then outstanding Common Stock pro rata in accordance with the number of shares of Common Stock held by each such holder.

## B. PREFERRED STOCK

Shares of Preferred Stock may be issued from time to time in one or more series, each of such series to have such terms as stated or expressed herein and in the resolution or resolutions providing for the creation and issuance of such series adopted by the Board of Directors as hereinafter provided.

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Authority is hereby expressly granted to the Board of Directors from time to time to issue the Preferred Stock in one or more series, and in connection with the creation of any such series, by adopting a resolution or resolutions providing for the issuance of the shares thereof and by filing a certificate of designation relating thereto in accordance with the DGCL (a “Certificate of Designation”), to determine and fix the number of shares of such series and such voting powers, full or limited, or no voting powers, and such designations, preferences and relative participating, optional or other special rights, and qualifications, limitations or restrictions thereof, including without limitation thereof, dividend rights, conversion rights, redemption privileges and liquidation preferences, and to increase or decrease (but not below the number of shares of such series then outstanding) the number of shares of any series as shall be stated and expressed in such resolutions, all to the fullest extent now or hereafter permitted by the DGCL. Without limiting the generality of the foregoing, the resolution or resolutions providing for the creation and issuance of any series of Preferred Stock may provide that such series shall be superior or rank equally or be junior to any other series of Preferred Stock to the extent permitted by law and this Restated Certificate (including any Certificate of Designation). Except as otherwise required by law, holders of any series of Preferred Stock shall be entitled only to such voting rights, if any, as shall expressly be granted thereto by this Restated Certificate (including any Certificate of Designation).

The number of authorized shares of Preferred Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority of the stock of the Corporation entitled to vote, irrespective of the provisions of Section 242(b)(2) of the DGCL.

## ARTICLE VI

Subject to the terms of this Article VI, shares of Class B Common Stock shall be convertible into a corresponding number of Class A Common Stock upon written notice by the holder thereof.

A. Notwithstanding anything to the contrary herein (but subject to Section B of this Article VI), no holder of Class B Common Stock shall be entitled to receive, and the Corporation shall not deliver to any such holder, any Class A Common Stock upon conversion of the Class B Common Stock to the extent (but only to the extent) that, after such receipt, such converting holder and its Affiliates (as defined below) (together, the “Related Holders”) would beneficially own in the aggregate, directly or indirectly, shares of Class A Common Stock in excess of 9.9% of such shares outstanding at such time (the “Section 16 Limitation”).

B. For avoidance of doubt, in the event that the Related Holders beneficially own in the aggregate, directly or indirectly, shares of Class A Common Stock in excess of the Section 16 Limitation without taking into account the conversion of Class B Common Stock, then none of the Class B Common Stock shall be convertible until such time as the Related Holders no longer beneficially own in the aggregate, directly or indirectly, shares of Class A Common Stock in excess of the Section 16 Limitation. Any conversion notice provided by a converting holder

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under this Article VI shall constitute the holder's acknowledgement and confirmation to the Corporation that (i) the acquisition of the shares of Class A Common Stock sought in the conversion notice will not result in Related Holders becoming in the aggregate, directly or indirectly, the beneficial owner of more shares of Class A Common Stock than permitted by the Section 16 Limitation and (ii) any Class A Common Stock to which the holder would be entitled but for the Section 16 Limitation will remain Class B Common Stock. Any purported delivery of shares of Class A Common Stock upon conversion of Class B Common Stock shall be void *ab initio* and shall have no effect to the extent (but only to the extent) that such delivery would result in the Related Holders becoming in the aggregate, directly or indirectly, the beneficial owner of more shares of Class A Common Stock than permitted by the Section 16 Limitation. Before any holder shall be entitled to exchange any shares of such Class B Common Stock pursuant to this provision, such holder shall give written notice to the Corporation at its principal corporate office, of the election to exchange the same and shall state therein the name or names in which the certificate or certificates for shares of Class A Common Stock are to be issued. The Corporation shall, as soon as practicable thereafter, issue and deliver to the holder, or to the nominee or nominees of such holder, a certificate or certificates (unless shares of Class A Common Stock are then maintained in book-entry form) for the number of shares of Class A Common Stock to which such holder shall be entitled as aforesaid. Such exchange shall be deemed to have been made immediately prior to the close of business on the date of such written notice, and the person or persons entitled to receive the shares of Class A Common Stock issuable upon such exchange shall be treated for all purposes as the record holder or holders of such shares of Class A Common Stock as of such date. Each share of Class B Common Stock that is exchanged pursuant to this Section B of Article VI shall be retired by the Corporation and shall not be available for reissuance. Within two business days of any request by a holder of Class B Common Stock, the Corporation shall inform such holder in writing of the then current number of outstanding shares of Class A Common Stock and Class B Common Stock.

C. Any shares of Class B Common Stock shall be exchanged for a corresponding number of fully paid and nonassessable shares of Class A Common Stock immediately upon request following a Non-Affiliate Transfer. A "Non-Affiliate Transfer" shall mean a transfer of shares of Class B Common Stock to any Person (as defined below) that is not an Affiliate of a holder of the Class B Common Stock immediately following the issuance thereof. The Corporation shall, upon the request of each such holder and a certification from such transferee holder of such holder's non-affiliation with the original holder of such Class B Common Stock, issue and deliver to such holder new certificates (unless shares of Class A Common Stock are then maintained in book-entry form) representing such non-Affiliate holder's shares of Class A Common Stock. Such exchange shall be deemed to have been made immediately prior to the close of business on the date of such request and certification, and the person or persons entitled to receive the shares of Class A Common Stock issuable upon such exchange shall be treated for all purposes as the record holder or holders of such shares of Class A Common Stock as of such date. Each share of Class B Common Stock that is exchanged pursuant to this Section C of Article VI shall be retired and canceled by the Corporation and shall not be available for reissuance.

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D. For purposes of this Article VI, the following definitions shall apply:

“Affiliate” shall mean, with respect to any specified Person, any other Person who directly or indirectly, controls, is controlled by or is under common control with such Person, including, without limitation, any general partner, managing member, officer, director or trustee of such Person, or any venture capital fund or other investment fund or account or registered investment company now or hereafter existing which is controlled by one or more general partners, managing members or investment advisers of, or shares the same management company or investment adviser with, such Person.

“Person” shall mean any individual, corporation, partnership, trust, limited liability company, association or other entity.

## ARTICLE VII

For the management of the business and for the conduct of the affairs of the Corporation it is further provided that:

A. Subject to the special rights of the holders of one or more outstanding series of Preferred Stock to elect directors, the directors of the Corporation shall be classified with respect to the time for which they severally hold office into three classes, designated as Class I, Class II and Class III. The initial Class I directors shall serve for a term expiring at the first annual meeting of the stockholders following the initial registration of the Corporation’s Class A Common Stock pursuant to the Securities Exchange Act of 1934, as amended; the initial Class II directors shall serve for a term expiring at the second annual meeting of the stockholders following such registration; and the initial Class III directors shall serve for a term expiring at the third annual meeting following such registration.

At each annual meeting of stockholders of the Corporation beginning with the first annual meeting of stockholders following the Effective Time, subject to any special rights of the holders of one or more outstanding series of Preferred Stock to elect directors, the successors of the class of directors whose term expires at that meeting shall be elected to hold office for a term expiring at the annual meeting of stockholders held in the third year following the year of their election. Each director shall hold office until his or her successor is duly elected and qualified or until his or her earlier death, resignation, disqualification or removal. No decrease in the number of directors shall shorten the term of any incumbent director. The Board of Directors is authorized to assign members of the Board of Directors already in office to Class I, Class II and Class III.

B. Except as otherwise expressly provided by the DGCL or this Restated Certificate, the business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors. The number of directors which shall constitute the whole Board of Directors shall be fixed exclusively by one or more resolutions adopted from time to time by the Board of Directors.

C. Subject to the special rights of the holders of one or more outstanding series of Preferred Stock to elect directors, the Board of Directors or any individual director may be removed from office at any time, but only for cause and only by the affirmative vote of the holders of at least two-thirds of the voting power of all of the then outstanding shares of voting stock of the Corporation entitled to vote at an election of directors.

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D. Subject to the special rights of the holders of one or more outstanding series of Preferred Stock to elect directors, except as otherwise provided by law, any vacancies on the Board of Directors resulting from death, resignation, disqualification, retirement, removal or other causes and any newly created directorships resulting from any increase in the number of directors shall be filled exclusively by the affirmative vote of a majority of the directors then in office, even though less than a quorum, or by a sole remaining director (other than any directors elected by the separate vote of one or more outstanding series of Preferred Stock), and shall not be filled by the stockholders. Any director appointed in accordance with the preceding sentence shall hold office until the expiration of the term of the class to which such director shall have been appointed or until his or her earlier death, resignation, retirement, disqualification, or removal.

E. Whenever the holders of any one or more series of Preferred Stock issued by the Corporation shall have the right, voting separately as a series or separately as a class with one or more such other series, to elect directors at an annual or special meeting of stockholders, the election, term of office, removal and other features of such directorships shall be governed by the terms of this Certificate of Incorporation (including any Certificate of Designation). Notwithstanding anything to the contrary in this Article VII, the number of directors that may be elected by the holders of any such series of Preferred Stock shall be in addition to the number fixed pursuant to paragraph B of this Article VII, and the total number of directors constituting the whole Board of Directors shall be automatically adjusted accordingly. Except as otherwise provided in the Certificate of Designation(s) in respect of one or more series of Preferred Stock, whenever the holders of any series of Preferred Stock having such right to elect additional directors are divested of such right pursuant to the provisions of such Certificate of Designation(s), the terms of office of all such additional directors elected by the holders of such series of Preferred Stock, or elected to fill any vacancies resulting from the death, resignation, disqualification or removal of such additional directors, shall forthwith terminate (in which case each such director thereupon shall cease to be qualified as, and shall cease to be, a director) and the total authorized number of directors of the Corporation shall automatically be reduced accordingly.

F. In furtherance and not in limitation of the powers conferred by statute, the Board of Directors is expressly authorized to adopt, amend or repeal Bylaws of the Corporation. In addition to any vote of the holders of any class or series of stock of the Corporation required by applicable law or by this Certificate of Incorporation (including any Certificate of Designation in respect of one or more series of Preferred Stock) or the Bylaws of the Corporation, the adoption, amendment or repeal of the Bylaws of the Corporation by the stockholders of the Corporation shall require the affirmative vote of the holders of at least two-thirds of the voting power of all of the then outstanding shares of voting stock of the Corporation entitled to vote generally in an election of directors.

G. The directors of the Corporation need not be elected by written ballot unless the Bylaws so provide.

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## ARTICLE VIII

The Corporation renounces any interest or expectancy of the Corporation in, or in being offered an opportunity to participate in, any Excluded Opportunity. An “Excluded Opportunity” is any matter, transaction or interest that is presented to, or acquired, created or developed by, or which otherwise comes into the possession of, any director of the Corporation who is not an employee or officer of the Corporation or any of its subsidiaries (a “Covered Person”), unless such matter, transaction or interest is presented to, or acquired, created or developed by, or otherwise comes into the possession of, a Covered Person expressly and solely in such Covered Person’s capacity as a director of the Corporation.

## ARTICLE IX

A. Any action required or permitted to be taken by the stockholders of the Corporation must be effected at an annual or special meeting of the stockholders of the Corporation, and shall not be taken by written consent in lieu of a meeting. Notwithstanding the foregoing, any action required or permitted to be taken by the holders of any series of Preferred Stock, voting separately as a series or separately as a class with one or more other such series, may be taken without a meeting, without prior notice and without a vote, to the extent expressly so provided by the applicable Certificate of Designation relating to such series of Preferred Stock, if a consent or consents in writing, setting forth the action so taken, shall be signed by the holders of outstanding shares of the relevant series of Preferred Stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted and shall be delivered to the Corporation in accordance with the applicable provisions of the DGCL.

B. Subject to the special rights of the holders of one or more series of Preferred Stock, special meetings of the stockholders of the Corporation may be called, for any purpose or purposes, at any time only by or at the direction of the Board of Directors, the Chairperson of the Board of Directors or the Chief Executive Officer, and shall not be called by any other person or persons.

C. Advance notice of stockholder nominations for the election of directors and of other business proposed to be brought by stockholders before any meeting of the stockholders of the Corporation shall be given in the manner provided in the Bylaws of the Corporation.

## ARTICLE X

No director of the Corporation shall have any personal liability to the Corporation or its stockholders for monetary damages for any breach of fiduciary duty as a director, except to the extent such exemption from liability or limitation thereof is not permitted under the DGCL as the same exists or hereafter may be amended.

Any amendment, repeal or modification of this Article X, or the adoption of any provision of the Restated Certificate inconsistent with this Article X, shall not adversely affect any right or protection of a director of the Corporation with respect to any act or omission occurring prior to such amendment, repeal, modification or adoption. If the DGCL is amended after approval by the stockholders of this Article X to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the DGCL as so amended.

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## ARTICLE XI

The Corporation shall have the power to provide rights to indemnification and advancement of expenses to its current and former officers, directors, employees and agents and to any person who is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise.

## ARTICLE XII

Unless the Corporation consents in writing to the selection of an alternative forum, (a) the Court of Chancery (the "Chancery Court") of the State of Delaware (or, in the event that the Chancery Court does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for (i) any derivative action, suit or proceeding brought on behalf of the Corporation, (ii) any action, suit or proceeding asserting a claim of breach of a fiduciary duty owed by any director, officer or stockholder of the Corporation to the Corporation or to the Corporation's stockholders, (iii) any action, suit or proceeding arising pursuant to any provision of the DGCL or the bylaws of the Corporation or this Restated Certificate (as either may be amended from time to time) or (iv) any action, suit or proceeding asserting a claim against the Corporation governed by the internal affairs doctrine; and (b) subject to the preceding provisions of this Article XII, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933, as amended. If any action the subject matter of which is within the scope of clause (a) of the immediately preceding sentence is filed in a court other than the courts in the State of Delaware (a "Foreign Action") in the name of any stockholder, such stockholder shall be deemed to have consented to (x) the personal jurisdiction of the state and federal courts in the State of Delaware in connection with any action brought in any such court to enforce the provisions of clause (a) of the immediately preceding sentence and (y) 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.

Any person or entity purchasing or otherwise acquiring any interest in any security of the Corporation shall be deemed to have notice of and consented to this Article XII. Notwithstanding the foregoing, the provisions of this Article XII shall not apply to suits brought to enforce any liability or duty created by the Securities Exchange Act of 1934, as amended, or any other claim for which the federal courts of the United States have exclusive jurisdiction.

If any provision or provisions of this Article XII shall be held to be invalid, illegal or unenforceable as applied to any circumstance for any reason whatsoever, (a) the validity, legality and enforceability of such provisions in any other circumstance and of the remaining provisions of this Article XII (including, without limitation, each portion of any paragraph of this Article XII containing any such provision held to be invalid, illegal or unenforceable that is not itself held to be invalid, illegal or unenforceable) shall not in any way be affected or impaired thereby and (b) the application of such provision to other persons or entities and circumstances shall not in any way be affected or impaired thereby.

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### ARTICLE XIII

A. Notwithstanding anything contained in this Restated Certificate to the contrary, in addition to any vote required by applicable law, the following provisions in this Restated Certificate may be amended, altered, repealed or rescinded (whether by merger, consolidation or otherwise), in whole or in part, or any provision inconsistent therewith or herewith may be adopted, only by the affirmative vote of the holders of at least 66 2/3% of the total voting power of all the then outstanding shares of stock of the Corporation entitled to vote thereon, voting together as a single class: Part B of Article V, Article VII, Article IX, Article X, Article XI, Article XII, and this Article XIII; provided that neither (w) the second, third and/or fourth paragraph of part A.2 of Article V, nor (x) parts A.3 or A.4 of Article V (as it relates to the equal treatment of the Class B Common Stock), nor (y) Article VI, nor (z) this proviso of Part A of Article XIII shall be waived, altered, amended or repealed (whether by merger, consolidation or otherwise), in whole or in part, without the unanimous vote of the holders of the outstanding shares of Class B Common Stock.

B. If any provision or provisions of this Restated Certificate shall be held to be invalid, illegal or unenforceable as applied to any circumstance for any reason whatsoever: (i) the validity, legality and enforceability of such provisions in any other circumstance and of the remaining provisions of this Restated Certificate (including, without limitation, each portion of any paragraph of this Restated Certificate containing any such provision held to be invalid, illegal or unenforceable that is not itself held to be invalid, illegal or unenforceable) shall not, to the fullest extent permitted by applicable law, in any way be affected or impaired thereby and (ii) to the fullest extent permitted by applicable law, the provisions of this Restated Certificate (including, without limitation, each such portion of any paragraph of this Restated Certificate containing any such provision held to be invalid, illegal or unenforceable) shall be construed so as to permit the Corporation to protect its directors, officers, employees and agents from personal liability in respect of their good faith service to or for the benefit of the Corporation to the fullest extent permitted by law.

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**AMENDED AND RESTATED  
BYLAWS  
OF  
IMMUNEERING CORPORATION  
(a Delaware corporation)**

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**AMENDED AND RESTATED BYLAWS  
OF  
IMMUNEERING CORPORATION**

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**ARTICLE I - CORPORATE OFFICES**

1.1 REGISTERED OFFICE

The registered office of Immuneering Corporation (the "Corporation") shall be fixed in the Corporation's certificate of incorporation, as the same may be amended and/or restated from time to time (the "certificate of incorporation").

1.2 OTHER OFFICES

The Corporation may have other offices at any place or places, either within or outside the State of Delaware, as the Corporation's board of directors (the "Board") shall from time to time determine or the business of the Corporation may from time to time require.

**ARTICLE II - MEETINGS OF STOCKHOLDERS**

2.1 PLACE OF MEETINGS

Meetings of stockholders shall be held at any place, within or outside the State of Delaware, designated by the Board. The Board may, in its sole discretion, determine that a meeting of stockholders shall not be held at any place, but may instead be held solely by means of remote communication as authorized by Section 211(a) of the General Corporation Law of the State of Delaware (the "DGCL"). In the absence of any such designation or determination, stockholders' meetings shall be held at the Corporation's principal executive office.

2.2 ANNUAL MEETING

The Board shall designate the date and time of the annual meeting. At the annual meeting, directors shall be elected and other proper business properly brought before the meeting in accordance with Section 2.4 of these bylaws may be transacted.

2.3 SPECIAL MEETING

A special meeting of the stockholders may be called at any time by the Board, chairperson of the Board, chief executive officer or president (in the absence of a chief executive

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officer) of the Corporation, but such special meetings may not be called by any other person or persons.

No business may be transacted at such special meeting other than the business specified in such notice to stockholders. Nothing contained in this paragraph of this Section 2.3 shall be construed as limiting, fixing, or affecting the time when a meeting of stockholders called by action of the Board may be held.

#### 2.4 ADVANCE NOTICE PROCEDURES FOR BUSINESS BROUGHT BEFORE A MEETING

(a) At an annual meeting of the stockholders, only such business shall be conducted as shall have been properly brought before the meeting. To be properly brought before an annual meeting, business must be (i) brought before the meeting by the Corporation and specified in a notice of meeting given by or at the direction of the Board, (ii) brought before the meeting by or at the direction of the Board (or a committee thereof) or (iii) otherwise properly brought before the meeting by a stockholder who (A) was a stockholder of record of the Corporation (and, with respect to any beneficial owner, if different, on whose behalf such business is proposed, only if such beneficial owner was the beneficial owner of shares of the Corporation) both at the time of giving the notice provided for in this Section 2.4 and at the time of the meeting, (B) is entitled to vote at the meeting and (C) has complied with this Section 2.4 as to such business. Except for proposals properly made in accordance with Rule 14a-8 under the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder (as so amended and inclusive of such rules and regulations, the “Exchange Act”), and included in the notice of meeting given by or at the direction of the Board, the foregoing clause (iii) shall be the exclusive means for a stockholder to propose business to be brought before an annual meeting of the stockholders. Stockholders shall not be permitted to propose business to be brought before a special meeting of the stockholders, and the only matters that may be brought before a special meeting are the matters specified in the notice of meeting given by or at the direction of the person calling the meeting pursuant to Section 2.3 of these bylaws. Stockholders seeking to nominate persons for election to the Board must comply with Section 2.5 of these bylaws, and this Section 2.4 shall not be applicable to nominations except as expressly provided in Section 2.5 of these bylaws.

(b) Without qualification, for business to be properly brought before an annual meeting by a stockholder pursuant to clause (iii) of the second sentence of Section 2.4(a) of these bylaws, the stockholder must (i) provide Timely Notice (as defined below) thereof in writing and in proper form to the secretary of the Corporation and (ii) provide any updates or supplements to such notice at the times and in the forms required by this Section 2.4. To be timely, a stockholder’s notice must be delivered to, or mailed and received by the Secretary at, the principal executive offices of the Corporation not less than ninety (90) days nor more than

one hundred twenty (120) days prior to the first anniversary of the preceding year's annual meeting; *provided, however*, that, if the date of the annual meeting is more than thirty (30) days before or more than sixty (60) days after such anniversary date, notice by the stockholder to be timely must be so delivered, or mailed and received, not earlier than the close of business on the one hundred twentieth (120<sup>th</sup>) day prior to such annual meeting and not later than the later of the close of business on the ninetieth (90<sup>th</sup>) day prior to such annual meeting and the close of business on the tenth (10<sup>th</sup>) day following the day on which public disclosure of the date of such annual meeting was first made (such notice within such time periods, "Timely Notice"); *provided, further*, that for the purposes of calculating Timely Notice for the first annual meeting held after the Company's initial public offering of its shares pursuant to a registration statement on Form S-1, the date of the immediately preceding annual meeting shall be deemed to be June 5, 2021. In no event shall any adjournment or postponement of an annual meeting or the announcement thereof commence a new time period (or extend any time period) for the giving of Timely Notice as described above.

(c) To be in proper form for purposes of this Section 2.4, a stockholder's notice to the secretary of the Corporation shall set forth:

(i) As to each Proposing Person (as defined below), (A) the name and address of such Proposing Person (including, without limitation, if applicable, the name and address that appear on the Corporation's books and records) and (B) the class or series and number of shares of the Corporation that are, directly or indirectly, owned of record or beneficially owned (within the meaning of Rule 13d-3 under the Exchange Act) by such Proposing Person, except that such Proposing Person shall in all events be deemed to beneficially own any shares of any class or series of the Corporation as to which such Proposing Person has a right to acquire beneficial ownership at any time in the future (the disclosures to be made pursuant to the foregoing clauses (A) and (B) are referred to as "Stockholder Information");

(ii) As to each Proposing Person, (A) any derivative, swap or other transaction or series of transactions engaged in, directly or indirectly, by such Proposing Person, the purpose or effect of which is to give such Proposing Person economic risk similar to ownership of shares of any class or series of the Corporation, including, without limitation, due to the fact that the value of such derivative, swap or other transactions are determined by reference to the price, value or volatility of any shares of any class or series of the Corporation, or which derivative, swap or other transactions provide, directly or indirectly, the opportunity to profit from any increase in the price or value of shares of any class or series of the Corporation ("Synthetic Equity Interests"), which Synthetic

Equity Interests shall be disclosed without regard to whether (x) the derivative, swap or other transactions convey any voting rights in such shares to such Proposing Person, (y) the derivative, swap or other transactions are required to be, or are capable of being, settled through delivery of such shares or (z) such Proposing Person may have entered into other transactions that hedge or mitigate the economic effect of such derivative, swap or other transactions, (B) any proxy (other than a revocable proxy or consent given in response to a solicitation made pursuant to, and in accordance with, Section 14(a) of the Exchange Act by way of a solicitation statement filed on Schedule 14A), agreement, arrangement, understanding or relationship pursuant to which such Proposing Person has or shares a right to vote any shares of any class or series of the Corporation, (C) any agreement, arrangement, understanding or relationship, including, without limitation, any repurchase or similar so-called “stock borrowing” agreement or arrangement, engaged in, directly or indirectly, by such Proposing Person, the purpose or effect of which is to mitigate loss to, reduce the economic risk (of ownership or otherwise) of shares of any class or series of the Corporation by, manage the risk of share price changes for, or increase or decrease the voting power of, such Proposing Person with respect to the shares of any class or series of the Corporation, or which provides, directly or indirectly, the opportunity to profit from any decrease in the price or value of the shares of any class or series of the Corporation (“Short Interests”), (D) any rights to dividends on the shares of any class or series of the Corporation owned beneficially by such Proposing Person that are separated or separable from the underlying shares of the Corporation, (E) any performance related fees (other than an asset based fee) that such Proposing Person is entitled to based on any increase or decrease in the price or value of shares of any class or series of the Corporation, or any Synthetic Equity Interests or Short Interests, if any, (F)(x) if such Proposing Person is not a natural person, the identity of the natural person or persons associated with such Proposing Person responsible for the formulation of and decision to propose the business to be brought before the meeting (such person or persons, the “Responsible Person”), the manner in which such Responsible Person was selected, any fiduciary duties owed by such Responsible Person to the equity holders or other beneficiaries of such Proposing Person, the qualifications and background of such Responsible Person and any material interests or relationships of such Responsible Person that are not shared generally by any other record or beneficial holder of the shares of any class or series of the Corporation and that reasonably could have influenced the decision of such Proposing Person to propose such business to be brought before the meeting, and (y) if such Proposing Person is a natural person, the qualifications and background of such natural person and any material interests or relationships of such natural person that are

not shared generally by any other record or beneficial holder of the shares of any class or series of the Corporation and that reasonably could have influenced the decision of such Proposing Person to propose such business to be brought before the meeting, (G) any significant equity interests or any Synthetic Equity Interests or Short Interests in any principal competitor of the Corporation held by such Proposing Persons, (H) any direct or indirect interest of such Proposing Person in any contract with the Corporation, any affiliate of the Corporation or any principal competitor of the Corporation (including, without limitation, in any such case, any employment agreement, collective bargaining agreement or consulting agreement), (I) any pending or threatened litigation in which such Proposing Person is a party or material participant involving the Corporation or any of its officers or directors, or any affiliate of the Corporation, (J) any material transaction occurring during the prior twelve months between such Proposing Person, on the one hand, and the Corporation, any affiliate of the Corporation or any principal competitor of the Corporation, on the other hand, (K) a summary of any material discussions regarding the business proposed to be brought before the meeting (x) between or among any of the Proposing Persons or (y) between or among any Proposing Person and any other record or beneficial holder of the shares of any class or series of the Corporation (including, without limitation, their names) and (L) any other information relating to such Proposing Person that would be required to be disclosed in a proxy statement or other filing required to be made in connection with solicitations of proxies or consents by such Proposing Person in support of the business proposed to be brought before the meeting pursuant to Section 14(a) of the Exchange Act (the disclosures to be made pursuant to the foregoing clauses (A) through (L) are referred to as “Disclosable Interests”); *provided, however*, that Disclosable Interests shall not include any such disclosures with respect to the ordinary course business activities of any broker, dealer, commercial bank, trust company or other nominee who is a Proposing Person solely as a result of being the stockholder directed to prepare and submit the notice required by these bylaws on behalf of a beneficial owner; and

(iii) As to each item of business that the stockholder proposes to bring before the annual meeting, (A) a reasonably brief description of the business desired to be brought before the annual meeting, the reasons for conducting such business at the annual meeting and any material interest in such business of each Proposing Person, (B) the text of the proposal or business (including, without limitation, the text of any resolutions proposed for consideration and in the event that such business includes a proposal to amend the bylaws of the Corporation, the language of the proposed amendment), (C) a reasonably detailed description

of all agreements, arrangements and understandings between or among any of the Proposing Persons or between or among any Proposing Person and any other person or entity (including, without limitation, their names) in connection with the proposal of such business by such stockholder, (D) a representation that the stockholder is a holder of record of stock of the Corporation entitled to vote at such meeting and intends to appear in person or by proxy at the meeting to propose such business, (E) a representation whether the Proposing Person intends or is part of a group which intends (1) to deliver a proxy statement and/or form of proxy to holders of at least the percentage of the Corporation's outstanding capital stock required to approve or adopt the proposal and/or (2) otherwise to solicit proxies or votes from stockholders in support of such proposal and (F) any other information relating to such item of business that would be required to be disclosed in a proxy statement or other filing required to be made in connection with solicitations of proxies in support of the business proposed to be brought before the meeting pursuant to Section 14(a) of the Exchange Act; *provided, however*, that the disclosures required by this paragraph (c)(iii) shall not include any disclosures with respect to any broker, dealer, commercial bank, trust company or other nominee who is a Proposing Person solely as a result of being the stockholder directed to prepare and submit the notice required by these bylaws on behalf of a beneficial owner.

(d) For purposes of this Section 2.4, the term "Proposing Person" shall mean (i) the stockholder providing the notice of business proposed to be brought before an annual meeting, (ii) the beneficial owner or beneficial owners, if different, on whose behalf the notice of the business proposed to be brought before the annual meeting is made, (iii) any affiliate or associate (each within the meaning of Rule 12b-2 under the Exchange Act for the purposes of these bylaws) of such stockholder or beneficial owner and (iv) any other person with whom such stockholder or beneficial owner (or any of their respective affiliates or associates) is Acting in Concert (as defined below).

(e) A person shall be deemed to be "Acting in Concert" with another person for purposes of these bylaws if such person knowingly acts (whether or not pursuant to an express agreement, arrangement or understanding) in concert with, or towards a common goal relating to the management, governance or control of the Corporation in parallel with, such other person where (i) each person is conscious of the other person's conduct or intent and this awareness is an element in their decision-making processes and (ii) at least one additional factor suggests that such persons intend to act in concert or in parallel, which such additional factors may include, without limitation, exchanging information (whether publicly or privately), attending meetings, conducting discussions, or making or soliciting invitations to act in concert or in parallel; *provided*, that a person shall not be deemed to be Acting in Concert with any other



person solely as a result of the solicitation or receipt of revocable proxies or consents from such other person in response to a solicitation made pursuant to, and in accordance with, Section 14(a) of the Exchange Act by way of a proxy or consent solicitation statement filed on Schedule 14A. A person Acting in Concert with another person shall be deemed to be Acting in Concert with any third party who is also Acting in Concert with such other person.

(f) A stockholder providing notice of business proposed to be brought before an annual meeting shall further update and supplement such notice, if necessary, so that the information provided or required to be provided in such notice pursuant to this Section 2.4 shall be true and correct as of the record date for determining stockholders entitled to notice of the annual meeting and as of the date that is ten (10) business days prior to the meeting or any adjournment or postponement thereof, and such update and supplement shall be delivered to, or mailed and received by, the secretary of the Corporation at the principal executive offices of the Corporation not later than five (5) business days after the record date for determining stockholders entitled to notice of the annual meeting (in the case of the update and supplement required to be made as of the record date), and not later than eight (8) business days prior to the date for the meeting or, if practicable, any adjournment or postponement thereof (and, if not practicable, on the first practicable date prior to the date to which the meeting has been adjourned or postponed) (in the case of the update and supplement required to be made as of ten (10) business days prior to the meeting or any adjournment or postponement thereof).

(g) Notwithstanding anything in these bylaws to the contrary and except as otherwise expressly provided in any applicable rule or regulation promulgated under the Exchange Act, no business shall be conducted at an annual meeting except in accordance with this Section 2.4. The presiding officer of an annual meeting of stockholders shall have the power and duty (a) to determine that any business was not properly brought before the meeting in accordance with this Section 2.4 (including whether the stockholder or beneficial owner, if any, on whose behalf the business proposed to be brought before the annual meeting is made, solicited (or is part of a group which solicited) or did not so solicit, as the case may be, proxies or votes in support of such stockholder's business in compliance with such stockholder's representation as required by clause (c)(iii)(E) of this Section 2.4); and (b) if any proposed business was not proposed in compliance with this Section 2.4 to declare to the meeting that any such business not properly brought before the meeting shall not be transacted.

(h) The foregoing notice requirements of this Section 2.4 shall be deemed satisfied by a stockholder with respect to business other than a nomination if the stockholder has notified the Corporation of his, her or its intention to present a proposal at an annual meeting in compliance with applicable rules and regulations promulgated under the Exchange Act and such stockholder's proposal has been included in a proxy statement that has been prepared by the Corporation to solicit proxies for such annual meeting. Nothing in this Section 2.4 shall be

deemed to affect the rights of stockholders to request inclusion of proposals in the Corporation's proxy statement pursuant to Rule 14a-8 under the Exchange Act.

(i) For purposes of these bylaws, "public disclosure" shall mean disclosure in a press release reported by a national news service or in a document publicly filed by the Corporation with the Securities and Exchange Commission pursuant to Sections 13, 14 or 15(d) of the Exchange Act.

(j) Notwithstanding the foregoing provisions of this Section 2.4, unless otherwise required by law, if the stockholder (or a qualified representative of the stockholder) does not appear at the annual meeting to present proposed business, such proposed business shall not be transacted, notwithstanding that proxies in respect of such vote may have been received by the Corporation. For purposes of this Section 2.4, except as provided under Rule 14a-8 under the Exchange Act, to be considered a qualified representative of the stockholder, a person must be a duly authorized officer, manager or partner of such stockholder or must be authorized by a writing executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as proxy at the annual meeting and such person must produce such writing or electronic transmission, or a reliable reproduction of the writing or electronic transmission, at the annual meeting.

(k) Notwithstanding the foregoing provisions of this Section 2.4, a stockholder shall also comply with all applicable requirements of the Exchange Act with respect to the matters set forth in this Section 2.4; provided however, that any references in these bylaws to the Exchange Act are not intended to and shall not limit any requirements applicable to proposals as to any business to be considered pursuant to this Section 2.4 (including paragraph (a)(iii) hereof), and compliance with paragraph (a)(iii) of this Section 2.4 shall be the exclusive means for a stockholder to submit business (other than, as provided in the first sentence of paragraph (h) of this Section 2.4, business brought properly under and in compliance with Rule 14a-8 of the Exchange Act, as may be amended from time to time).

## 2.5 ADVANCE NOTICE PROCEDURES FOR NOMINATIONS OF DIRECTORS.

(a) Nominations of any person for election to the Board at an annual meeting or at a special meeting (but, in the case of a special meeting, only if the election of directors is a matter specified in the notice of meeting given by or at the direction of the person calling such special meeting) may be made at such meeting only (i) by or at the direction of the Board or any committee thereof, or (ii) by a stockholder who (A) was a stockholder of record of the Corporation (and, with respect to any beneficial owner, if different, on whose behalf such nomination is proposed to be made, only if such beneficial owner was the beneficial owner of shares of the Corporation) both at the time of giving the notice provided for in this Section 2.5 and at the time of the meeting, (B) is entitled to vote at the meeting and (C) has complied with

this Section 2.5 as to such nomination. The foregoing clause (ii) shall be the exclusive means for a stockholder to make any nomination of a person or persons for election to the Board to be considered by the stockholders at an annual meeting or special meeting.

(b) Without qualification, for a stockholder to make any nomination of a person or persons for election to the Board at an annual meeting, the stockholder must (i) provide Timely Notice (as defined in Section 2.4(b) of these bylaws) thereof in writing and in proper form to the secretary of the Corporation and (ii) provide any updates or supplements to such notice at the times and in the forms required by this Section 2.5. Notwithstanding anything in this paragraph to the contrary, in the event that the number of directors to be elected to the Board at an annual meeting is increased effective after the time period for which nominations would otherwise be due under this paragraph (b) and there is no public announcement by the Corporation naming the nominees for the additional directorships at least one hundred (100) days prior to the first anniversary of the preceding year's annual meeting, a stockholder's notice required by paragraph (b) of this Section 2.5 shall also be considered timely, but only with respect to nominees for the additional directorships, if it shall be delivered to the Secretary at the principal executive offices of the Corporation not later than the close of business on the tenth (10th) day following the day on which such public announcement is first made by the Corporation. Without qualification, if the election of directors is a matter specified in the notice of meeting given by or at the direction of the person calling such special meeting, then for a stockholder to make any nomination of a person or persons for election to such position(s) as specified in the notice of the special meeting, the stockholder must (i) provide timely notice thereof in writing and in proper form to the secretary of the Corporation at the principal executive offices of the Corporation and (ii) provide any updates or supplements to such notice at the times and in the forms required by this Section 2.5. To be timely, a stockholder's notice for nominations to be made at a special meeting must be delivered to, or mailed and received at, the principal executive offices of the Corporation not earlier than the close of business on the one hundred twentieth (120<sup>th</sup>) day prior to such special meeting and not later than the later of the close of business on the ninetieth (90<sup>th</sup>) day prior to such special meeting and the close of business on the tenth (10<sup>th</sup>) day following the day on which public disclosure (as defined in Section 2.4(i) of these bylaws) of the date of such special meeting was first made. In no event shall any adjournment or postponement of an annual meeting or special meeting or the announcement thereof commence a new time period (or extend any time period) for the giving of a stockholder's notice as described above.

(c) To be in proper form for purposes of this Section 2.5, a stockholder's notice to the secretary of the Corporation shall set forth:

(i) As to each Nominating Person (as defined below), the Stockholder Information (as defined in Section 2.4(c)(i) of these bylaws) except that for

purposes of this Section 2.5, the term “Nominating Person” shall be substituted for the term “Proposing Person” in all places it appears in Section 2.4(c)(i);

(ii) As to each Nominating Person, any Disclosable Interests (as defined in Section 2.4(c)(ii), except that for purposes of this Section 2.5 the term “Nominating Person” shall be substituted for the term “Proposing Person” in all places it appears in Section 2.4(c)(ii) and the disclosure in clause (L) of Section 2.4(c)(ii) shall be made with respect to the election of directors at the meeting) provided, however, that Disclosable Interests shall not include any such disclosures with respect to the ordinary course business activities of any broker, dealer, commercial bank, trust company or other nominee who is a Nominating Person solely as a result of being the stockholder directed to prepare and submit the notice required by these bylaws on behalf of a beneficial owner; and;

(iii) As to each person whom a Nominating Person proposes to nominate for election as a director, (A) all information with respect to such proposed nominee that would be required to be set forth in a stockholder’s notice pursuant to this Section 2.5 if such proposed nominee were a Nominating Person, (B) all information relating to such proposed nominee that is required to be disclosed in a proxy statement or other filings required to be made in connection with solicitations of proxies for election of directors in a contested election pursuant to Section 14(a) under the Exchange Act (including, without limitation, such proposed nominee’s written consent to being named in the proxy statement as a nominee and to serving as a director if elected), (C) a statement whether the proposed nominee, if elected, intends to tender, promptly following such person’s failure to receive the required vote for election as a director at any subsequent meeting at which such person is nominated for re-election, a resignation that will become effective upon the acceptance of such resignation by the Board of Directors, (D) a description of all direct and indirect compensation and other material monetary agreements, arrangements and understandings during the past three (3) years, and any other material relationships, between or among any Nominating Person, on the one hand, and each proposed nominee, his or her respective affiliates and associates and any other persons with whom such proposed nominee (or any of his or her respective affiliates and associates) is Acting in Concert (as defined in Section 2.4(e) of these bylaws), on the other hand, including, without limitation, all information that would be required to be disclosed pursuant to Item 404 under Regulation S-K if such Nominating Person were the “registrant” for purposes of such rule and the proposed nominee were a director or executive officer of such registrant (the disclosures to be made pursuant to the foregoing clauses (A) through (C) are referred to as “Nominee”

Information”), (E) a representation that the Nominating Person is a holder of record of stock of the Corporation entitled to vote at such meeting and intends to appear in person or by proxy at the meeting to propose such nomination, (F) a representation whether the Nominating Person intends or is part of a group which intends (1) to deliver a proxy statement and/or form of proxy to holders of at least the percentage of the Corporation’s outstanding capital stock required to elect the nominee and/or (2) otherwise to solicit proxies or votes from stockholders in support of such nomination and (G) a completed and signed questionnaire, representation and agreement as provided in Section 2.5(g); and

(iv) The Corporation may require any proposed nominee to furnish such other information (A) as may reasonably be required by the Corporation to determine the eligibility of such proposed nominee to serve as an independent director of the Corporation in accordance with the Corporation’s Corporate Governance Guidelines or (B) that could be material to a reasonable stockholder’s understanding of the independence or lack of independence of such proposed nominee.

(d) For purposes of this Section 2.5, the term “Nominating Person” shall mean (i) the stockholder providing the notice of the nomination proposed to be made at the meeting, (ii) the beneficial owner or beneficial owners, if different, on whose behalf the notice of the nomination proposed to be made at the meeting is made, (iii) any affiliate or associate of such stockholder or beneficial owner and (iv) any other person with whom such stockholder or such beneficial owner (or any of their respective affiliates or associates) is Acting in Concert.

(e) A stockholder providing notice of any nomination proposed to be made at a meeting shall further update and supplement such notice, if necessary, so that the information provided or required to be provided in such notice pursuant to this Section 2.5 shall be true and correct as of the record date for determining stockholders entitled to notice of the meeting and as of the date that is ten (10) business days prior to the meeting or any adjournment or postponement thereof, and such update and supplement shall be delivered to, or mailed and received by, the secretary of the Corporation at the principal executive offices of the Corporation not later than five (5) business days after the record date for determining stockholders entitled to notice of the meeting (in the case of the update and supplement required to be made as of the record date), and not later than eight (8) business days prior to the date for the meeting or, if practicable, any adjournment or postponement thereof (and, if not practicable, on the first practicable date prior to the date to which the meeting has been adjourned or postponed) (in the case of the update and supplement required to be made as of ten (10) business days prior to the meeting or any adjournment or postponement thereof).

(f) Notwithstanding anything in these bylaws to the contrary, no person shall be eligible for election as a director of the Corporation unless nominated in accordance with this Section 2.5, except as otherwise expressly provided in any applicable rule or regulation promulgated under the Exchange Act. The presiding officer at any meeting of stockholders shall have the power and duty to (a) determine that a nomination was not properly made in accordance with this Section 2.5 (including whether the stockholder or beneficial owner, if any, on whose behalf the nomination was made, solicited or is part of a group which solicited) or did not so solicit, as the case may be, proxies or votes in support of such stockholder's nomination in compliance with such stockholder's representation as required by clause (c)(iii)(E) of this Section 2.5); and (b) if any proposed nomination was not made in compliance with this Section 2.5 to declare such determination to the meeting that the defective nomination shall be disregarded.

(g) To be eligible to be a nominee for election as a director of the Corporation, the proposed nominee must deliver (in accordance with the time periods prescribed for delivery of notice under this Section 2.5) to the secretary of the Corporation at the principal executive offices of the Corporation a written questionnaire with respect to the background and qualification of such proposed nominee (which questionnaire shall be provided by the secretary upon written request) and a written representation and agreement (in form provided by the secretary upon written request) that such proposed nominee (i) is not and will not become a party to (A) any agreement, arrangement or understanding with, and has not given any commitment or assurance to, any person or entity as to how such proposed nominee, if elected as a director of the Corporation, will act or vote on any issue or question (a "Voting Commitment") that has not been disclosed to the Corporation or (B) any Voting Commitment that could limit or interfere with such proposed nominee's ability to comply, if elected as a director of the Corporation, with such proposed nominee's fiduciary duties under applicable law, (ii) is not, and will not become a party to, any agreement, arrangement or understanding with any person or entity other than the Corporation with respect to any direct or indirect compensation, reimbursement or indemnification in connection with candidacy, service or action as a director that has not been disclosed to the Corporation and (iii) in such proposed nominee's individual capacity and on behalf of the stockholder (and the beneficial owner, if different, on whose behalf the nomination is made) would be in compliance, if elected as a director of the Corporation, and will comply with applicable publicly disclosed corporate governance, conflict of interest, confidentiality and stock ownership and trading policies and guidelines of the Corporation.

(h) In addition to the requirements of this Section 2.5 with respect to any nomination proposed to be made at a meeting, each Nominating Person shall comply with all applicable requirements of the Exchange Act with respect to any such nominations.

(i) Notwithstanding the foregoing provisions of this Section 2.5, unless otherwise required by law, if the stockholder (or a qualified representative of the stockholder) does not appear at the meeting to present the proposed nomination, such proposed nomination shall not be considered, notwithstanding that proxies in respect of such vote may have been received by the Corporation. For purposes of this Section 2.5, to be considered a qualified representative of the stockholder, a person must be a duly authorized officer, manager or partner of such stockholder or must be authorized by a writing executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as proxy at the meeting of stockholders and such person must produce such writing or electronic transmission, or a reliable reproduction of the writing or electronic transmission, at the meeting.

## 2.6 NOTICE OF STOCKHOLDERS' MEETINGS.

Unless otherwise provided by law, the certificate of incorporation or these bylaws, the notice of any meeting of stockholders shall be given in accordance with either Section 2.7 or Section 8.1 of these bylaws not less than ten (10) nor more than sixty (60) days before the date of the meeting to each stockholder entitled to vote at such meeting as of the record date for determining the stockholders entitled to notice of the meeting. The notice shall specify the place, if any, date and hour of the meeting, the record date for determining the stockholders entitled to vote at the meeting (if such date is different from the record date for stockholders entitled to notice of the meeting), the means of remote communication, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such meeting, and, in the case of a special meeting, the purpose or purposes for which the meeting is called.

2.7 MANNER OF GIVING NOTICE; AFFIDAVIT OF NOTICE  
Notice of any meeting of stockholders shall be deemed given:

- (a) if mailed, when deposited in the United States mail, postage prepaid, directed to the stockholder at such stockholder's address as it appears on the Corporation's records; or
- (b) if electronically transmitted, as provided in Section 8.1 of these bylaws.

An affidavit of the secretary or an assistant secretary of the Corporation or of the transfer agent or any other agent of the Corporation that the notice has been given by mail or by a form of electronic transmission, as applicable, shall, in the absence of fraud, be prima facie evidence of the facts stated therein.

## 2.8 QUORUM

Unless otherwise provided by law, the certificate of incorporation or these bylaws, the holders of a majority in voting power of the capital stock issued and outstanding and entitled to vote, present in person, or by remote communication, if applicable, or represented by proxy, shall constitute a quorum for the transaction of business at all meetings of the stockholders. A quorum, once established at a meeting, shall not be broken by the withdrawal of enough votes to leave less than a quorum. If, however, a quorum is not present or represented at any meeting of the stockholders, then either (a) the chairperson of the meeting or (b) a majority in voting power of the stockholders entitled to vote thereon, present in person, or by remote communication, if applicable, or represented by proxy, shall have power to adjourn the meeting from time to time in the manner provided in Section 2.9 of these bylaws until a quorum is present or represented. At such adjourned meeting at which a quorum is present or represented, any business may be transacted that might have been transacted at the meeting as originally noticed.

## 2.9 ADJOURNED MEETING; NOTICE

When a meeting is adjourned to another time or place, unless these bylaws otherwise require, notice need not be given of the adjourned meeting if the time, place, if any, thereof, and the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such adjourned meeting are announced at the meeting at which the adjournment is taken. At the adjourned meeting, the Corporation may transact any business which might have been transacted at the original meeting. If the adjournment is for more than thirty (30) days, or if after the adjournment a new record date for determining the stockholders entitled to vote is fixed for the adjourned meeting, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the adjourned meeting as of the record date for determining the stockholders entitled to notice of the adjourned meeting.

## 2.10 CONDUCT OF BUSINESS

The date and time of the opening and the closing of the polls for each matter upon which the stockholders will vote at a meeting shall be announced at the meeting by the person presiding over the meeting. The Board may adopt by resolution such rules and regulations for the conduct of the meeting of stockholders as it shall deem appropriate. Except to the extent inconsistent with such rules and regulations as adopted by the Board, the person presiding over any meeting of stockholders shall have the right and authority to convene and (for any or no reason) to recess and/or adjourn the meeting, to prescribe such rules, regulations and procedures (which need not be in writing) and to do all such acts as, in the judgment of such presiding person, are appropriate for the proper conduct of the meeting. Such rules, regulations or procedures, whether adopted by the Board or prescribed by the presiding person of the meeting, may include, without limitation, the following: (a) the establishment of an agenda or order of business for the meeting; (b) rules



and procedures for maintaining order at the meeting and the safety of those present (including, without limitation, rules and procedures for removal of disruptive persons from the meeting); (c) limitations on attendance at or participation in the meeting to stockholders entitled to vote at the meeting, their duly authorized and constituted proxies or such other persons as the presiding person of the meeting shall determine; (d) restrictions on entry to the meeting after the time fixed for the commencement thereof; and (e) limitations on the time allotted to questions or comments by participants. The presiding person at any meeting of stockholders, in addition to making any other determinations that may be appropriate to the conduct of the meeting (including, without limitation, determinations with respect to the administration and/or interpretation of any of the rules, regulations or procedures of the meeting, whether adopted by the Board or prescribed by the person presiding over the meeting), shall, if the facts warrant, determine and declare to the meeting that a matter or business was not properly brought before the meeting and if such presiding person should so determine, such presiding person shall so declare to the meeting and any such matter or business not properly brought before the meeting shall not be transacted or considered. Unless and to the extent determined by the Board or the person presiding over the meeting, meetings of stockholders shall not be required to be held in accordance with the rules of parliamentary procedure.

## 2.11 VOTING

The stockholders entitled to vote at any meeting of stockholders shall be determined in accordance with the provisions of Section 2.13 of these bylaws, subject to Section 217 (relating to voting rights of fiduciaries, pledgors and joint owners of stock) and Section 218 (relating to voting trusts and other voting agreements) of the DGCL.

Except as may be otherwise provided in the certificate of incorporation or these bylaws, each stockholder shall be entitled to one (1) vote for each share of capital stock held by such stockholder.

At all duly called or convened meetings of stockholders, at which a quorum is present, for the election of directors, a plurality of the votes cast shall be sufficient to elect a director. All other elections and questions presented to the stockholders at a duly called or convened meeting, at which a quorum is present, shall, unless a different or minimum vote is required by the certificate of incorporation, these bylaws, the rules or regulations of any stock exchange applicable to the Corporation, or any law or regulation applicable to the Corporation or its securities, in which case such different or minimum vote shall be the applicable vote on the matter, be decided by the affirmative vote of the holders of a majority in voting power of the votes cast affirmatively or negatively (excluding abstentions) at the meeting by the holders entitled to vote thereon.

## 2.12 STOCKHOLDER ACTION BY WRITTEN CONSENT WITHOUT A MEETING

Any action required or permitted to be taken by the stockholders of the Corporation must be effected at a duly called annual or special meeting of stockholders of the Corporation and may not be effected by any consent in writing by such stockholders.

## 2.13 RECORD DATE FOR STOCKHOLDER NOTICE; VOTING.

In order that the Corporation may determine the stockholders entitled to notice of any meeting of stockholders or any adjournment thereof, the Board may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board, and which record date shall, unless otherwise required by law, not be more than sixty (60) nor less than ten (10) days before the date of such meeting. If the Board so fixes a date, such date shall also be the record date for determining the stockholders entitled to vote at such meeting unless the Board determines, at the time it fixes such record date, that a later date on or before the date of the meeting shall be the date for making such determination. If no record date is fixed by the Board, the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be at the close of business on the day next preceding the day on which notice is given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held. A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; *provided, however*, that the Board may fix a new record date for determination of stockholders entitled to vote at the adjourned meeting, and in such case shall also fix as the record date for stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of stockholders entitled to vote in accordance herewith at the adjourned meeting.

In order that the Corporation may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment of any rights, or entitled to exercise any rights in respect of any change, conversion or exchange of stock or for the purpose of any other lawful action, the Board may fix a record date, which shall not be more than sixty (60) days prior to such other action. If no such record date is fixed, the record date for determining stockholders for any such purpose shall be at the close of business on the day on which the Board adopts the resolution relating thereto.

## 2.14 PROXIES

Each stockholder entitled to vote at a meeting of stockholders may authorize another person or persons to act for such stockholder by proxy, but no such proxy shall be voted or acted upon after three (3) years from its date, unless the proxy provides for a longer period. The revocability of a proxy that states on its face that it is irrevocable shall be governed by the

provisions of Section 212 of the DGCL. A proxy may be in the form of a telegram, cablegram or other means of electronic transmission which sets forth or is submitted with information from which it can be determined that the telegram, cablegram or other means of electronic transmission was authorized by the stockholder.

#### 2.15 LIST OF STOCKHOLDERS ENTITLED TO VOTE

The Corporation shall prepare, at least ten (10) days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting (*provided, however*, if the record date for determining the stockholders entitled to vote is less than ten (10) days before the date of the meeting, the list shall reflect the stockholders entitled to vote as of the tenth day before the date of the meeting), arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. The Corporation shall not be required to include electronic mail addresses or other electronic contact information on such list.

Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting for a period of at least ten (10) days prior to the meeting: (a) on a reasonably accessible electronic network, provided that the information required to gain access to such list is provided with the notice of the meeting, or (b) during ordinary business hours, at the Corporation's principal executive office. In the event that the Corporation determines to make the list available on an electronic network, the Corporation may take reasonable steps to ensure that such information is available only to stockholders of the Corporation. If the meeting is to be held at a place, then the list shall be produced and kept at the time and place of the meeting during the whole time thereof, and may be inspected by any stockholder who is present. If the meeting is to be held solely by means of remote communication, then the list shall also be open to the examination of any stockholder during the whole time of the meeting on a reasonably accessible electronic network, and the information required to access such list shall be provided with the notice of the meeting.

Except as otherwise provided by law, the stock ledger shall be the only evidence as to the identity of the stockholders entitled to vote in person or by proxy and the number of shares held by each of them, and as to the stockholders entitled to examine the list of stockholders.

#### 2.16 POSTPONEMENT, ADJOURNMENT AND CANCELLATION OF MEETING.

Any previously scheduled annual or special meeting of the stockholders may be postponed or adjourned, and any previously scheduled annual or special meeting of the stockholders may be canceled, by resolution of the Board.

#### 2.17 INSPECTORS OF ELECTION.

Before any meeting of stockholders, the Board shall appoint an inspector or inspectors of election to act at the meeting or its adjournment or postponement and make a written report

thereof. The number of inspectors shall be either one (1) or three (3). If any person appointed as inspector fails to appear or fails or refuses to act, then the chairperson of the meeting may, and upon the request of any stockholder or a stockholder's proxy shall, appoint a person to fill that vacancy. Unless otherwise required by law, inspectors may be officers, employees or agents of the Corporation. Such inspectors shall have the duties prescribed by law. Each inspector, before entering upon the discharge of his or her duties, shall take and sign an oath to execute faithfully the duties of inspector with strict impartiality and according to the best of his or her ability. If there are three (3) inspectors of election, the decision, act or certificate of a majority is effective in all respects as the decision, act or certificate of all. Any report or certificate made by the inspectors of election is prima facie evidence of the facts stated therein.

## **ARTICLE III - DIRECTORS**

### **3.1 POWERS**

Subject to the provisions of the DGCL and any limitations in the certificate of incorporation, the business and affairs of the Corporation shall be managed and all corporate powers shall be exercised by or under the direction of the Board.

### **3.2 NUMBER OF DIRECTORS**

The authorized number of directors shall be determined from time to time by resolution of the Board, provided the Board shall consist of at least one (1) member. No reduction of the authorized number of directors shall have the effect of removing any director before that director's term of office expires.

### **3.3 ELECTION, QUALIFICATION AND TERM OF OFFICE OF DIRECTORS**

Except as provided in Section 3.4 of these bylaws, each director, including, without limitation, a director elected to fill a vacancy, shall hold office until the expiration of the term for which elected and until such director's successor is elected and qualified or until such director's earlier death, resignation or removal. Directors need not be stockholders unless so required by the certificate of incorporation or these bylaws. The Corporation may also have, at the discretion of the Board, a chairperson of the Board and a vice chairperson of the Board. The certificate of incorporation or these bylaws may prescribe other qualifications for directors.

### **3.4 RESIGNATION AND VACANCIES**

Any director may resign at any time upon notice given in writing or by electronic transmission to the chairperson of the Board or the Corporation's chief executive officer,

president or secretary. When one or more directors so resigns and the resignation is effective at a future date, a majority of the directors then in office, including those who have so resigned, shall have power to fill such vacancy or vacancies, the vote thereon to take effect when such resignation or resignations shall become effective, and each director so chosen shall hold office as provided in this section in the filling of other vacancies.

Unless otherwise provided in the certificate of incorporation or these bylaws, vacancies and newly created directorships resulting from any increase in the authorized number of directors shall, unless the Board determines by resolution that any such vacancies or newly created directorships shall be filled by stockholders, be filled only by a majority of the directors then in office, although less than a quorum, or by a sole remaining director. Any director elected in accordance with the preceding sentence shall hold office for the remainder of the full term of the director for which the vacancy was created or occurred and until such director's successor shall have been elected and qualified. A vacancy in the Board shall be deemed to exist under these bylaws in the case of the death, removal or resignation of any director.

### 3.5 PLACE OF MEETINGS; MEETINGS BY TELEPHONE

The Board may hold meetings, both regular and special, either within or outside the State of Delaware.

Unless otherwise restricted by the certificate of incorporation or these bylaws, members of the Board, or any committee designated by the Board, may participate in a meeting of the Board, or any committee, by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and such participation in a meeting pursuant to this bylaw shall constitute presence in person at the meeting.

### 3.6 REGULAR MEETINGS

Regular meetings of the Board may be held without notice at such time and at such place as shall from time to time be determined by the Board; *provided* that any director who is absent when such determination is made shall be given notice of the determination. A regular meeting of the Board may be held without notice immediately after and at the same place as the annual meeting of stockholders.

### 3.7 SPECIAL MEETINGS; NOTICE

Special meetings of the Board for any purpose or purposes may be called at any time by the chairperson of the Board, the chief executive officer, the president, the secretary or a majority of the authorized number of directors.

Notice of the time and place of special meetings shall be:

- (a) delivered personally by hand, by courier or by telephone;
- (b) sent by United States first-class mail, postage prepaid;
- (c) sent by facsimile; or
- (d) sent by electronic mail, electronic transmission or other similar means,

directed to each director at that director's address, telephone number, facsimile number or electronic mail or other electronic address, as the case may be, as shown on the Corporation's records.

If the notice is (a) delivered personally by hand, by courier or by telephone, (b) sent by facsimile or (c) sent by electronic mail or electronic transmission, it shall be delivered or sent at least twenty-four (24) hours before the time of the holding of the meeting. If the notice is sent by United States mail, it shall be deposited in the United States mail at least four (4) days before the time of the holding of the meeting. Any oral notice may be communicated to the director. The notice need not specify the place of the meeting (if the meeting is to be held at the Corporation's principal executive office) nor the purpose of the meeting.

### 3.8 QUORUM

The greater of (a) a majority of the directors at any time in office and (b) one-third of the number of directors established by the Board pursuant to Section 3.2 of these bylaws shall constitute a quorum of the Board for the transaction of business. The vote of a majority of the directors present at any meeting at which a quorum is present shall be the act of the Board, except as may be otherwise specifically provided by statute, the certificate of incorporation or these bylaws. If a quorum is not present at any meeting of the Board, then the directors present thereat may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum is present.

### 3.9 BOARD ACTION BY CONSENT WITHOUT A MEETING

Unless otherwise restricted by the certificate of incorporation or these bylaws, any action required or permitted to be taken at any meeting of the Board, or of any committee thereof, may be taken without a meeting if all members of the Board or committee, as the case may be, consent thereto in writing or by electronic transmission and the writing or writings or electronic transmission or transmissions are filed with the minutes of proceedings of the Board or

committee. Such filing shall be in paper form if the minutes are maintained in paper form and shall be in electronic form if the minutes are maintained in electronic form.

### 3.10 FEES AND COMPENSATION OF DIRECTORS

Unless otherwise restricted by the certificate of incorporation or these bylaws, the Board shall have the authority to fix the compensation of directors.

### 3.11 REMOVAL OF DIRECTORS

Subject to the rights of the holders of the shares of any series of preferred stock of the Corporation, the Board or any individual director may be removed from office only for cause and only by the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock of the Corporation entitled to vote thereon.

## ARTICLE IV - COMMITTEES

### 4.1 COMMITTEES OF DIRECTORS

The Board may designate one (1) or more committees, each committee to consist of one (1) or more of the directors of the Corporation. The Board may designate one (1) or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may unanimously appoint another member of the Board to act at the meeting in the place of any such absent or disqualified member. Any such committee, to the extent provided in the resolution of the Board or in these bylaws, shall have and may exercise all the powers and authority of the Board in the management of the business and affairs of the Corporation, and may authorize the seal of the Corporation to be affixed to all papers that may require it; but no such committee shall have the power or authority to (a) approve or adopt, or recommend to the stockholders, any action or matter (other than the election or removal of directors) expressly required by the DGCL to be submitted to stockholders for approval, or (b) adopt, amend or repeal any bylaw of the Corporation.

### 4.2 COMMITTEE MINUTES

Each committee shall keep regular minutes of its meetings and report the same to the Board when required.

#### 4.3 MEETINGS AND ACTION OF COMMITTEES

Meetings and actions of committees shall be governed by, and held and taken in accordance with, the provisions of:

- (a) Section 3.5 of these bylaws (place of meetings and meetings by telephone);
- (b) Section 3.6 of these bylaws (regular meetings);
- (c) Section 3.7 of these bylaws (special meetings and notice);
- (d) Section 3.8 of these bylaws (quorum);
- (e) Section 7.12 of these bylaws (waiver of notice); and
- (f) Section 3.9 of these bylaws (action without a meeting),

with such changes in the context of those bylaws as are necessary to substitute the committee and its members for the Board and its members. *However:*

- (i) the time of regular meetings of committees may be determined either by resolution of the Board or by resolution of the committee;
- (ii) special meetings of committees may also be called by resolution of the Board; and
- (iii) notice of special meetings of committees shall also be given to all alternate members, who shall have the right to attend all meetings of the committee. The Board may adopt rules for the governance of any committee not inconsistent with the provisions (or any part thereof) of these bylaws.

### ARTICLE V - OFFICERS

#### 5.1 OFFICERS

The officers of the Corporation shall be a president and a secretary. The Corporation may also have, at the discretion of the Board, a chief executive officer, a chief financial officer or treasurer, one (1) or more vice presidents, one (1) or more assistant vice presidents, one (1) or more assistant treasurers, one (1) or more assistant secretaries, and any such other officers as



may be appointed in accordance with the provisions of these bylaws. Any number of offices may be held by the same person.

#### 5.2 APPOINTMENT OF OFFICERS

The Board shall appoint the officers of the Corporation, except such officers as may be appointed in accordance with the provisions of Section 5.3 of these bylaws, subject to the rights, if any, of an officer under any contract of employment.

#### 5.3 SUBORDINATE OFFICERS

The Board may appoint, or empower the chief executive officer or, in the absence of a chief executive officer, the president, to appoint, such other officers and agents as the business of the Corporation may require. Each of such officers shall hold office for such period, as is provided in these bylaws or as the Board may from time to time determine.

#### 5.4 REMOVAL AND RESIGNATION OF OFFICERS

Subject to the rights, if any, of an officer under any contract of employment, any officer may be removed, either with or without cause, by the Board at any regular or special meeting of the Board or, except in the case of an officer chosen by the Board, by any officer upon whom such power of removal may be conferred by the Board.

Any officer may resign at any time by giving written notice to the Corporation. Any resignation shall take effect at the date of the receipt of that notice or at any later time specified in that notice. Unless otherwise specified in the notice of resignation, the acceptance of the resignation shall not be necessary to make it effective. Any resignation is without prejudice to the rights, if any, of the Corporation under any contract to which the officer is a party.

#### 5.5 VACANCIES IN OFFICES

Any vacancy occurring in any office of the Corporation shall be filled by the Board or as provided in Section 5.3 of these bylaws.

#### 5.6 REPRESENTATION OF SHARES OF OTHER ENTITIES

The chairperson of the Board, the president, any vice president, the treasurer, the secretary or assistant secretary of this Corporation, or any other person authorized by the Board or the president or a vice president, is authorized to vote, represent and exercise on behalf of this Corporation all rights incident to any and all securities of any other entity or entities standing in the name of this Corporation. The authority granted herein may be exercised either by such

person directly or by any other person authorized to do so by proxy or power of attorney duly executed by such person having the authority.

#### 5.7 AUTHORITY AND DUTIES OF OFFICERS

All officers of the Corporation shall respectively have such authority and perform such duties in the management of the business of the Corporation as may be designated from time to time by the Board and, to the extent not so provided, as generally pertain to their respective offices, subject to the control of the Board.

### ARTICLE VI - RECORDS AND REPORTS

#### 6.1 MAINTENANCE OF RECORDS

Subject to applicable law, the Corporation shall, either at its principal executive office or at such place or places as designated by the Board, keep a record of its stockholders listing their names and addresses and the number and class of shares held by each stockholder, a copy of these bylaws as amended to date, accounting books and other records.

### ARTICLE VII - GENERAL MATTERS

#### 7.1 EXECUTION OF CORPORATE CONTRACTS AND INSTRUMENTS

The Board, except as otherwise provided in these bylaws, may authorize any officer or officers, or agent or agents, to enter into any contract or execute any instrument in the name of and on behalf of the Corporation; such authority may be general or confined to specific instances. Unless so authorized or ratified by the Board or within the agency power of an officer, no officer, agent or employee shall have any power or authority to bind the Corporation by any contract or engagement or to pledge its credit or to render it liable for any purpose or for any amount.

#### 7.2 STOCK CERTIFICATES; PARTLY PAID SHARES

The shares of the Corporation shall be represented by certificates provided that the Board may provide by resolution or resolutions that some or all of any or all classes or series of stock shall be uncertificated shares. Certificates for the shares of stock, if any, shall be in such form as is consistent with the certificate of incorporation and applicable law. Every holder of stock represented by a certificate shall be entitled to have a certificate signed by, or in the name of the Corporation by any two authorized officers of the Corporation representing the number of shares registered in certificate form. Any or all of the signatures on the certificate may be a facsimile.

In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate has ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the Corporation with the same effect as if he were such officer, transfer agent or registrar at the date of issue.

The Corporation may issue the whole or any part of its shares as partly paid and subject to call for the remainder of the consideration to be paid therefor. Upon the face or back of each stock certificate issued to represent any such partly paid shares, or upon the books and records of the Corporation in the case of uncertificated partly paid shares, the total amount of the consideration to be paid therefor and the amount paid thereon shall be stated. Upon the declaration of any dividend on fully paid shares, the Corporation shall declare a dividend upon partly paid shares of the same class, but only upon the basis of the percentage of the consideration actually paid thereon.

### 7.3 MULTIPLES CLASSES OR SERIES OF STOCK

If the Corporation is authorized to issue more than one class of stock or more than one series of any class, then the powers, the designations, the preferences and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights shall be set forth in full or summarized on the face or back of the certificate that the Corporation shall issue to represent such class or series of stock; *provided, however*, that, except as otherwise provided in Section 202 of the DGCL, in lieu of the foregoing requirements, there may be set forth on the face or back of the certificate that the Corporation shall issue to represent such class or series of stock a statement that the Corporation will furnish without charge to each stockholder who so requests the powers, the designations, the preferences and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights. Within a reasonable time after the issuance or transfer of uncertificated stock, the Corporation shall send to the registered owner thereof a written notice containing the information required to be set forth or stated on certificates pursuant to the DGCL or a statement that the Corporation will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights.

### 7.4 LOST CERTIFICATES

Except as provided in this Section 7.4, no new certificates for shares shall be issued to replace a previously issued certificate unless the latter is surrendered to the Corporation in accordance with applicable law. The Corporation may issue a new certificate of stock or uncertificated shares in the place of any certificate theretofore issued by it, alleged to have been

lost, stolen or destroyed, and the Corporation may require the owner of the lost, stolen or destroyed certificate, or such owner's legal representative, to give the Corporation a bond sufficient to indemnify it against any claim that may be made against it on account of the alleged loss, theft or destruction of any such certificate or the issuance of such new certificate or uncertificated shares.

#### 7.5 CONSTRUCTION; DEFINITIONS

Unless the context requires otherwise, the general provisions, rules of construction and definitions in the DGCL shall govern the construction of these bylaws. Without limiting the generality of this provision, the singular number includes the plural, the plural number includes the singular, and the term "person" includes both a corporation and a natural person.

#### 7.6 DIVIDENDS

The Board, subject to any restrictions contained in either (a) the DGCL or (b) the certificate of incorporation, may declare and pay dividends upon the shares of its capital stock. Dividends may be paid in cash, in property or in shares of the Corporation's capital stock.

The Board may set apart out of any of the funds of the Corporation available for dividends a reserve or reserves for any proper purpose and may abolish any such reserve. Such purposes shall include but not be limited to equalizing dividends, repairing or maintaining any property of the Corporation, and meeting contingencies.

#### 7.7 FISCAL YEAR

The fiscal year of the Corporation shall be fixed by resolution of the Board and may be changed by the Board.

#### 7.8 SEAL

The Corporation may adopt a corporate seal, which shall be adopted and which may be altered by the Board. The Corporation may use the corporate seal by causing it or a facsimile thereof to be impressed or affixed or in any other manner reproduced.

#### 7.9 TRANSFER OF STOCK

Shares of the Corporation shall be transferable in the manner prescribed by law and in these bylaws. Shares of stock of the Corporation shall be transferred on the books of the Corporation only by the holder of record thereof or by such holder's attorney duly authorized in writing, upon surrender to the Corporation of the certificate or certificates representing such shares endorsed by the appropriate person or persons (or by delivery of duly executed

instructions with respect to uncertificated shares), with such evidence of the authenticity of such endorsement or execution, transfer, authorization and other matters as the Corporation may reasonably require, and accompanied by all necessary stock transfer stamps. To the fullest extent permitted by law, no transfer of stock shall be valid as against the Corporation for any purpose until it shall have been entered in the stock records of the Corporation by an entry showing the names of the persons from and to whom it was transferred.

#### 7.10 STOCK TRANSFER AGREEMENTS

The Corporation shall have power to enter into and perform any agreement with any number of stockholders of any one or more classes of stock of the Corporation to restrict the transfer of shares of stock of the Corporation of any one or more classes owned by such stockholders in any manner not prohibited by the DGCL.

#### 7.11 REGISTERED STOCKHOLDERS

The Corporation, to the fullest extent permitted by law,:

(a) shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends and to vote as such owner;

(b) shall be entitled to hold liable for calls and assessments the person registered on its books as the owner of shares; and

(c) shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of another person, whether or not it shall have express or other notice thereof, except as otherwise provided by the laws of Delaware.

#### 7.12 WAIVER OF NOTICE

Whenever notice is required to be given under any provision of the DGCL, the certificate of incorporation or these bylaws, a written waiver, signed by the person entitled to notice, or a waiver by electronic transmission by the person entitled to notice, whether before or after the time of the event for which notice is to be given, shall be deemed equivalent to notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the stockholders need be specified in any written waiver of notice or any waiver by electronic transmission unless so required by the certificate of incorporation or these bylaws.

## ARTICLE VIII - NOTICE BY ELECTRONIC TRANSMISSION

### 8.1 NOTICE BY ELECTRONIC TRANSMISSION

Without limiting the manner by which notice otherwise may be given effectively to stockholders pursuant to the DGCL, the certificate of incorporation or these bylaws, any notice to stockholders given by the Corporation under any provision of the DGCL, the certificate of incorporation or these bylaws shall be effective if given by a form of electronic transmission consented to by the stockholder to whom the notice is given. Any such consent shall be revocable by the stockholder by written notice to the Corporation. Any such consent shall be deemed revoked if:

(a) the Corporation is unable to deliver by electronic transmission two (2) consecutive notices given by the Corporation in accordance with such consent; and

(b) such inability becomes known to the secretary or an assistant secretary of the Corporation or to the transfer agent, or other person responsible for the giving of notice.

However, the inadvertent failure to treat such inability as a revocation shall not invalidate any meeting or other action.

Any notice given pursuant to the preceding paragraph shall be deemed given:

(a) if by facsimile telecommunication, when directed to a number at which the stockholder has consented to receive notice;

(b) if by electronic mail, when directed to an electronic mail address at which the stockholder has consented to receive notice;

(c) if by a posting on an electronic network together with separate notice to the stockholder of such specific posting, upon the later of (i) such posting and (ii) the giving of such separate notice; and

(d) if by any other form of electronic transmission, when directed to the stockholder.

An affidavit of the secretary or an assistant secretary of the Corporation or of the transfer agent or other agent of the Corporation that the notice has been given by a form of electronic transmission shall, in the absence of fraud, be prima facie evidence of the facts stated therein.

## 8.2 DEFINITION OF ELECTRONIC TRANSMISSION

For the purposes of these bylaws, an “electronic transmission” means any form of communication, not directly involving the physical transmission of paper, that creates a record that may be retained, retrieved and reviewed by a recipient thereof, and that may be directly reproduced in paper form by such a recipient through an automated process.

## ARTICLE IX - INDEMNIFICATION AND ADVANCEMENT

### 9.1 ACTIONS, SUITS AND PROCEEDINGS OTHER THAN BY OR IN THE RIGHT OF THE CORPORATION.

The Corporation shall indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the Corporation) by reason of the fact that he or she is or was, or has agreed to become, a director or officer of the Corporation, or, while a director or officer of the Corporation, is or was serving, or has agreed to serve, at the request of the Corporation, as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (including, without limitation, any employee benefit plan) (all such persons being referred to hereafter as an “Indemnitee”), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including, without limitation, attorneys’ fees), liabilities, losses, judgments, fines (including, without limitation, excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974), and amounts paid in settlement actually and reasonably incurred by or on behalf of Indemnitee in connection with such action, suit or proceeding and any appeal therefrom, if Indemnitee acted in good faith and in a manner which Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction or upon a plea of nolo contendere or its equivalent, shall not, of itself, create a presumption that Indemnitee did not act in good faith and in a manner which Indemnitee reasonably believed to be in, or not opposed to, the best interests of the Corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that his or her conduct was unlawful.

### 9.2 ACTIONS OR SUITS BY OR IN THE RIGHT OF THE CORPORATION.

The Corporation shall indemnify any Indemnitee who was or is a party to or threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the Corporation to procure a judgment in its favor by reason of the fact that Indemnitee is or was, or

has agreed to become, a director or officer of the Corporation, or, while a director or officer of the Corporation, is or was serving, or has agreed to serve, at the request of the Corporation, as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (including, without limitation, any employee benefit plan), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including, without limitation, attorneys' fees) actually and reasonably incurred by or on behalf of Indemnatee in connection with such action, suit or proceeding and any appeal therefrom, if Indemnatee acted in good faith and in a manner which Indemnatee reasonably believed to be in, or not opposed to, the best interests of the Corporation, except that no indemnification shall be made under this Section 9.2 in respect of any claim, issue or matter as to which Indemnatee shall have been adjudged to be liable to the Corporation, unless, and only to the extent, that the Court of Chancery of Delaware or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of such liability but in view of all the circumstances of the case, Indemnatee is fairly and reasonably entitled to indemnity for such expenses (including, without limitation, attorneys' fees) which the Court of Chancery of Delaware or such other court shall deem proper.

### 9.3 INDEMNIFICATION FOR EXPENSES OF SUCCESSFUL PARTY.

Notwithstanding any other provisions of this Article IX, to the extent that an Indemnatee has been successful, on the merits or otherwise, in defense of any action, suit or proceeding referred to in Sections 9.1 and 9.2 of these bylaws, or in defense of any claim, issue or matter therein, or on appeal from any such action, suit or proceeding, Indemnatee shall be indemnified to the fullest extent permitted by law against all expenses (including, without limitation, attorneys' fees) actually and reasonably incurred by or on behalf of Indemnatee in connection therewith.

### 9.4 NOTIFICATION AND DEFENSE OF CLAIM.

As a condition precedent to an Indemnatee's right to be indemnified, such Indemnatee must notify the Corporation in writing as soon as practicable of any action, suit, proceeding or investigation involving such Indemnatee for which indemnity will or could be sought. With respect to any action, suit, proceeding or investigation of which the Corporation is so notified, the Corporation will be entitled to participate therein at its own expense and/or to assume the defense thereof at its own expense, with legal counsel reasonably acceptable to Indemnatee. After notice from the Corporation to Indemnatee of its election so to assume such defense, the Corporation shall not be liable to Indemnatee for any legal or other expenses subsequently incurred by Indemnatee in connection with such action, suit, proceeding or investigation, other than as provided below in this Section 9.4. Indemnatee shall have the right to employ his or her own counsel in connection with such action, suit, proceeding or investigation, but the fees and expenses of such counsel incurred after notice from the Corporation of its



assumption of the defense thereof shall be at the expense of Indemnitee unless (a) the employment of counsel by Indemnitee has been authorized by the Corporation, (b) counsel to Indemnitee shall have reasonably concluded that there may be a conflict of interest or position on any significant issue between the Corporation and Indemnitee in the conduct of the defense of such action, suit, proceeding or investigation or (c) the Corporation shall not in fact have employed counsel to assume the defense of such action, suit, proceeding or investigation, in each of which cases the fees and expenses of counsel for Indemnitee shall be at the expense of the Corporation, except as otherwise expressly provided by this Article IX. The Corporation shall not be entitled, without the consent of Indemnitee, to assume the defense of any claim brought by or in the right of the Corporation or as to which counsel for Indemnitee shall have reasonably made the conclusion provided for in clause (b) above. The Corporation shall not be required to indemnify Indemnitee under this Article IX for any amounts paid in settlement of any action, suit, proceeding or investigation effected without its written consent. The Corporation shall not settle any action, suit, proceeding or investigation in any manner which would impose any penalty or limitation on Indemnitee without Indemnitee's written consent. Neither the Corporation nor Indemnitee will unreasonably withhold or delay its consent to any proposed settlement.

#### 9.5 ADVANCE OF EXPENSES.

Subject to the provisions of Sections 9.4 and 9.6 of these bylaws, in the event of any threatened or pending action, suit, proceeding or investigation of which the Corporation receives notice under this Article IX, any expenses (including, without limitation, attorneys' fees) incurred by or on behalf of Indemnitee in defending an action, suit, proceeding or investigation or any appeal therefrom shall be paid by the Corporation in advance of the final disposition of such matter to the fullest extent permitted by law; *provided, however*, that, to the extent required by law, the payment of such expenses incurred by or on behalf of Indemnitee in advance of the final disposition of such matter shall be made only upon receipt of an undertaking by or on behalf of Indemnitee to repay all amounts so advanced in the event that it shall ultimately be determined by final judicial decision from which there is no further right to appeal that Indemnitee is not entitled to be indemnified by the Corporation as authorized in this Article IX or otherwise; and *provided further* that no such advancement of expenses shall be made under this Article IX if it is determined (in the manner described in Section 9.6 of these bylaws) that (a) Indemnitee did not act in good faith and in a manner he or she reasonably believed to be in, or not opposed to, the best interests of the Corporation, or (b) with respect to any criminal action or proceeding, Indemnitee had reasonable cause to believe his or her conduct was unlawful. Such undertaking shall be accepted without reference to the financial ability of Indemnitee to make such repayment.

## 9.6 PROCEDURE FOR INDEMNIFICATION AND ADVANCEMENT OF EXPENSES.

In order to obtain indemnification or advancement of expenses pursuant to Section 9.1, 9.2, 9.3 or 9.5 of these bylaws, an Indemnitee shall submit to the Corporation a written request. Any such advancement of expenses shall be made promptly, and in any event within 60 days after receipt by the Corporation of the written request of Indemnitee, unless (a) the Corporation has assumed the defense pursuant to Section 9.4 of these bylaws (and none of the circumstances described in Section 9.4 of these bylaws that would nonetheless entitle the Indemnitee to indemnification for the fees and expenses of separate counsel have occurred) or (b) the Corporation determines within such 60-day period that Indemnitee did not meet the applicable standard of conduct set forth in Section 9.1, 9.2 or 9.5 of these bylaws, as the case may be. Any such indemnification, unless ordered by a court, shall be made with respect to requests under Section 9.1 or 9.2 of these bylaws only as authorized in the specific case upon a determination by the Corporation that the indemnification of Indemnitee is proper because Indemnitee has met the applicable standard of conduct set forth in Section 9.1 or 9.2 of these bylaws, as the case may be. Such determination shall be made in each instance (a) by a majority vote of the directors of the Corporation consisting of persons who are not at that time parties to the action, suit or proceeding in question (“disinterested directors”), whether or not a quorum, (b) by a committee of disinterested directors designated by majority vote of disinterested directors, whether or not a quorum, (c) if there are no disinterested directors, or if the disinterested directors so direct, by independent legal counsel (who may, to the extent permitted by law, be regular legal counsel to the Corporation) in a written opinion or (d) by the stockholders of the Corporation.

## 9.7 REMEDIES.

To the fullest extent permitted by law, the right to indemnification or advancement of expenses as granted by this Article IX shall be enforceable by Indemnitee in any court of competent jurisdiction. Neither the failure of the Corporation to have made a determination prior to the commencement of such action that indemnification is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor an actual determination by the Corporation pursuant to Section 9.6 of these bylaws that Indemnitee has not met such applicable standard of conduct, shall be a defense to the action or create a presumption that Indemnitee has not met the applicable standard of conduct. In any suit brought by Indemnitee to enforce a right to indemnification or advancement, or brought by the Corporation to recover an advancement of expenses pursuant to the terms of an undertaking, the Corporation shall have the burden of proving that Indemnitee is not entitled to be indemnified, or to such advancement of expenses, under this Article IX. Indemnitee’s expenses (including, without limitation, attorneys’ fees) reasonably incurred in connection with successfully establishing Indemnitee’s right to

indemnification or advancement, in whole or in part, in any such proceeding shall also be indemnified by the Corporation to the fullest extent permitted by law. Notwithstanding the foregoing, in any suit brought by Indemnitee to enforce a right to indemnification hereunder it shall be a defense that the Indemnitee has not met any applicable standard for indemnification set forth in the DGCL.

#### 9.8 LIMITATIONS.

Notwithstanding anything to the contrary in this Article IX, except as set forth in Section 9.7 of these bylaws, the Corporation shall not indemnify an Indemnitee pursuant to this Article IX in connection with a proceeding (or part thereof) initiated by such Indemnitee unless the initiation thereof was approved by the Board. Notwithstanding anything to the contrary in this Article IX, the Corporation shall not indemnify (or advance expenses to) an Indemnitee to the extent such Indemnitee is reimbursed (or advanced expenses) from the proceeds of insurance, and in the event the Corporation makes any indemnification (or advancement) payments to an Indemnitee and such Indemnitee is subsequently reimbursed from the proceeds of insurance, such Indemnitee shall promptly refund indemnification (or advancement) payments to the Corporation to the extent of such insurance reimbursement.

#### 9.9 SUBSEQUENT AMENDMENT.

No amendment, termination or repeal of this Article IX or of the relevant provisions of the DGCL or any other applicable laws shall adversely affect or diminish in any way the rights of any Indemnitee to indemnification or advancement of expenses under the provisions hereof with respect to any action, suit, proceeding or investigation arising out of or relating to any actions, transactions or facts occurring prior to the final adoption of such amendment, termination or repeal.

#### 9.10 OTHER RIGHTS.

The indemnification and advancement of expenses provided by this Article IX shall not be deemed exclusive of any other rights to which an Indemnitee seeking indemnification or advancement of expenses may be entitled under any law (common or statutory), agreement or vote of stockholders or disinterested directors or otherwise, both as to action in Indemnitee's official capacity and as to action in any other capacity while holding office for the Corporation, and shall continue as to an Indemnitee who has ceased to be a director or officer, and shall inure to the benefit of the estate, heirs, executors and administrators of Indemnitee. Nothing contained in this Article IX shall be deemed to prohibit, and the Corporation is specifically authorized to enter into, agreements with officers and directors providing indemnification and advancement rights and procedures different from those set forth in this Article IX. In addition, the Corporation may, to the extent authorized from time to time by the Board, grant indemnification

and advancement rights to other employees or agents of the Corporation or other persons serving the Corporation and such rights may be equivalent to, or greater or less than, those set forth in this Article IX.

#### 9.11 PARTIAL INDEMNIFICATION.

If an Indemnitee is entitled under any provision of this Article IX to indemnification by the Corporation for some or a portion of the expenses (including, without limitation, attorneys' fees), liabilities, losses, judgments, fines (including, without limitation, excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974, as amended) or amounts paid in settlement actually and reasonably incurred by or on behalf of Indemnitee in connection with any action, suit, proceeding or investigation and any appeal therefrom but not, however, for the total amount thereof, the Corporation shall nevertheless indemnify Indemnitee for the portion of such expenses (including, without limitation, attorneys' fees), liabilities, losses, judgments, fines (including, without limitation, excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974, as amended) or amounts paid in settlement to which Indemnitee is entitled.

#### 9.12 INSURANCE.

The Corporation may purchase and maintain insurance, at its expense, to protect itself and any director, officer, employee or agent of the Corporation or another corporation, partnership, joint venture, trust or other enterprise (including, without limitation, any employee benefit plan) against any expense, liability or loss incurred by him or her in any such capacity, or arising out of his or her status as such, whether or not the Corporation would have the power to indemnify such person against such expense, liability or loss under the DGCL.

#### 9.13 SAVINGS CLAUSE.

If this Article IX or any portion hereof shall be invalidated on any ground by any court of competent jurisdiction, then the Corporation shall nevertheless indemnify each Indemnitee as to any expenses (including, without limitation, attorneys' fees), liabilities, losses, judgments, fines (including, without limitation, excise taxes and penalties arising under the Employee Retirement Income Security Act of 1974, as amended) and amounts paid in settlement in connection with any action, suit, proceeding or investigation, whether civil, criminal or administrative, including, without limitation, an action by or in the right of the Corporation, to the fullest extent permitted by any applicable portion of this Article IX that shall not have been invalidated and to the fullest extent permitted by applicable law.

9.14 DEFINITIONS.

Terms used in this Article IX and defined in Section 145(h) and Section 145(i) of the DGCL shall have the respective meanings assigned to such terms in such Section 145(h) and Section 145(i).

**AMENDMENTS.** Subject to the limitations set forth in Section 9.9 of these bylaws or the provisions of the certificate of incorporation, the Board is expressly empowered to adopt, amend or repeal the bylaws of the Corporation. The stockholders also shall have power to adopt, amend or repeal the bylaws of the Corporation; *provided, however,* that, in addition to any vote of the holders of any class or series of stock of the Corporation required by law or by the certificate of incorporation, such action by stockholders shall require the affirmative vote of the holders of at least two-thirds in voting power of the outstanding shares of capital stock of the Corporation entitled to vote thereon.

## CERTIFICATION

I, Benjamin J. Zeskind, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Immuneering Corporation.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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) Omitted;
  - (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 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: September 9, 2021

By: /s/ Benjamin J. Zeskind

Name: Benjamin J. Zeskind, Ph.D

Title: Co-Founder, President, Chief Executive Officer and  
Director (Principal Executive Officer)

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## CERTIFICATION

I, Biren Amin, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Immuneering Corporation.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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) Omitted;
  - (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 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: September 9, 2021

By: /s/ Biren Amin

Name: Biren Amin

Title: Chief Financial Officer and Treasurer  
(Principal Financial Officer and Principal  
Accounting Officer)

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

In connection with the Quarterly Report on Form 10-Q of Immuneering Corporation. (the "Company") for the quarterly period ended June 30, 2021 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, the undersigned, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

- (1) The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: September 9, 2021

By: /s/ Benjamin J. Zeskind

Name: Benjamin J. Zeskind, Ph.D.

Title: Co-Founder, President, Chief Executive Officer and  
Director (Principal Executive Officer)

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

In connection with the Quarterly Report on Form 10-Q of Immuneering Corporation. (the "Company") for the quarterly period ended June 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, the undersigned, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, to the best of my knowledge, that:

- (1) The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: September 9, 2021

By: /s/ Biren Amin  
Name: Biren Amin  
Title: Chief Financial Officer and Treasurer  
(Principal Financial Officer and Principal Accounting Officer)

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