UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 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: 001-39425

Checkmate Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**36-4813934**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

245 Main Street, 2nd Floor
Cambridge, MA 02142
(617) 682-3625
(Address of principal executive offices including zip code)

Registrant's telephone number, including area code: (617) 682-3625

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

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

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

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

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

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

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

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

As of August 11, 2021, the registrant had 21,625,891 shares of common stock, $0.0001 par value per share outstanding.

SUMMARY OF THE MATERIAL RISKS ASSOCIATED WITH OUR BUSINESS

- We are a clinical-stage biopharmaceutical company with a very limited operating history. We have incurred net losses since our inception and anticipate that we will continue to incur substantial and increasing net losses in the foreseeable future. We may never achieve or sustain profitability.
- A pandemic, epidemic, or outbreak of an infectious disease, such as the global novel coronavirus disease 2019 ("COVID-19") pandemic, may materially and adversely affect our business, including our preclinical studies, clinical trials, third-parties on whom we rely, our supply chain, our ability to raise capital, and our financial results.
- We have never generated any revenue from product sales, and our ability to generate revenue from product sales and become profitable will depend significantly on our success in achieving a number of goals and on other factors.
- We will require substantial additional financing to achieve our goals, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our research, product development or commercialization efforts.
- We are heavily dependent on the success of vidutolimod (formerly CMP-001), our only current product candidate.
- We will not be able to commercialize vidutolimod and future product candidates if our preclinical studies do not produce successful results and our clinical trials do not demonstrate the safety and efficacy of vidutolimod and future product candidates.
- Vidutolimod is based on a novel approach to the treatment of cancer, which makes it difficult to predict the time and cost of product candidate development.
- Difficulty in enrolling patients could delay or prevent clinical trials of vidutolimod and future product candidates. We may find it difficult to enroll patients in our clinical trials or any subsequent trials that we may conduct.
- Vidutolimod is being, and future product candidates may be, evaluated in combination with third-party drugs, and we do not have control over the supply, regulatory status, or regulatory approval of such drugs.
- We currently rely on third-party contract manufacturing organizations ("CMOs") for the production of clinical supply of vidutolimod and may rely on CMOs for the production of commercial supply of vidutolimod, if approved. This reliance on CMOs increases the risk that we will not have sufficient quantities of such materials, product candidates, or any therapies that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.
- We rely, and expect to continue to rely, on third parties to conduct, supervise, and monitor our preclinical studies and clinical trials. If those third parties do not perform satisfactorily, we may be unable to obtain regulatory approval for vidutolimod or any future product candidates or any approvals that may be obtained may be delayed.
- Our collaboration agreements with any future third-parties may not be successful, which could adversely affect our ability to develop and commercialize vidutolimod or any future product candidates.
- The regulatory approval processes of the U.S. Food and Drug Administration (the "FDA") and comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are not able to obtain, or experience delays in obtaining, required regulatory approvals, we will not be able to commercialize vidutolimod and future product candidates as expected, and our ability to generate revenue may be materially impaired or eliminated.
- Our relationships with patients and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.
- We face significant competition, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us. If competitive product candidates are shown to be safer or more effective than ours, our commercial opportunity may be reduced or eliminated.
- If we are unable to obtain, maintain and protect our intellectual property rights for our technology and our product candidates, or if our intellectual property rights are inadequate, our competitive position could be harmed.
- Our success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These statements involve risks, uncertainties, and other factors that may cause actual results, levels of activity, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management and expected market growth are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "target," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements include, among other things, statements about:

- our current expectations and anticipated results of operations;
- the timing and the success of preclinical studies and clinical trials of vidutolimod and future product candidates, including our current Phase 2 trial for anti-PD-1 refractory melanoma, our current randomized Phase 2/3 trial for first-line melanoma, and our current Phase 2 proof of concept study in advanced head and neck squamous cell carcinoma ("HNSCC") and our currently anticipated Phase 2 proof of concept, multi-indication trial in cutaneous squamous cell carcinoma and Merkel cell carcinoma;
- the initiation and completion of any clinical trials of vidutolimod and future product candidates;
- the ongoing impact of the COVID-19 pandemic on our business;
- our need to raise additional funding before we can expect to generate any revenues from product sales and our ability to raise capital, including in light of the impact of the COVID-19 global pandemic and the related potential impact on the US and global economies;
- our ability to conduct successful clinical trials or obtain regulatory approval for vidutolimod or any future product candidates that we may identify or develop;
- our ability to ensure adequate supply of vidutolimod and any future candidates;
- our ability to maintain third-party relationships necessary to conduct our business;
- our dependence upon the success of our research to generate and advance additional product candidates;
- our ability to establish an adequate safety and efficacy profile for vidutolimod or any future product candidates that we may pursue;
- the implementation of our strategic plans for our business, vidutolimod and any other product candidates we may develop and our technology;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates and technology;
- the rate and degree of market acceptance and clinical utility for vidutolimod and any other product candidates we may develop;
- our estimates about the size of our market opportunity;
- our ability to maintain and establish collaborations and strategic relationships, including our clinical trial collaborations with an affiliate of Merck KGaA ("Merck"), Pfizer Inc. ("Pfizer"), Bristol-Myers Squibb Company ("BMS"), and Regeneron Pharmaceuticals, Inc. ("Regeneron");
- the potential benefits of the continued research, development, testing and manufacturing services provided by contract manufacturing organizations;
- our financial performance and liquidity;
- our ability to effectively manage our anticipated growth;
- developments relating to our competitors and our industry, including the impact of government regulation;
- our ability to retain the continued service of our key professionals and to identify, hire and retain additional qualified professionals;
- our ability to maintain adequate internal controls over financial reporting;
- our expectations regarding the period during which we qualify as an "emerging growth company" under the Jumpstart Our Business Startups Act (the "JOBS Act");
- our expectations regarding the period during which we qualify as a "smaller reporting company";

- our use of proceeds from our initial public offering and our expectations regarding our estimated expenses, the sufficiency of our cash resources, our expected cash runway and our need for additional financing, and
- other risks and uncertainties, including those listed under the section titled “Risk Factors.”

The forward-looking statements in this Quarterly Report on Form 10-Q represent our views as of the date of this Quarterly Report on Form 10-Q. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should therefore not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Quarterly Report on Form 10-Q.

We may from time-to-time provide estimates, projections and other information concerning our industry, our business and the markets for our product candidate or future product candidates. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market, and other data from our own internal estimates and research as well as from reports, research surveys, studies, and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. These estimates involve numerous assumptions, are subject to risks and uncertainties and are subject to change based on various factors.

CHECKMATE PHARMACEUTICS, INC.

QUARTERLY REPORT ON FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2021

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PART I. – FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements

CHECKMATE PHARMACEUTICALS, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except share and per share amounts)
(Unaudited)

	June 30, 2021	December 31, 2020
Assets		
Current Assets:		
Cash and cash equivalents	$ 63,110	$ 43,055
Restricted cash	20	20
Short-term investments	22,240	51,831
Prepaid expenses and other current assets	5,704	7,195
Total current assets	91,074	102,101
Investments, non-current	10,240	30,973
Machinery and equipment, net	367	—
Total assets	$ 101,681	$ 133,074
Liabilities and Stockholders' Equity		
Current Liabilities:		
Accounts payable	$ 2,198	$ 2,297
Accrued expenses	4,504	5,578
Total current liabilities	6,702	7,875
Total liabilities	6,702	7,875
Commitments and Contingencies (Note 9)		
Stockholders' Equity:		
Preferred stock, $0.0001 par value, 10,000,000 shares authorized as of June 30, 2021 and December 31, 2020; no shares outstanding as of June 30, 2021 and December 31, 2020	—	—
Common stock, $0.0001 par value; 300,000,000 authorized as of June 30, 2021 and December 31, 2020; 21,625,891 and 21,560,398 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively	2	2
Additional paid-in capital	268,179	265,342
Accumulated other comprehensive gain (loss)	(33)	(74)
Accumulated deficit	(173,169)	(140,071)
Total stockholders' equity	94,979	125,199
Total liabilities and stockholders' equity	$ 101,681	$ 133,074

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

CHECKMATE PHARMACEUTICALS, INC. AND SUBSIDIARY
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 14,865	$ 6,476	$ 25,243	$ 12,789
General and administrative	4,090	1,795	7,893	3,305
Total operating expenses	18,955	8,271	33,136	16,094
Loss from operations	(18,955)	(8,271)	(33,136)	(16,094)
Other income (expense), net:				
Interest income	20	6	73	28
Loss on sale of available-for-sale investments	(35)	—	(35)	—
Change in fair value of convertible loan notes	—	(83)	—	(83)
Total other income (expense), net	(15)	(77)	38	(55)
Net loss	$ (18,970)	$ (8,348)	$ (33,098)	$ (16,149)
Reconciliation of net loss attributable to common stockholders:				
Net loss	$ (18,970)	$ (8,348)	$ (33,098)	$ (16,149)
Accretion of issuance costs on redeemable convertible preferred stock	—	(429)	—	(456)
Accrued dividends on redeemable convertible preferred stock	—	(2,187)	—	(3,957)
Net loss attributable to common stockholders	$ (18,970)	$ (10,964)	$ (33,098)	$ (20,562)
Weighted-average common shares outstanding—basic and diluted	21,624,568	1,488,489	21,603,563	1,488,489
Net loss per share attributable to common stockholders—basic and diluted	$ (0.88)	$ (7.37)	$ (1.53)	$ (13.81)
Comprehensive loss:				
Net loss	$ (18,970)	$ (8,348)	$ (33,098)	$ (16,149)
Unrealized gain on available-for-sale investments	50	—	41	—
Comprehensive loss	$ (18,920)	$ (8,348)	$ (33,057)	$ (16,149)

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

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

	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series C Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive Gain/(Loss)	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at December 31, 2020	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**21,560,398**	**$ 2**	**$ 265,342**	**$ (140,071)**	**$ (74)**	**$ 125,199**
Exercise of stock options	—	—	—	—	—	—	59,225	—	118	—	—	118
Stock-based compensation expense	—	—	—	—	—	—	—	—	1,216		—	1,216
Unrealized losses on available-for-sale investments	—	—	—	—	—	—	—	—	—	—	(9)	(9)
Net loss	—	—	—	—	—	—	—	—	—	(14,128)	—	(14,128)
Balances at March 31, 2021	**—**	**—**	**—**	**—**	**—**	**—**	**21,619,623**	**2**	**266,676**	**(154,199)**	**(83)**	**112,396**
Exercise of stock options	—	—	—	—	—	—	6,268	—	16	—	—	16
Stock-based compensation expense	—	—	—	—	—	—	—	—	1,487	—	—	1,487
Unrealized gains on available-for-sale investments	—	—	—	—	—	—	—	—	—	—	50	50
Net loss	—	—	—	—	—	—	—	—	—	(18,970)	—	(18,970)
Balances at June 30, 2021	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**21,625,891**	**$ 2**	**$ 268,179**	**$ (173,169)**	**$ (33)**	**$ 94,979**

	Series A Redeemable Convertible Preferred Stock		Series B Redeemable Convertible Preferred Stock		Series C Redeemable Convertible Preferred Stock		Common Stock		Additional Paid - In Capital	Accumulated Deficit	Accumulated Other Comprehensive Gain/(Loss)	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at December 31, 2019	**25,000,000**	**$ 32,482**	**26,283,386**	**$ 64,446**	**—**	**$ —**	**1,488,489**	**$ 1**	**$ —**	**$ (97,437)**	**$ —**	**$ (97,436)**
Issuance of series B redeemable convertible preferred stock at $2.1687 per share, net of issuance costs of $27	—	—	3,688,898	7,973	—	—	—	—	—	—	—	—
Exercise of series B preferred stock tranche right	—	—	—	300	—	—	—	—	—	—	—	—
Accretion of issuance costs related to redeemable convertible preferred stock	—	—	—	27	—	—	—	—	—	(27)	—	(27)
Stock-based compensation expense	—	—	—	—	—	—	—	—	101	—	—	101
Accrued dividends on redeemable convertible preferred stock	—	498	—	1,272	—	—	—	—	(101)	(1,669)	—	(1,770)
Net loss	—	—	—	—	—	—	—	—	—	(7,801)	—	(7,801)
Balances at March 31, 2020	**25,000,000**	**32,980**	**29,972,284**	**74,018**	**—**	**—**	**1,488,489**	**1**	**—**	**(106,934)**	**—**	**(106,933)**
Issuance of series C redeemable convertible preferred stock at $1.6016 per share, net of issuance costs of $429	—	—	—	—	46,828,167	74,571	—	—	—	—	—	—
Conversion of convertible notes into series C convertible redeemable preferred stock	—	—	—	—	6,295,756	10,083	—	—	—	—	—	—
Accretion of issuance costs related to redeemable convertible preferred stock	—	—	—	—	—	429	—	—	—	(429)	—	(429)
Stock-based compensation expense	—	—	—	—	—	—	—	—	100	—	—	100
Accrued dividends on redeemable convertible preferred stock	—	499	—	1,296	—	392	—	—	(100)	(2,087)	—	(2,187)
Net loss	—	—	—	—	—	—	—	—	—	(8,348)	—	(8,348)
Balances at June 30, 2020	**25,000,000**	**$ 33,479**	**29,972,284**	**$ 75,314**	**53,123,923**	**$ 85,475**	**1,488,489**	**$ 1**	**$ —**	**$ (117,798)**	**$ —**	**$ (117,797)**

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

CHECKMATE PHARMACEUTICALS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Six Months Ended June 30,	
	2021	2020
Cash flows from operating activities		
Net loss	$ (33,098)	$ (16,149)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock based compensation	2,703	201
Depreciation	11	—
Change in fair value of notes payable	—	83
Amortization/accretion of investments	370	—
Change in operating assets and liabilities:		
Prepaid expenses and other current assets	1,491	(610)
Accounts payable	(98)	(31)
Accrued expenses	(1,075)	464
Net cash used in operating activities	(29,696)	(16,042)
Cash flows from investing activities		
Purchases of investments	(10,197)	—
Maturities of investments	29,500	—
Sale of investments	30,692	—
Purchase of machinery and equipment	(378)	—
Net cash provided by investing activities	49,617	—
Cash flows from financing activities		
Proceeds from stock option exercises	134	—
Cash paid for initial public offering costs	—	(398)
Proceeds from issuance of convertible preferred stock, net of issuance costs	—	82,544
Proceeds from issuance of convertible loan notes	—	10,000
Net cash provided by financing activities	134	92,146
Net increase in cash, cash equivalents and restricted cash	20,055	76,104
Cash, cash equivalents and restricted cash at beginning of period	43,075	4,205
Cash, cash equivalents and restricted cash at end of period	$ 63,130	$ 80,309
Supplemental disclosure of non-cash financing activities:		
Accretion of issuance costs to redeemable convertible preferred stock	$ —	$ 456
Exercise of Series B preferred stock tranche right	$ —	$ 300
Accrued dividends on redeemable convertible preferred stock	$ —	$ 3,957
Conversion of loan notes into series C preferred stock	$ —	$ 10,083
Deferred offering costs included in prepaid expenses and other current assets and accounts payable or accrued expenses	$ —	$ 1,217

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

CHECKMATE PHARMACEUTICALS, INC.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS
(Unaudited)

1 – Nature of Business

Nature of Business

Checkmate Pharmaceuticals, Inc. ("Checkmate" or the "Company"), headquartered in Cambridge, Massachusetts, is a clinical stage biotechnology company incorporated under the laws of the State of Delaware in July 2015 that is focused on developing and commercializing its proprietary technology to harness the power of the immune system to combat cancer. Since its inception, the Company has devoted substantially all of its efforts to the research and development activities, including recruiting management and technical staff, raising capital, producing materials for non-clinical and clinical studies and building infrastructure to support such activities, and has not yet generated any revenue. Expenses have primarily been for research and development and related administrative costs. The Company has financed its operations through the sale of common stock, convertible debt and redeemable convertible preferred stock.

Initial Public Offering

On August 11, 2020, the Company closed its initial public offering ("IPO"), at which time the Company issued and sold 5,000,000 shares of its common stock, at a price to the public of $15.00 per share. On September 3, 2020, the underwriters of the IPO exercised a portion of their overallotment option by purchasing an additional 109,861 shares from the Company at the IPO price. The Company received approximately $67.7 million in net proceeds, inclusive of the over-allotment exercise and after deducting underwriting discounts and commissions and other offering expenses payable by the Company.

In connection with the closing of the IPO, all outstanding shares of the Company's preferred stock were converted into 14,948,241 shares of the Company's common stock.

On July 31, 2020, the Company effected a one-for-7.4771 reverse stock split of its common stock. All shares, stock options, warrants, redeemable convertible preferred stock conversion prices, ratios and per share information presented in the condensed consolidated financial statements have been adjusted to reflect the reverse stock split on a retroactive basis for all periods presented. The par value per share and the authorized number of shares of common stock were not adjusted as a result of the reverse stock split.

Risks and Uncertainties

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, the outcome of clinical trials, development by competitors of new therapeutics and technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, ability to secure additional capital to fund operations, and risks associated with the ongoing COVID-19 global pandemic or future pandemics, including known and potential delays associated with its ongoing and anticipated trials and the Company's ability to raise additional capital to finance its operations. There can be no assurance that the Company will be able to successfully complete the development of, or receive regulatory approval for, any products developed, and if approved, that any products will be commercially viable. Any products resulting from the Company's current research and development efforts will require significant additional research and development, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts will require significant amounts of additional capital, adequate personnel, infrastructure and extensive compliance reporting capabilities. The Company has not generated any revenues from the sale of any products to date. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales.

The Company may seek additional funding through private or public equity financings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing agreements. If the Company is unable to obtain additional funding, the Company may be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects, or the Company may be unable to continue operations. Although management continues to pursue these plans, there is no assurance that the Company will be successful in obtaining sufficient funding on terms acceptable to the Company to fund continuing operations, if at all.

The Company expects that its cash, cash equivalents and available-for-sale investments of $95.6 million as of June 30, 2021 will be sufficient to fund its operating expenses and capital requirements for at least 12 months beyond the date of issuance of these condensed consolidated financial statements.

2 – Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 2, *Summary of Significant Accounting Policies*, to the financial statements for the year ended December 31, 2020 in the Company's 2020 Annual Report on Form 10-K. There have been no material changes to the significant accounting policies during the six-month period ended June 30, 2021, except as noted below.

Basis of Presentation

The accompanying condensed consolidated financial statements are prepared in accordance with accounting principles generally accepted in the United States ("U.S. GAAP") and include the accounts of the Company and its wholly owned subsidiary Checkmate Pharmaceuticals Security Corporation. Any reference in these notes to applicable guidance is meant to refer to the authoritative accounting principles generally accepted in the United States as found in the Accounting Standard Codification (ASC) and Accounting Standards Update (ASU) of the Financial Accounting Standards Board (FASB).

Unaudited interim financial information

The accompanying interim condensed consolidated financial statements and related disclosures are unaudited and have been prepared in accordance with GAAP for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X of the Exchange Act. Accordingly, they do not include all the information and footnotes required by GAAP for complete financial statements and should be read in conjunction with the Company's financial statements and related footnotes as of and for the year ended December 31, 2020, included in the Company's 2020 Annual Report on Form 10-K. The Company's financial information as of June 30, 2021, and for the three and six months ended June 30, 2021 and 2020 is unaudited, but in the opinion of management, includes all adjustments, consisting only of normal recurring adjustments, considered necessary for a fair presentation of the financial position, results of operations and cash flows at the dates and for the periods presented. The balance sheet data as of December 31, 2020 was derived from audited financial statements. The results of the Company's operations for any interim period are not necessarily indicative of the results that may be expected for any other interim period or for a full fiscal year.

Use of estimates

The preparation of the Company's condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the reported amounts of expenses during the reporting periods. Significant estimates and assumptions reflected in these condensed consolidated financial statements include, but are not limited to, the accrual of research and development expenses and the valuation of stock-based awards before the Company's IPO. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors that it believes to be reasonable under the circumstances. Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Changes in estimates are recorded in the period in which they become known. Actual results may differ from those estimates or assumptions.

Machinery and equipment

Machinery and equipment is recorded at cost less accumulated depreciation. Depreciation is recognized using the straight-line method over the estimated useful life of five years for each asset. Accumulated depreciation at June 30, 2021 was $11,000.

Recently issued accounting pronouncement

In June 2016, the FASB issued ASU 2016-13, "Credit Losses (Topic 326)." ASU 2016-13 requires that financial assets measured at amortized cost, such as trade receivables and investments, be represented net of expected credit losses, which may be estimated based on relevant information such as historical experience, current conditions, and future expectation for each pool of similar financial asset. The new guidance requires enhanced disclosures related to trade receivables and associated credit losses. In May 2019, the FASB issued ASU No. 2019-05, "Financial Instruments—Credit Losses (Topic 326) Targeted Transition Relief," which allows for a transition election on certain instruments. The guidance is effective for Smaller Reporting Companies for fiscal years beginning after December 15, 2022 and interim periods in those fiscal years. In November 2019, the FASB issued ASU No. 2019-11 which amends certain aspects of ASU No. 2016-13, including transition relief for trouble debt restructuring, among other topics. The Company is currently evaluating the impact of this pronouncement on its consolidated financial statements.

3 – Investments and Fair Value Measurement

The following tables summarizes the amortized cost and estimated fair value of the Company's investments, which are considered to be available-for-sale investments as of June 30, 2021 and December 31, 2020.

As of June 30, 2021

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	Short-term Investments	Investments, non-current
			(in thousands)			
Commercial paper	$ 2,991	$ —	$ —	$ 2,991	$ 2,991	$ —
Corporate debt securities	29,522	—	(33)	29,489	19,249	10,240
Total	$ 32,513	$ —	$ (33)	$32,480	$ 22,240	$ 10,240

As of December 31, 2020

	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value	Short-term Investments	Investments, non-current
			(in thousands)			
Commercial paper	$ 42,709	$ 8	$ (16)	$42,701	$ 42,701	$ —
Corporate debt securities	41,169	—	(66)	41,103	10,130	30,973
Total	$ 83,878	$ 8	$ (82)	$83,804	$ 52,831	$ 30,973

The amortized cost and estimated fair value of investments by contractual maturity at June 30, 2021 are as follows:

	Amortized Cost	Estimated Fair Value
	(in thousands)	
Due in one year or less	$ 22,258	$ 22,240
Due after one year through two years	10,255	10,240
	$ 32,513	$ 32,480

At June 30, 2021, there were no available-for-sale securities in the Company's total investment portfolio that were in a continuous unrealized loss position for more than 12 months. The Company concluded that the net declines in market value of available-for-sale securities were temporary in nature and did not consider any of investments to be other-than-temporarily impaired.

The following tables set forth the fair value of the Company's financial assets and liabilities by level within the fair value hierarchy that are measured at fair value on a recurring basis:

	June 30, 2021			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
Money markets funds (included in cash equivalents)	$61,907	$ —	$ —	$61,907
Commercial paper	—	2,991	—	2,991
Corporate debt securities	—	29,489	—	29,489
Total assets	$61,907	$32,480	$ —	$94,387

	December 31, 2020			
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
Money markets funds (included in cash equivalents)	$7,839	$ —	$ —	$ 7,839
Commercial paper	—	42,701	—	42,701
Corporate debt securities	—	41,103	—	41,103
Total assets	$7,839	$83,804	$ —	$91,643

Investments classified as Level 2 within the valuation hierarchy consist of commercial paper and corporate debt securities. The Company estimates the fair values of these marketable securities by taking into consideration valuations obtained from third-party pricing sources.

4 – Accrued Expenses

Accrued expenses consist of the following:

	June 30, 2021	December 31, 2020
	(in thousands)	
Payroll and employee related expenses	$1,677	$ 1,555
External research and development	2,077	3,633
Other accrued expenses	750	390
Total accrued expenses	$4,504	$ 5,578

5 – Redeemable Convertible Preferred Stock

On August 11, 2020, in connection with the closing of the IPO, all outstanding shares of the Company's preferred stock were converted into 14,948,241 shares of common stock. As a result of the conversion, the Company reclassified the carrying value of its preferred stock, which included all cumulative but unpaid dividends, to common stock and additional paid-in-capital and therefore there was no outstanding redeemable convertible preferred stock as of June 30, 2021 and December 31, 2020.

6 – EQUITY

The holders of the common stock are entitled to one vote for each share of common stock held at all meetings of stockholders. Common stockholders are entitled to receive dividends declared out of funds legally available, subject to the payment in full of all preferential dividends to which the holders of preferred stock are entitled.

On August 11, 2020, the Company filed a restated certificate of incorporation in the State of Delaware, which, among other things, restated the number of shares of all classes of stock that the Company has authority to issue up to 310,000,000 shares, consisting of (i) 300,000,000 shares of common stock, $0.0001 par value per share, and (ii) 10,000,000 shares of preferred stock, $0.0001 par value per share. The shares of preferred stock are currently undesignated and no shares are outstanding.

Also on August 11, 2020, the Company completed its IPO, pursuant to which it issued and sold 5,109,861 shares of common stock, inclusive of 109,861 shares sold by the Company 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 $67.7 million, after deducting underwriting discounts and commissions and other offering costs

7 – STOCK-BASED COMPENSATION

Total stock-based compensation expense was classified in the accompanying condensed consolidated statements of operations and comprehensive loss as follows:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
	(in thousands)		(in thousands)	
Research and development	$ 608	$ 39	$ 1,094	$ 78
General and administrative	879	61	1,609	123
Total stock-based compensation expense	$ 1,487	$ 100	$ 2,703	$ 201

During the six months ended June 30, 2021, the Company granted options with service-based vesting conditions for the purchase of 862,350 shares of common stock with a weighted average exercise price of $12.70 per share and a weighted average grant-date fair value of $8.85 per share.

8 – NET LOSS PER SHARE

Net Loss Per Share Attributable To Common Stockholders

Because the Company reports a net loss attributable to common stockholders, basic and diluted net loss per share attributable to common stockholders are the same for both years presented. All preferred stock and stock options have been excluded from the computation of diluted weighted-average shares outstanding because such securities would have an antidilutive impact. The following common stock equivalents outstanding at June 30, 2021 and 2020 have been excluded from the calculation of diluted net loss per share because their inclusion would have been antidilutive:

	June 30,	
	2021	2020
Options to purchase common stock	3,284,323	1,073,044
Redeemable convertible preferred stock	—	14,948,249

9 – COMMITMENTS AND CONTINGENCIES

Operating Lease

The Company has a month-to-month lease agreement for its corporate space in Cambridge, Massachusetts. Rent expense is recognized as incurred. Rent expense for the three months ended June 30, 2021 and 2020 was $0.2 million and $0.1 million, respectively. Rent expense for each of the six months ended June 30, 2021 and 2020 was $0.3 million.

Clinical Trial Collaboration and Supply Agreements

On May 10, 2021, the Company entered into a Supply and Non-Exclusive License Agreement ("SNLA") with Regeneron Pharmaceuticals, Inc. ("Regeneron"). The SNLA dictates the general terms that govern specific collaborative studies between the Company and Regeneron, including a Phase 2 proof of concept trial, with patient cohorts in anti-PD-1 naïve and anti-PD-1 refractory cutaneous squamous cell carcinoma and anti-PD-1 refractory Merkel cell carcinoma. Pursuant to the SNLA, Regeneron agreed to provide cemiplimab, a drug to be used concurrently or in combination with vidutolimod in the aforementioned studies, at its own expense. As part of the SNLA, the parties granted each other non-exclusive licenses to use background intellectual property and regulatory documentation to seek regulatory approval of the other party's compound solely for use as a combination therapy. The Company does not expect any future consideration to be payable to Regeneron pursuant to the SNLA.

On December 7, 2020, the Company entered into the Master Clinical Trial Collaboration Agreement ("MCTCA") with Bristol-Myers Squibb Company ("BMS"). The MCTCA dictates the general terms that govern specific collaborative studies between the companies, including the Company's Phase 2 refractory melanoma study and Phase 2 front-line melanoma study (collectively, the "collaborative studies"). Pursuant to the MCTCA, BMS agreed to provide nivolumab, a drug to be used in combination with vidutolimod in the collaborative studies, at its own expense. As part of the MCTCA, the parties granted each other non-exclusive licenses to use background intellectual property and regulatory documentation to seek regulatory approval of the other party's compound solely for use as a combination therapy. The Company does not expect any further consideration to be payable to BMS pursuant to the MCTCA.

On August 22, 2018, the Company entered into the Clinical Trial Collaboration and Supply Agreement ("CTCSA") with an affiliate of Merck KGaA ("Merck") and Pfizer Inc. ("Pfizer") (Merck and Pfizer together are referred to herein as the "Alliance"). Pursuant to the CTCSA, the Company, and the Alliance will each provide compound drug product that will be dosed concurrently or in combination in a clinical trial sponsored by Pfizer. This agreement was amended on March 4, 2019. In addition to providing a compound drug product to be used in the clinical trial, the Company will reimburse Pfizer for each patient dosed in the study using the Company's compound at a specified rate outlined in the CTCSA. In no event will the amount of costs due by the Company to Pfizer exceed $4.0 million over the term of the CTCSA. The costs of services performed, and material used in connection with the research and development activities of the CTCSA, including reimbursements due to Pfizer, are included in research and development costs and expensed as incurred. The Company incurred $1.0 million and $0.5 million of expense during the years ended December 31, 2020 and 2019, respectively. By mutual agreement of the Company and the Alliance, the clinical trial was discontinued in 2020, and the Company does not expect to incur any further costs in connection with the CTCSA.

License Agreement

In June 2015, the Company entered into an exclusive license agreement with Cytos Biotechnology LTD (now Kuros Biosciences AG, or "Kuros") as amended in August 2017 and as further amended in January 2018 (the "Kuros License Agreement"). Pursuant to the Kuros License Agreement, in return for payments made, the Company was granted an exclusive, royalty-bearing, sublicensable, worldwide license, under all of Kuro's intellectual property rights, including any intellectual property rights arising during the term of the agreement, to commercially develop, manufacture, use, distribute, and sell certain therapeutic products, including vidutolimod, (the "Licensed Products") for the diagnosis, treatment and prevention of all indications in humans and animals. Under the terms of the Kuros License Agreement, the Company is required to use commercially reasonable efforts to develop at least one Licensed Product. Under the Kuros License Agreement, the Company agreed to make payments to Kuros for each product that achieves certain development and regulatory milestones, including payments of up to $56.0 million for the Company's current oncology programs. As of June 30, 2021, the Company has incurred license fees and milestone payments totaling $8.3 million pursuant to the Kuros License Agreement. These payments are comprised of: (i) a license fee of $1.0 million which was recognized in research and development expense in 2015, (ii) a $1.0 million milestone payment in connection with the dosing of the first patient in our first Phase 1 clinical trial, which was recognized in research and development expense in 2016, (iii) a $0.3 million license amendment fee in connection with the signing of the second amendment to the Kuros License Agreement, which was recognized in research and development expense in 2018, (iv) a $2.0 million milestone payment in connection with the dosing of the first patient in the Phase 2 first-line melanoma trial for vidutolimod, which was recognized in the statement of operations for the three months ended March 31, 2021 and (v) a $4.0 million milestone payment in connection with the dosing in a Phase 2 trial intended to assess the efficacy and safety of vidutolimod in combination with nivolumab for the treatment of patients with anti-PD-1 refractory melanoma and to potentially support a Biologics License Application ("BLA") and marketing approval of vidutolimod, which was recognized in the consolidated statements of operations for the three months ended June 30, 2021.

The Company is also required to pay tiered royalties of high single-digit to low teens percentages on annual net sales of Licensed Products that are covered by a licensed patent, as well as royalties at 50% of the foregoing amounts with respect to sales of Licensed Products that are not covered by a licensed patent, but are covered by licensed know-how. The Kuros License Agreement expires upon the expiration of the last-to-expire royalty term for the Licensed Products in the territory. Either party has the right to terminate the agreement in full for an uncured material breach of the agreement upon written 60 days' notice to the other party. The Company has the right to terminate the agreement for any reason upon 90 days' written notice to Kuros.

Other Contingencies

During the ordinary course of its operations, the Company may become a party to contractual disputes, litigation, and potential claims. The Company does not believe that the resolution of any of these matters, if any, will have a material adverse effect on its financial position or results of operations.

Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis should be read in conjunction with the unaudited condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q and our audited financial statements and related notes thereto for the year ended December 31, 2020 included in our 2020 Annual Report on Form 10-K. This discussion and analysis and other parts of this Quarterly Report on Form 10-Q contain forward-looking statements based upon current beliefs, plans and expectations that involve risks, uncertainties and assumptions, such as statements regarding our plans, objectives, expectations, intentions and projections. Our actual results and the timing of selected events could differ materially from those anticipated in these forward-looking statements as a result of several factors, including those set forth in the "Risk Factors" section of this Quarterly Report on Form 10-Q and in other filings with the SEC. Please also see the section entitled "Note Regarding Forward-Looking Statements" contained in the Quarterly Report on Form 10-Q.

Overview

We are a clinical-stage biotechnology company focused on developing and commercializing our proprietary technology to harness the power of the immune system to combat cancer. Our product candidate, vidutolimod (formerly CMP-001), is a differentiated Toll-like receptor 9 ("TLR9"), agonist delivered as a biologic virus-like particle ("VLP"), utilizing a CpG-A oligonucleotide as a key component. When injected into a tumor, vidutolimod is designed to trigger the body's innate immune system, thereby altering the tumor microenvironment and directing activated anti-tumor T cells to attack both the injected tumor and also tumors throughout the body. In a clinical trial of vidutolimod in combination with a systemic checkpoint inhibitor ("CPI"), in patients whose tumors were unresponsive or no longer responsive to a CPI, we have observed a best objective response rate ("ORR"), of 28% (27/98), including post-progression responders. We are evaluating vidutolimod across multiple tumor types in combination with other immunotherapy agents. Our founder, Art Krieg, first reported the discovery of immunostimulatory cytosine-phosphate-guanine ("CpG"), DNA in 1995, which, combined with the discovery of TLR9, led to the recognition that synthetic CpG-A oligonucleotides have the potential to stimulate the TLR9 receptor for therapeutic purposes. Our goal is to establish vidutolimod as a foundational immuno-oncology therapy that engages the innate immune system to fight cancer and improve outcomes for patients with a broad range of solid tumors.

Since our inception, we have devoted substantially all of our efforts and financial resources to the research and development activities related to our technology and our vidutolimod program, and the administrative support for such activities including raising capital, business planning, undertaking pre-clinical studies and clinical trials and other support activities. We do not have any products approved for sale and have not generated any revenue from product sales or any other sources and do not expect to generate any revenue for the next several years. We have not yet successfully completed any registrational clinical trials, obtained any regulatory approvals, manufactured a commercial-scale drug, or conducted sales and marketing activities.

We have funded our operations to date primarily with proceeds from the sale of preferred stock, convertible debt and common stock. Since inception and through June 30, 2021, we have received net cash proceeds of $241.7 million from sales of our preferred stock, convertible debt and common stock.

We have incurred recurring losses and had negative operating cash flows since inception and our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of vidutolimod or any other products we acquire or develop. Our net losses were $28.3 million and $36.9 million for the years ended December 31, 2019 and 2020, respectively, and for the six months ended June 30, 2021, our net loss was $33.1 million. As of June 30, 2021, we had an accumulated deficit of $173.2 million. We expect to continue to incur significant expenses and to increase operating losses for at least the next several years.

We expect our expenses and capital requirements will increase substantially in connection with our ongoing activities, particularly as we:

- prepare for, initiate and conduct additional clinical trials and preclinical studies of vidutolimod, including, among others, our current Phase 2 trial in anti-PD-1 refractory melanoma, our current randomized Phase 2/3 trial in first-line melanoma, our current Phase 2 proof of concept study in head and neck squamous cell carcinoma, and our currently anticipated Phase 2 proof of concept trial with patient cohorts in anti-PD-1 naïve and anti-PD-1 refractory cutaneous squamous cell carcinoma and Merkel cell carcinoma;
- conduct the necessary scale-up activities to support the potential commercialization of vidutolimod, if approved;
- hire additional clinical and scientific personnel to support our ongoing preclinical activities and clinical trials of vidutolimod and any other product candidates we choose to develop;

- develop any future product candidates;
- seek marketing approval for vidutolimod and any other product candidates that successfully complete clinical development;
- acquire or in-license additional product candidates;
- maintain compliance with applicable regulatory requirements;
- maintain, expand, protect and enforce our intellectual property portfolio;
- develop and expand our sales, marketing and distribution capabilities for vidutolimod and any other product candidates for which we obtain marketing approval;
- take precautionary measures to help minimize the risk of the coronavirus or any other future pandemic to our employees and encounter continued delays or interruptions related to current development activities, our supply chain, or the third-parties on whom we rely due to the COVID-19 pandemic;
- expand our infrastructure and facilities to accommodate the planned growth of our employee base; and
- expand our operational, financial and management systems and increase administrative personnel, including to support our clinical development and commercialization efforts and our operations as a public company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing and distribution or licensing arrangements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of vidutolimod or any of our future product candidates.

On August 11, 2020, we completed our initial public offering (“IPO”), pursuant to which we issued and sold 5,000,000 shares of our common stock, at a price to the public of $15.00 per share. On September 3, 2020, the underwriters of the IPO exercised a portion of their over-allotment option by purchasing an additional 109,861 shares from us at the IPO price. We received approximately $67.7 million in net proceeds, inclusive of the partial over-allotment exercise and after deducting underwriting discounts and commissions and other offering expenses payable by us. In connection with the IPO, on August 11, 2020, all redeemable convertible preferred stock was converted into shares of common stock.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder.

COVID-19

In March 2020 the World Health Organization declared the global novel coronavirus disease 2019 (“COVID-19”) a pandemic. Although we have experienced some impact of the COVID-19 pandemic on our business and operations, including delays in initiation of study sites and enrolling patients, we cannot currently predict the scope and severity of any potential business shutdowns or disruptions or the resulting impact on future clinical trials. As of the date hereof, certain of our ongoing clinical trials are nearing completion and have not been materially affected by the COVID-19 pandemic, and the schedules for the near-term manufacture of vidutolimod at our contract manufacturers have also been largely unaffected to date. Certain of our clinical trials that commenced in 2020 were adversely affected by the COVID-19 pandemic, resulting in patient enrollment delays in the first half of 2021. We are also in the planning stages for new clinical trials, and a number of activities are required in order to initiate patient enrollment into these trials that could be impacted by COVID-19 as the pandemic continues to evolve.

While the COVID-19 pandemic did not materially impact our results of operations during 2020, the ultimate impact on our operations is unknown and will depend on future developments, which, despite progress in vaccination efforts, remain uncertain and cannot be predicted with confidence, including the duration of the COVID-19 pandemic, new strains of the virus which may impact rates of infection and vaccination efforts, developments or perceptions regarding the safety of vaccines, new information which may emerge, and any additional preventative and protective actions that governments, or we, may direct, which may result in extending ongoing business disruptions, reduced patient traffic and reduced operations. We are continuing to monitor the latest developments regarding the COVID-19 pandemic, including the pace of vaccinations and the emergence of new and more contagious strains of the virus, and any resulting impact on our business, financial condition, results of operations and prospects. Any resulting financial impact cannot be reasonably estimated at this time and may have a material adverse impact on our business, financial condition and results of operations.

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue from any sources and do not expect to generate any revenue from the sale of products for the next several years. If our development efforts for vidutolimod or any future product candidates are successful and result in regulatory approval, we may generate revenue in the future from product sales. However, we cannot predict whether, when, or to what extent we will generate revenue from the commercialization and sale of vidutolimod or any future product candidates as we may never succeed in obtaining regulatory approval for any of our product candidates. If we enter into license or collaboration agreements for any of our product candidates or intellectual property, we may generate revenue in the future from payments as a result of such license or collaboration agreements, however there can be no assurance that we will be able to enter into any license or collaboration agreements.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities and the development of our VLP technology and our vidutolimod program and include:

- expenses incurred in connection with the preclinical and clinical development of our technology and vidutolimod, including clinical trials under agreements with contract research organizations ("CROs"), clinical investigators and consultants;
- employee-related expenses, including salaries, benefits and travel and stock-based compensation expense, for employees engaged in research and development functions;
- the cost of contract manufacturing organizations ("CMOs"), that manufacture drug product for use in our preclinical studies and clinical trials and perform analytical testing, scale-up and other services in connection with our development activities;
- costs related to compliance with regulatory requirements;
- payments made under third-party licensing agreements, such as the exclusive license agreement we entered into with Cytos Biotechnology LTD (now Kuros Biosciences AG, or "Kuros") (the "Kuros License Agreement");
- facilities and other expenses, which include direct and allocated expenses for facilities, insurance and supplies; and
- costs related to compliance with regulatory requirements.

We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers. This process involves reviewing open contracts, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. Any nonrefundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. Such amounts are expensed as the related goods are delivered or the related services are performed, or until it is no longer expected that the goods will be delivered or the services rendered.

Upfront payments under license agreements are expensed upon receipt of the license, and any annual maintenance fees under license agreements are expensed in the period in which they are incurred. Milestone payments under license agreements are accrued and a corresponding expense is recognized in the period in which the milestone is determined to be probable of achievement and the related amount is reasonably estimable.

We do not track our research and development expenses by indication. Our direct external research and development expenses consist primarily of external costs, such as fees paid to CROs, CMOs, research/testing laboratories and outside consultants in connection with our preclinical development, process development, manufacturing and clinical development activities. Our direct research and development expenses also include fees incurred under licensing agreements. We do not allocate these costs to specific indications because they are deployed across the entire the vidutolimod development program and, as such, are not separately classified. We use internal resources primarily to manage our preclinical development, outsourced clinical trials, process development, manufacturing and clinical development activities. These employees work across the entire the vidutolimod development program and, therefore, we do not track their costs by indication.

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have 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 that our research and development expenses will continue to increase substantially over the next several years as we advance vidutolimod into later stages of clinical development toward potential regulatory approval, advance vidutolimod for additional indications, as well as conduct translational research efforts and other preclinical and clinical development, including submitting regulatory filings for any other product candidates we may acquire or develop. In addition to the expected increase in third-party costs, we expect our personnel costs, including costs associated with stock-based compensation, will also increase substantially in the future. In addition, as we advance vidutolimod into potentially registrational clinical trials and, subject to positive data and regulatory approvals, potentially commercialize vidutolimod, we expect to incur additional expenses from milestone and royalty payments related to the Kuros License Agreement.

We do not believe that it is possible at this time to accurately project total program-specific expenses through commercialization of vidutolimod or any other product candidates we may acquire or develop. This is due to numerous factors, some of which are beyond our control, that are associated with the successful development and commercialization of vidutolimod and any other product candidates we may acquire or develop, including the following:

- the scope, progress, outcome and costs of our preclinical studies and clinical trials for vidutolimod or any other product candidates we may acquire or develop;
- making arrangements with third-party manufacturers for both clinical and commercial supplies of vidutolimod or any other product candidates;
- successful patient enrollment in, and the initiation and completion of clinical trials;
- raising additional funds necessary to complete clinical development and the potential commercialization, of vidutolimod or any other product candidates;
- receipt, timing and related terms of marketing approvals from applicable regulatory authorities;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- developing and implementing marketing and reimbursement strategies;
- establishing sales, marketing and distribution capabilities and launching commercial sales of vidutolimod or any other products, if approved, whether alone or in collaboration with others;
- acceptance of vidutolimod or any other products, if approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies and/or changes in standard of care;
- obtaining and maintaining third-party coverage and adequate reimbursement;
- obtaining and maintaining patent, trade secret and other intellectual property protection and regulatory exclusivity for our product candidates;
- protecting and enforcing our rights in our intellectual property portfolio;
- significant and changing government regulations; and
- maintaining an acceptable tolerability profile of the products following approval, if any.

A change in the outcome of any of these variables with respect to the development of vidutolimod or any future product candidates would significantly change the costs and timing associated with the development of that product candidate. We may never succeed in obtaining regulatory approval for any product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and benefits, stock-based compensation and travel expense for personnel in executive, business development, finance, human resources, legal and support functions. General and administrative expenses also include direct and allocated facility-related costs as well as insurance costs and professional fees for legal, patent, consulting, accounting and audit services, investor and public relations services and outsourced information technology services.

We anticipate that our general and administrative expenses will continue to increase in the future as we increase our headcount to support the continued advancement of vidutolimod toward potential commercialization and the future development of any other product candidates that we may pursue. We also anticipate that we will continue to experience an increase in accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with operating as a public company. Additionally, if we believe a regulatory approval of vidutolimod or any other product candidate appears likely, we anticipate an increase in payroll and other employee-related expenses as a result of our preparation for commercial operations to market and sell that product candidate.

Interest Income

Interest income consists of interest earned on our cash, cash equivalent and available-for-sale investments balances. We expect that our interest income will fluctuate based on prevailing interest rates, our ability to raise additional funds as well as the amount of expenditures for our clinical development of vidutolimod and ongoing business operations.

Income Taxes

There were no provisions for income taxes for the three and six months ended June 30, 2021 and 2020 because we have historically incurred operating losses and we maintain a full valuation allowance against our net deferred tax assets.

Results of operations

Comparison of the three months ("Q2") and six months ("Q2 YTD") ended June 30, 2021 and 2020

The following table summarizes our results of operations for the three and six months ended June 30, 2021 and 2020:

	Three months ended June 30,		Increase	Six months ended June 30,		Increase
	2021	2020	(Decrease)	2021	2020	(Decrease)
	(unaudited, in thousands)					
Operating expenses:						
Research and development	$ 14,865	$ 6,476	$ 8,389	$ 25,243	$ 12,789	$ 12,454
General and administrative	4,090	1,795	2,295	7,893	3,305	4,588
Total operating expenses	18,955	8,271	10,684	33,136	16,094	17,042
Loss from operations	(18,955)	(8,271)	10,684	(33,136)	(16,094)	17,042
Total other income (expense), net	(15)	(77)	(62)	38	(55)	93
Net loss	$(18,970)	$(8,348)	$ 10,622	$(33,098)	$(16,149)	$ 16,949

Research and Development Expenses

Research and development expenses were $14.9 million in Q2 2021 compared to $6.5 million in the same quarter of 2020. The increase of approximately $8.4 million was primarily related to the $4.0 million milestone payment due to Kuros in Q2 2021, which became payable upon initiating dosing of the first patient in a Phase 2 anti-PD-1 refractory melanoma trial for vidutolimod in May 2021. This Phase 2 trial is intended to potentially support a BLA and marketing approval of vidutolimod and therefore triggered the Phase 3 study milestone as defined under our license agreement with Kuros. Also contributing to the increase was higher clinical costs of $1.5 million associated ongoing trials, higher contract manufacturing of $2.0 million related to producing vidutolimod to meet the needs of the clinical trials, and higher personnel and consulting costs of $0.3 million as well as stock-based compensation expense of $0.6 million associated with increased staffing.

Research and development expenses were $25.2 million in Q2 YTD 2021 compared to $12.8 million for the same period of 2020, an increase of $12.5 million. The increase was due to combined milestones payments of $6.0 million to Kuros which became payable upon the Company initiating dosing of patients in trials which triggered Phase 2 and Phase 3 milestone payments. Also contributing to the increase was increased clinical trials costs of $2.6 million and outsourced contract manufacturing costs of $2.4 million related to greater activity in our ongoing clinical trials, as well as additional personnel and consulting costs of $0.7 million and stock-based compensation costs of $1.0 million associated with increased staffing.

General and Administrative Expenses

General and administrative expenses were $4.1 million in Q2 2021 compared to $1.8 million in the same quarter of 2020. The increase of $2.3 million was primarily comprised of an increase in directors and officers insurance of $0.9 million associated with being a public company in 2021, an increase is stock-based compensation expenses of $0.8 million related to stock options granted after our IPO and an increase in personnel and consulting expense of $0.2 million associated with increased staffing.

General and administrative expenses were $7.9 million in Q2 YTD 2021 compared $3.3 million in the same period of 2020, an increase of $4.6 million. The increase was primarily due to increased directors and officers insurance of $1.7 million, increased stock-based compensation of $1.5 million and increased personnel and consulting expense of $0.6 million.

Other income (expense), net

Other income (expense), net in the three and six month periods of 2021 include interest income, which was more than offset by losses on the sale of available-for-sale securities in Q2 2021 and partially offset by losses on the sale of available-for-sale investments in Q2 YTD 2021.

Other income (expense), net in the three and six month periods of 2020 primarily reflects the change in the fair value change of the convertible loan notes we issued to certain investors in April 2020 (the "Convertible Loan Notes") by $0.1 million, primarily related to the accrued interest earned on the Convertible Loan Notes prior to conversion upon the sale of Series C preferred stock in June 2020, slightly offset by interest income.

Liquidity and capital resources

Overview

We have funded our operations to date primarily with proceeds from the sale of preferred stock, convertible debt and common stock. Since inception and through June 30, 2021, we have received net cash proceeds of $241.7 million from sales of our preferred stock, convertible debt and common stock. In April 2020, we received $10.0 million from the issuance of Convertible Loan Notes and in June 2020, we received $74.6 million in additional net proceeds from the sale of Series C preferred stock. The Convertible Loan Notes were converted into shares of Series C preferred stock in June 2020.

As noted above, in August 2020, we completed an IPO in which we received net proceeds of approximately $67.7 million, inclusive of the partial exercise of the over-allotment exercise and after deducting underwriting discounts and commissions and other offering expenses payable by us. In connection with the IPO, all outstanding shares of our redeemable preferred stock were converted to common stock.

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 several years, if at all. As of June 30, 2021, we had cash, cash equivalents and available-for-sale investments of $95.6 million.

We believe that the net proceeds from the IPO, together with our existing cash, cash equivalents and available-for-sale investments as of June 30, 2021, will enable us to fund our operating expenses and capital expenditure requirements through the end of 2022. 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. Our future viability beyond that point is dependent on our ability to raise additional capital to finance our operations.

Cash Flows

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

	Six months ended June 30,		Increase
	2021	2020	(Decrease)
	(in thousands)		
Net cash used in operating activities	$ (29,696)	$ (16,042)	$ 13,654
Net cash provided by investing activities	49,617	—	49,617
Net cash provided by financing activities	134	92,146	(92,012)
Net increase in cash, cash equivalents and restricted cash	$ 20,055	$ 76,104	$(56,049)

Operating Activities

During Q2 YTD 2021, net cash used in operating activities was $29.7 million, primarily resulting from of our net loss of $33.1 million, which was partially offset by non-cash charges of $3.1 million and cash provided by working capital of $0.3 million.

During Q2 YTD 2020, net cash used in operating activities was $16.0 million, primarily resulting from our net loss of $16.1 million and cash used in working capital of $0.2 million, partially offset by non-cash charges of $0.3 million.

Investing Activities

Net cash provided by investing activities of $49.6 million during Q2 YTD 2021 reflects net liquidations of the Company's available-for-sale investments of $50.0 million to fund current and future operating activities, partially offset by investments in machinery and equipment of $0.4 million.

Financing Activities

Net cash provided by financing activities in Q2 YTD 2021 was $0.1 million and consisted of proceeds from the exercise of stock options.

Net cash provided by financing activities in Q2 YTD 2020 was $92.1 million and consisted of the net proceeds from the issuance of Series B and Series C redeemable convertible preferred stock of $82.5 million and the proceeds from the issuance of the Convertible Loan Notes of $10.0 million. These were partially offset by $0.4 million in expenditures related for issuance costs in anticipation of the Company's IPO.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities and clinical trials for vidutolimod and any other product candidates that we may develop or acquire in the future. In addition, we have incurred, and expect to incur, additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company. The timing and amount of our operating expenditures will depend largely on:

- the initiation, progress, timing, costs and results of current and future preclinical studies and clinical trials for vidutolimod and any other product candidates we may develop or acquire in the future;
- the cost and timing of the manufacture of additional clinical trial materials and the completion of commercial-scale outsourced manufacturing activities;
- the costs to seek regulatory approvals for any product candidates that successfully complete clinical trials;
- the extent to which we experience delays or interruptions to preclinical studies and clinical trials, to our third-party service providers on whom we rely, or to our supply chain due to the COVID-19 pandemic;
- the need to hire additional clinical, quality assurance, quality control and other scientific personnel
- the number and characteristics of product candidates that we develop or may in-license;
- the outcome, timing and cost of meeting and maintaining compliance with regulatory requirements established by the U.S. Food and Drug Administration (the "FDA"), the European Medical Agency (the "EMA") and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending and enforcing our patent claims and other intellectual property rights;
- the terms of any collaboration agreements we may choose to enter into;
- the cost associated with the expansion of our operational, financial and management systems and increased personnel, including personnel to support our operations as a public company; and
- 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, if approved, on our own.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. We do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, ownership interests may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants limiting or restricting our ability to take

specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, debt financing would result in fixed payment obligations. If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, limit, reduce or terminate our research, product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual obligations and other commitments

We enter into contracts in the normal course of business with CROs, CMOs and other third parties for clinical trials, preclinical research studies and testing and manufacturing services. These contracts are cancelable by us upon prior written notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation. The amount and timing of such payments are not known.

We have also entered into license and collaboration agreements with third parties, which are in the normal course of business. We have not included future payments under these agreements since obligations under these agreements are contingent upon future events such as our achievement of specified development, regulatory, and commercial milestones, or royalties on net product sales.

Pursuant to the Kuros License Agreement, we are required to make payments to Kuros for each product that achieves certain development and regulatory milestones. We are obligated to make up to $56.0 million in milestone payments to Kuros related to vidutolimod. We are also required to pay royalties on sales of future products, if any. As of June 30, 2021, we have incurred license fees and milestone payments totaling $8.3 million pursuant to the Kuros License Agreement. These payments are comprised of (i) a license fee of $1.0 million which was recognized in research and development expense in 2015, (ii) $1.0 million milestone payment in connection with the dosing of the first patient in our first Phase 1 clinical trial, which was recognized in research and development expense in 2016, (iii) a $0.3 million license amendment fee in connection with the signing of the second amendment to the Kuros License Agreement, which was recognized in research and development expense in 2018, (iv) a $2.0 million milestone payment in connection with the dosing of the first patient in the Phase 2 first-line melanoma trial for vidutolimod, which we recognized in March 2021 and (v) a $4.0 million milestone payment in connection with the dosing in a Phase 2 trial intended to assess the efficacy and safety of vidutolimod in combination with nivolumab for the treatment of patients with anti-PD-1 refractory melanoma and to potentially support a Biologics License Application (“BLA”) and marketing approval of vidutolimod, which we recognized in May 2021.

We do not currently have any long-term leases. We rent our office space in Cambridge, Massachusetts based on a month-to-month license agreement with the landlord.

Critical Accounting Policies and Significant Judgments and Estimates

Our unaudited condensed consolidated financial statements are prepared in accordance with GAAP. The preparation of our unaudited condensed consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

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 Use of Estimates” in our 2020 Annual Report on Form 10-K. There have been no changes to the critical accounting policies during the six months ended June 30, 2021.

Off-balance sheet arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the Securities and Exchange Commission.

Recent accounting pronouncements

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

Emerging Growth Company and Smaller Reporting Company Status

The Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"), permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to not "opt out" of this provision and, as a result, we will adopt new or revised accounting standards at the time private companies adopt the new or revised accounting standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company. Other exemptions and reduced reporting requirements under the JOBS Act for emerging growth companies include presentation of only two years of audited financial statements in a registration statement for an initial public offering, an exemption from the requirement to provide an auditor's report on internal controls over financial reporting pursuant to the Sarbanes-Oxley Act of 2012, an exemption from any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation, and less extensive disclosure about our executive compensation arrangements. We would cease to be an emerging growth company upon the earliest of: (1) the last day of the fiscal year ending after the fifth anniversary of our initial public offering; (2) the last day of the fiscal year in which we have more than $1.07 billion in annual revenue; (3) the last day of the fiscal year in which we qualify as a "large accelerated filer," with at least $700.0 million of equity securities held by non-affiliates as of the prior June 30th; or (4) the issuance, in any three-year period, by our company of more than $1.0 billion in non-convertible debt securities held by non-affiliates.

We are also a "smaller reporting company" and we may take advantage of certain of the scaled disclosures available to smaller reporting companies until the fiscal year following the determination that (i) the market value of our stock held by non-affiliates is more than $250 million or (ii) our annual revenue was more than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest rate risk

We are exposed to market risk related to changes in interest rates. Our current investment policy is to maintain an investment portfolio consisting mainly of United States money market, government-secured, and high-grade corporate securities, directly or through managed funds, with maturities of twenty-four months or less. Our cash is deposited in and invested through highly rated financial institutions in North America. Our investments are subject to interest rate risk and will fall in value if market interest rates increase. However, due to the conservative nature of our investments, low prevailing market rates and relatively short effective maturities of debt instruments, interest rate risk is mitigated. If market interest rates were to increase immediately and uniformly by 10% from levels at June 30, 2021, we estimate that the fair value of our investment portfolio would decline by an immaterial amount. We do not own derivative financial instruments in our investment portfolio.

Foreign currency exchange risk

Our primary exposure to market risk is foreign exchange rate sensitivity to the British Pound. Foreign currency losses were neglectable in each of the six months ended June 30, 2021 and 2020. These foreign currency transaction losses were recorded as a component of general and administrative expense in our condensed consolidated statements of operations. At June 30, 2021, an immediate 5% change in the British Pound exchange rate would not have a material effect on our results of operations.

As we continue to grow our business, our results of operations and cash flows may increasingly be subject to fluctuations due to changes in foreign currency exchange rates, which could adversely impact our results of operations. To date, we have not entered into any foreign currency hedging contracts to mitigate our exposure to foreign currency exchange risk.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We have carried out an evaluation, under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act), as of June 30, 2021. Based upon that evaluation, our principal executive officer and principal financial officer concluded that, as of the end of the period covered by this report, our disclosure controls and procedures are effective in ensuring that (a) the information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and (b) such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, our management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the six months ended June 30, 2021 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

Systems of disclosure controls and internal controls over financial reporting and their associated policies and procedures, no matter how well conceived and operated, are designed to provide a reasonable, but not an absolute, level of assurance that the objectives of the system of control are achieved. Further, the design of a control system must be balanced against resource constraints, and therefore the benefits of controls must be considered relative to their costs. Given the inherent limitations in all systems of controls, no evaluation of controls can provide absolute assurance all control issues and instances of fraud, if any, within a company have been detected. These inherent limitations include the realities that judgments in decision making can be faulty, and that breakdowns can occur because of a simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of the controls. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions; over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Accordingly, given the inherent limitations in a cost-effective system of internal control, financial statement misstatements due to error or fraud may occur and may not be detected. Our disclosure controls and procedures are designed to provide a reasonable assurance of achieving their objectives. We conduct periodic evaluations of our systems of controls to enhance, where necessary, our control policies and procedures.

PART II. – OTHER INFORMATION

Item 1. Legal Proceedings

From time-to-time, we may become involved in legal proceedings arising in the ordinary course of our business. As of the date of this Quarterly Report on Form 10-Q, we were not a party to any material legal matters or claims. In the future, we may become party to legal matters and claims in the ordinary course of business, the resolution of which we do not anticipate would have a material adverse impact on our financial position, results of operations or cash flows.

Item 1A. Risk Factors

In evaluating the Company and our business, careful consideration should be given to the following risk factors, in addition to the other information set forth in this Quarterly Report on Form 10-Q and in other documents that we file with the SEC. Investing in our common stock involves a high degree of risk. If any of the following risks and uncertainties actually occurs, our business, prospects, financial condition or results of operations could be materially and adversely affected. The risks described below are not intended to be exhaustive and are not the only risks facing the Company. New risk factors can emerge from time to time, and it is not possible to predict the impact that any factor or combination of factors may have on our business, prospects, financial condition or results of operations.

Risks related to our financial position and need for additional capital

We are a clinical-stage biopharmaceutical company with a very limited operating history. We have incurred net losses since our inception and anticipate that we will continue to incur substantial and increasing net losses in the foreseeable future. We may never achieve or sustain profitability.

We are a clinical-stage biopharmaceutical company with a limited operating history, and we are early in our development efforts. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain marketing approval and become commercially viable. We have financed our operations to date primarily through the sale of equity securities. Since our inception, most of our resources have been dedicated to the preclinical and clinical development of our vidutolimod program and our VLP technology. To date, no drugs based on our VLP technology have been approved. The size of our future net losses will depend, in part, on our future expenses and our ability to generate revenue, if any.

We are not profitable, have never generated any revenue and have incurred losses in each period since our inception. For the years ended December 31, 2019 and 2020, we reported net losses of $28.3 million and $36.9 million, respectively. For the six months ended June 30, 2021, we reported a net loss of $33.1 million. At June 30, 2021, we had an accumulated deficit of $173.2 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek marketing approvals for, vidutolimod and future product candidates we may develop.

Even if we succeed in receiving marketing approval for and commercializing vidutolimod or any other product candidate, we will continue to incur substantial research and development and other expenditures to develop and market additional potential indications or products. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. 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 stockholders' equity and working capital.

We have never generated any revenue from product sales, and our ability to generate revenue from product sales and become profitable will depend significantly on our success in achieving a number of goals and on other factors.

We have no products approved for commercial sale, have not generated any revenue from product sales, and do not anticipate generating any revenue from product sales until after we have received marketing approval for the commercial sale of a product candidate, if ever. Our ability to generate revenue and achieve profitability depends significantly on our success in achieving a number of goals, including:

- initiating and completing preclinical and clinical development of vidutolimod and future product candidates, including our current Phase 2 trial for anti-PD-1 refractory melanoma, our current randomized Phase 2/3 trial for first-line melanoma, our current Phase 2 proof of concept study in advanced head and neck squamous cell carcinoma and our currently anticipated Phase 2 proof of concept, multi-indication trial in cutaneous squamous cell carcinoma and Merkel cell carcinoma;
- obtaining regulatory and marketing approvals for vidutolimod and future product candidates for which we complete clinical trials;
- achieving and maintaining compliance with all regulatory requirements applicable to vidutolimod or any other product candidates;
- establishing and maintaining commercially viable supply and manufacturing relationships with third parties for vidutolimod and future product candidates;
- launching and commercializing vidutolimod, if approved, and future product candidates for which we obtain marketing approvals, either directly or with a collaborator or distributor;
- obtaining market acceptance of vidutolimod, if approved, and future product candidates as viable treatment options by patients, the medical community and third-party payors;

- addressing any competing technological and market developments;
- identifying, assessing, acquiring and developing new product candidates;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;
- obtaining, maintaining, protecting, and expanding our portfolio of intellectual property rights, including patents, trade secrets, and know-how; and
- attracting, hiring, and retaining qualified personnel.

Even if vidutolimod or any future product candidates that we develop are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any such product candidate. Our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration (the "FDA") or comparable foreign regulatory authorities to change our manufacturing processes or assays, or to perform clinical, nonclinical, or other types of studies in addition to those that we currently anticipate.

If we are successful in obtaining regulatory approvals to market vidutolimod or any future product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain marketing approval, the accepted price for the product, the ability to get reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, the labels for vidutolimod and future product candidates contain significant safety warnings, regulatory authorities impose burdensome or restrictive distribution requirements, or the reasonably accepted patient population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate revenue from the sale of any approved products, we could be prevented from or significantly delayed in achieving profitability.

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

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the clinical and preclinical development of vidutolimod and future product candidates. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives. If we are able to gain marketing approval of any product candidate, we will require significant additional amounts of cash in order to launch and commercialize such product. In addition, other unanticipated costs may arise.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing vidutolimod and our VLP technology and future product candidates, and conducting preclinical studies and clinical trials, including our current Phase 2 trial for anti-PD-1 refractory melanoma, our current randomized Phase 2/3 trial for first-line melanoma, our current Phase 2 proof of concept study in advanced head and neck squamous cell carcinoma and our currently anticipated Phase 2 proof of concept, multi-indication trial in cutaneous squamous cell carcinoma and Merkel cell carcinoma, including any unforeseen costs we may incur as a result of trial delays or other impacts due to the ongoing global pandemic associated with COVID-19 (the "COVID-19 pandemic"), discussed below;
- the timing of, and the costs involved in, obtaining regulatory and marketing approvals for vidutolimod and future product candidates if clinical trials are successful;
- the success of existing or any future collaborations;
- the cost of commercialization activities for any approved product, including marketing, sales and distribution costs;
- the cost of manufacturing vidutolimod and future product candidates for clinical trials;
- our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements, including the Kuros License Agreement, the BMS CTCSA and the Regeneron SNLA;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the timing, receipt, and amount of sales of, or royalties on, our future products, if any; and
- the emergence, and regulatory approval, of competing cancer therapies and other adverse market developments.

We do not have any committed external source of funds or other support for our development efforts. Until we can generate sufficient product revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing arrangements and other marketing or distribution arrangements. We can provide no assurance that we will be able to finance our future cash needs on favorable terms, if at all.

We expect that our existing cash and cash equivalents and available-for-sale investments, will enable us to fund our operating expenses and capital expenditure requirements through the end of 2022. 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. In addition, because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of vidutolimod or any future product candidates.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies or vidutolimod and future product candidates.

Until such time, if ever, as we can generate substantial drug revenues, we may finance our cash needs through a combination of private and public equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of funds. To the extent that we raise additional capital through the sale of common stock or securities convertible or exchangeable into common stock, our stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that materially adversely affect your rights as a common stockholder. Debt financing, if available, would increase our fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our intellectual property, future revenue streams, research programs or vidutolimod and future product candidates or to grant licenses on terms that may not be favorable to us. Market volatility, the size of our public float, and competitive dynamics could also adversely impact our ability to access capital as and when needed and the terms thereof, if we can raise capital at all. If we are unable to raise adequate additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to develop and market vidutolimod and future product candidates that we would otherwise prefer to develop and market ourselves.

Risks related to our business and industry

We are heavily dependent on the success of vidutolimod, our only product candidate.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures over the next several years will be devoted to our vidutolimod program, which is currently our only product candidate. Accordingly, our business currently depends heavily on the successful development, regulatory approval, and commercialization of vidutolimod. We can provide no assurance that vidutolimod will receive regulatory approval or be successfully commercialized even if we receive regulatory approval. If we were required to discontinue development of vidutolimod or if vidutolimod does not receive regulatory approval or fails to achieve significant market acceptance, we would be delayed by many years in our ability to achieve profitability, if ever.

The research, testing, manufacturing, safety, efficacy, recordkeeping, labeling, approval, licensure, sale, marketing, advertising, promotion and distribution of vidutolimod is, and will remain, subject to comprehensive regulation by the FDA and foreign regulatory authorities. Failure to obtain regulatory approval for vidutolimod in the United States, Europe, Japan, China and other major markets around the world will prevent us from commercializing and marketing vidutolimod in such jurisdictions.

Even if we were to successfully obtain approval from the FDA and foreign regulatory authorities for vidutolimod, any approval might contain significant limitations related to use, including limitations on the stage or type of cancer vidutolimod is approved to treat, as well as restrictions for specified age groups, warnings, precautions or contraindications, or requirement for a risk evaluation and mitigation strategy ("REMS"). Any such limitations or restrictions could similarly impact any supplemental marketing approvals we may obtain for vidutolimod. Furthermore, even if we obtain regulatory approval for vidutolimod, we will still need to develop a commercial infrastructure or develop relationships with collaborators to commercialize, establish a commercially viable pricing structure and obtain coverage and adequate reimbursement from third-party payors, including government healthcare programs. If we, or any future collaborators, are unable to successfully commercialize vidutolimod, we may not be able to generate sufficient revenue to continue our business.

If we fail to develop additional product candidates, our commercial opportunity could be limited.

We expect to focus our resources on the development of vidutolimod in the near term. Part of our strategy, however, is to pursue clinical development of additional product candidates using our VLP technology. Developing, obtaining marketing approval for, and commercializing any future product candidates will require substantial additional funding and will be subject to the risks of failure inherent in drug product development. We cannot assure you that we will be able to successfully advance any future product candidates through the development process.

Even if we obtain approval from the FDA or comparable foreign regulatory authorities to market any future product candidates for any indication, we cannot assure you that any such product candidates will be successfully commercialized, widely accepted in the marketplace, or more effective than other commercially available alternatives. If we are unable to successfully develop and commercialize additional product candidates, our commercial opportunity may be limited and our business, financial condition, results of operations, stock price and prospects may be materially harmed.

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.

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

We will not be able to commercialize vidutolimod and future product candidates if our preclinical studies do not produce successful results and our clinical trials do not demonstrate the safety and efficacy of vidutolimod and future product candidates.

We are currently conducting clinical studies with vidutolimod in patients with melanoma, both in combination with certain checkpoint inhibitor immunotherapies and as a monotherapy, and in clinical studies evaluating vidutolimod in HNSCC in combination with avelumab and other immunomodulators. Vidutolimod and future product candidates that we may develop will require extensive preclinical and clinical trials before we can submit a marketing application to the applicable regulatory authorities. These product candidates are susceptible to the risks of failure inherent at any stage of product development, including the occurrence of unexpected or unacceptable adverse events or the failure to demonstrate efficacy in clinical trials. Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain.

The results of preclinical studies, preliminary study results, and early clinical trials of vidutolimod and future product candidates may not be predictive of the results of later-stage clinical trials or of the results of clinical trials conducted in other types of cancer or non-cancer indications. Even if early-stage clinical trials are successful, we may need to conduct additional clinical trials of our product candidates in additional patient populations or under different treatment conditions before we are able to seek regulatory approvals from the FDA or other regulatory authorities. Vidutolimod and future product candidates may not perform as we expect, and we may be unable to demonstrate to the FDA's satisfaction that vidutolimod or any future product candidates are safe, pure, and potent, or effective for their desired indications. These setbacks may result in enhanced scrutiny by regulators or institutional review boards ("IRBs") of clinical trials of product candidates, including vidutolimod, which could result in regulators or IRBs prohibiting the commencement of clinical trials, requiring additional nonclinical studies as a precondition to commencing clinical trials or imposing restrictions on the design or scope of clinical trials, as well as increasing the costs of trials or limiting the significance of the results of trials. Such setbacks could also adversely impact the desire of investigators to enroll patients in, and the desire of patients to enroll in, clinical trials of our product candidates.

Additionally, most of our trials are open-label studies, such as our current Phase 1b and our Phase 2 and Phase 2/3 trials, where both the patient and investigator know whether the patient is receiving the investigational product candidate or an existing approved drug, introducing bias in early interpretation of the results. Most typically, open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a "patient bias" where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results with any of our product candidates for which we include an open-label clinical trial when studied in a controlled environment with a placebo or active control.

We may also experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize vidutolimod and future product candidates, including that:

- we may fail to reach an agreement with regulators or IRBs regarding the scope, design, or implementation of our clinical trials;
- the FDA, comparable foreign regulators or IRBs may not authorize us or our investigators to commence a clinical trial, to conduct a clinical trial at a prospective trial site or to amend trial protocols, or such regulators or IRBs may require that we modify or amend our clinical trial protocols in ways that make further clinical trials impractical or not financially prudent;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites or contract research organizations ("CROs");
- we may be unable to initiate or complete preclinical studies or clinical trials on time or at all due to the evolving impacts of the COVID-19 pandemic, and the spread of COVID-19 may affect the operations of research sites, CROs, IRBs, or key governmental agencies, such as the FDA, which may delay the development of vidutolimod or any future product candidates;
- the supply or quality of raw materials or manufactured product candidates (whether provided by us or third parties) or other materials necessary to conduct clinical trials of our product candidates may be insufficient, inadequate or not available at an acceptable cost, or in a timely manner, or we may experience interruptions in supply;
- the number of patients required for clinical trials of vidutolimod and future product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or be lost to follow-up at a higher rate than we anticipate;
- patients that enroll in our studies may misrepresent their eligibility or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the patients from the study or clinical trial, increase the needed enrollment size for the clinical trial or extend its duration;
- clinical trial participants may elect to participate in alternative clinical trials sponsored by our competitors with product candidates that treat the same indications as vidutolimod and future product candidates;
- our third-party contractors may fail to comply with regulatory requirements or the clinical trial protocol, or meet their contractual obligations to us in a timely manner, or at all, and we may be required to engage in additional clinical trial site monitoring to review our contractors' performance;
- we, regulators, or IRBs may require that we or our investigators suspend or terminate clinical trials for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks, undesirable side effects, or other unexpected characteristics of the product candidate, or if such undesirable effects are found to be caused by a chemically or mechanistically similar therapeutic or therapeutic candidate;
- clinical trials of vidutolimod and future product candidates may produce negative or inconclusive results, or our studies may fail to reach the necessary level of statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials, analyses, reports, data, or preclinical trials or abandon product development programs;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we expect or statutes, regulations clinical trial or site policies could be amended or new ones could be adopted;

- the cost of clinical trials of vidutolimod and future product candidates may be greater than we anticipate or we may have insufficient funds or resources to pursue or complete certain aspects of our clinical trial program or to do so within the timeframes we planned;
- we may have insufficient funds to pay the substantial user fees required by the FDA upon the submission of a BLA or equivalent authorizations from comparable foreign regulatory authorities;
- we may have delays in adding new investigators or clinical trial sites, or we may experience a withdrawal of clinical trial sites;
- there may be regulatory questions or disagreements regarding interpretations of data and results, or new information may emerge regarding vidutolimod and future product candidates;
- the FDA or comparable foreign regulatory authorities may not accept data from studies with clinical trial sites in foreign countries;
- the FDA or comparable foreign regulatory authorities may disagree with our proposed indications, fail to approve or subsequently find fault with the manufacturing processes or our manufacturing facilities for clinical and future commercial supplies, and may take longer than we anticipate to review any regulatory submissions we may make for vidutolimod or any future product candidates;
- the data collected from clinical trials of vidutolimod and future product candidates may not be sufficient for or to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a BLA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- we may not be able to demonstrate that a product candidate provides an advantage over current standards of care or current or future competitive therapies in development; and
- regarding trials managed by our existing or any future collaborators, our collaborators may face any of the above issues, and may conduct clinical trials in ways they view as advantageous to them but potentially suboptimal for us.

In addition, ongoing disruptions caused by the COVID-19 pandemic or future pandemics may increase the likelihood that we encounter such difficulties or delays in initiating, enrolling, conducting or completing our planned and ongoing clinical trials. For example, certain of our clinical trials that commenced in 2020 were adversely affected by the COVID-19 pandemic, resulting in site initiation and patient enrollment delays. 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. A suspension or termination of a trial may be imposed 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 vidutolimod or any future 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 protocols as a result of differences in healthcare services or cultural customs, and managing both additional administrative burdens associated with foreign regulatory schemes, and the political and economic risks relevant to such foreign countries.

Moreover, principal investigators for our clinical trials 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 authority 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 authority 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 authority, 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 testing or approvals, our development costs will also increase, and we may not have sufficient funding to complete the testing and approval process for vidutolimod and future product candidates. We may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of vidutolimod and future product candidates. See "Risks related to our financial position and need for additional capital." We do not know whether any preclinical tests or clinical trials beyond what we currently have anticipated or planned will be required, will begin as anticipated or planned, will need to be restructured, or will be completed on schedule, or at all. Significant delays relating to any preclinical studies or clinical trials also could shorten any periods during which we may have the exclusive right to commercialize vidutolimod and future product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize vidutolimod and future product candidates and may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays in clinical trials may ultimately lead to the denial of marketing approval of vidutolimod and future product candidates. If any of these occur, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Vidutolimod is based on a novel approach to the treatment of cancer, which makes it difficult to predict the time and cost of product candidate development.

While immuno-oncology therapeutics are an emerging class of cancer treatment, they remain a novel approach. We have concentrated all of our research and development efforts on vidutolimod, and our future success depends on the successful development of this therapeutic approach. Should we encounter development problems, the FDA and foreign regulatory authorities may refuse to approve vidutolimod, or may require additional information, tests, or trials, which could significantly delay product development and significantly increase our development costs. Moreover, even if we are able to provide the requested information or clinical data to the FDA or foreign regulatory authority, there would be no guarantee that the FDA or foreign regulatory authority would accept them or approve vidutolimod. We or our CMOs may also experience delays in developing a sustainable, reproducible and scalable manufacturing process, or developing or qualifying and validating product release assays, other testing and manufacturing methods, and our or their equipment and facilities in a timely manner, which may prevent us from completing our clinical trials or commercializing vidutolimod or future product candidates on a timely or profitable basis, if at all.

In addition, the clinical trial requirements of the FDA and comparable foreign regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity, novelty and intended use and market of the potential products. The FDA and comparable foreign regulatory authorities have limited experience with the approval of oncolytic immunotherapies, which could lengthen the regulatory review process. Any product candidates that are approved may be subject to extensive post-approval regulatory requirements, including requirements pertaining to manufacturing, distribution, and promotion. We may need to devote significant time and resources to compliance with these requirements which could increase our development costs and delay or prevent commercialization of vidutolimod or any future product candidates.

Further, negative clinical trial results for other immuno-oncology therapeutics may adversely impact product development and medical interest in vidutolimod, which may prevent us from completing our clinical trials, obtaining regulatory approval or commercializing vidutolimod on a timely or profitable basis, if at all.

Difficulty in enrolling patients could delay or prevent clinical trials of vidutolimod and future product candidates. We may find it difficult to enroll patients in our clinical trials or any subsequent trials that we may conduct.

Identifying and qualifying patients to participate in clinical studies of vidutolimod and future product candidates is critical to our success. The timing of completion of our clinical studies depends in part on the speed at which we can recruit patients to participate in testing vidutolimod and future product candidates, and we may experience delays in our clinical trials if we encounter difficulties in enrollment or due to other unforeseen factors such as the impact of the COVID-19 pandemic. For example, certain of our clinical trials that commenced in 2020 were adversely affected by the COVID-19 pandemic resulting in patient enrollment delays in the first half of 2021. We may not be able to initiate or continue clinical trials for vidutolimod and future product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. In particular, because we are initially focused on patients with melanoma and HNSCC, our ability to enroll eligible patients may be limited or may result in slower enrollment than we anticipate. For example, with respect to vidutolimod, we cannot be certain of the status of other competitive products in development, whether trial designs and sites for other similar products are more accessible for eligible patients or that we will be able to find enough qualified investigators and sites willing to participate in our trials. In addition, some of our competitors or potential competitors have ongoing clinical trials for product candidates that treat the same indications as vidutolimod, and patients who would otherwise be eligible for our clinical trials may instead enroll in clinical trials of our competitors' product candidates.

The eligibility criteria of our planned clinical trials will further limit the pool of available study participants, as we will require that patients have specific characteristics that we can measure to assure their cancer is at the appropriate level to include them in a study. Additionally, the process of finding patients for our planned clinical trials may prove costly. We also may not be able to identify, recruit and enroll a sufficient number of patients to complete our clinical studies because of the perceived risks or lack of benefits of the product candidate under study, the availability and efficacy of competing therapies and clinical trials, the proximity and availability of clinical study sites for prospective patients, the patient referral practices of physicians or as a result of disruptions caused by the COVID-19 pandemic. If patients are unwilling to participate in our studies for any reason, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of potential products may be delayed. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which may further reduce the number of patients who are available for our clinical trials at such clinical trial sites.

The enrollment of patients further depends on many factors, including:

- the design of the clinical trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to administer vidutolimod according to the protocol dose, schedule and route of administration;
- our ability to obtain and maintain patient consents;
- reporting of the preliminary results of any of our clinical trials;
- the ability to monitor patients adequately during and after treatment; and
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before clinical trial completion.

If we experience delays in the completion of, or termination of, any clinical trial of vidutolimod or any future product candidates, the commercial prospects of vidutolimod or such future product candidates will be harmed, and our ability to generate product revenue from such product candidates could be delayed or prevented.

Interim, "top-line," and preliminary data from our clinical trials that we may 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, 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, any 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 data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line 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 ongoing clinical trials 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 any preliminary or interim data we disclose and final data could significantly harm our business prospects.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

Vidutolimod is being, and future product candidates may be, evaluated in combination with third-party drugs, and we will have limited or no control over the supply, regulatory status, or regulatory approval of such drugs.

Vidutolimod is being, and future product candidates may be, evaluated in combination with checkpoint inhibitors ("CPIs") or other compounds. In September 2018, we entered into a clinical collaboration with Merck and Pfizer to evaluate vidutolimod in combination with avelumab, in December 2020, we entered into a clinical collaboration with BMS to evaluate vidutolimod in combination with nivolumab and in May 2021, we entered into a supply agreement with Regeneron to evaluate vidutolimod concurrently or in combination with cemiplimab. Our ability to develop and ultimately commercialize vidutolimod and future product candidates used in combination with avelumab, nivolumab, cemiplimab, pembrolizumab, atezolizumab, ipilimumab or any other CPIs or other compounds will depend on our ability to access such drugs on commercially reasonable terms for the clinical trials and their availability for use with the commercialized product, if approved. We cannot be certain that current or potential future commercial relationships will provide us with a steady supply of such drugs on commercially reasonable terms or at all.

Any failure to maintain or enter into new successful commercial relationships, or inability to source or purchase CPIs or other potential combination agents in the market, may delay our development timelines, increase our costs and jeopardize our ability to develop vidutolimod and future product candidates as potential combination therapies, which may materially harm our business, financial condition, results of operations, stock price and prospects.

Moreover, the development of product candidates for use in combination with another product or product candidate may present challenges that are not encountered when developing single-agent product candidates. For example, the FDA may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. During an end-of-Phase 1 meeting held in March 2020 to discuss the planned registration path for vidutolimod in melanoma, the FDA indicated that one single-arm Phase 2 trial may not be sufficient to support accelerated approval of a BLA for vidutolimod for the treatment of anti-PD-1 failure patients with metastatic or unresectable melanoma in combination with pembrolizumab. The FDA also recommended that we conduct a randomized trial in the proposed patient population to evaluate the contribution of each component to the potential treatment effect of the combination. Additionally, following product approval, the FDA may require that products used in conjunction with each other be cross labeled for combined use. To the extent that we do not have rights to the other product, this may require us to work with a third party under terms unfavorable to us to satisfy such a requirement. Moreover, developments related to the other product may impact our clinical trials for the combination as well as our commercial prospects should we receive marketing approval. Such developments may include changes to the other product's safety or efficacy profile, changes to the availability of the approved product, and changes to the standard of care.

In the event that Merck, Pfizer, BMS, Regeneron or any future collaborator or supplier cannot continue to supply their products on commercially reasonable terms, we would need to identify alternatives for accessing such CPIs. Additionally, should the supply of products from Merck and Pfizer, or any future collaborator or supplier be interrupted, delayed or otherwise be unavailable to us or our collaborators, our clinical collaborations may be delayed. In the event we are unable to source an alternative supply, or are unable to do so on commercially reasonable terms, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

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

As product candidates are developed through preclinical studies to later-stage clinical trials towards 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 processes and results. Any of these changes could cause vidutolimod or any future product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, or notification to, or approval by, the FDA or a comparable foreign regulatory authority. This could delay completion of clinical trials, require the conduct of bridging clinical trials or studies, require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of vidutolimod and future product candidates and jeopardize our ability to commence product sales and generate revenue.

If we are unable to successfully commercialize vidutolimod or any product candidate for which we receive regulatory approval, or experience significant delays in doing so, our business will be materially harmed.

If we are successful in obtaining marketing approval from applicable regulatory authorities for vidutolimod or any future product candidates, our ability to generate revenues from vidutolimod or any future product candidates will depend on our success in:

- launching commercial sales of vidutolimod and future product candidates, whether alone or in collaboration with others;

- receiving an approved label with claims that are necessary or desirable for successful marketing, and that does not contain safety or other limitations that would impede our ability to market vidutolimod or any future product candidates;
- creating market demand for our product candidates through marketing, sales and promotion activities;
- hiring, training, and deploying a sales force or contracting with third parties to commercialize vidutolimod or any future product candidates in the United States;
- manufacturing, either on our own or through third parties, product candidates in sufficient quantities and at acceptable quality and cost to meet commercial demand at launch and thereafter;
- establishing and maintaining agreements with wholesalers, distributors, and group purchasing organizations on commercially reasonable terms;
- creating partnerships with, or offering licenses to, third parties to promote and sell product candidates in foreign markets where we receive marketing approval;
- maintaining patent and trade secret protection and regulatory exclusivity for vidutolimod or any future product candidates;
- achieving market acceptance of vidutolimod or any future product candidates by patients, the medical community, and third-party payors;
- achieving appropriate reimbursement for vidutolimod or any future product candidates;
- effectively competing with other therapies; and
- maintaining an acceptable tolerability profile of vidutolimod or any future product candidates following launch.

To the extent we are not able to do any of the foregoing, our business, financial condition, results of operations, stock price and prospects will be materially harmed.

We face significant competition from other biopharmaceutical and biotechnology companies, academic institutions, government agencies, and other research organizations, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us. If their product candidates are shown to be safer or more effective than ours, our commercial opportunity may be reduced or eliminated.

The development and commercialization of cancer immunotherapy products is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary rights. We face competition with respect to vidutolimod, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major biopharmaceutical companies, specialty biopharmaceutical companies, and biotechnology companies worldwide. There are a number of large biopharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of solid tumors, including oncolytic immunotherapy and cancer vaccine approaches. Additionally, certain companies whom we view as our most direct potential competitors are currently developing in cancer immunotherapy that may have utility for similar indications that we are targeting, as well as competing therapies utilizing LAG-3 and other approaches. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

While vidutolimod is intended to be used in combination with other drugs with different mechanisms of action, if and when marketed it will still compete with a number of drugs that are currently marketed or in development that also target cancer. To compete effectively with these drugs, vidutolimod or any future product candidates will need to demonstrate advantages in clinical efficacy and safety compared to these competitors when used alone or in combination with other drugs.

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 side effects, are easier to administer or are less expensive alone or in combination with other therapies than any products that we may develop alone or in combination with other therapies. Our competitors also may obtain the FDA's or comparable foreign regulatory authorities' approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors coverage decisions.

Many of the companies with which we are competing or may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals, and marketing approved products than we do. Mergers and acquisitions in the biopharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in developing or acquiring technologies complementary to, or necessary for, our programs. If we are unable to successfully compete with these companies our business, financial condition, results of operations, stock price and prospects may be materially harmed.

If we are unable to establish effective marketing, sales and distribution capabilities or enter into agreements with third parties to market and sell vidutolimod or any future product candidates, if they are approved, the revenues that we generate may be limited and we may never become profitable.

We currently do not have a commercial infrastructure for the marketing, sale, and distribution of our cancer immunotherapies. If vidutolimod or any future product candidates receive marketing approval, we intend to commercialize such product candidates on our own in the United States and potentially with pharmaceutical or biotechnology partners in other geographies. In order to commercialize our products, we must build our marketing, sales, and distribution capabilities or make arrangements with third parties to perform these services. We may not be successful in doing so. Should we decide to move forward in developing our own marketing capabilities, we may incur expenses prior to product launch or even approval in order to recruit a sales force and develop a marketing and sales infrastructure. If a commercial launch is delayed as a result of the FDA's or comparable foreign regulatory authority's requirements or for other reasons, we would incur these expenses prior to being able to realize any revenue from sales of vidutolimod and future product candidates. Even if we are able to effectively hire a sales force and develop a marketing and sales infrastructure, our sales force and marketing teams may not be successful in commercializing vidutolimod or any future product candidates. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

We may also or alternatively decide to collaborate with third-party marketing and sales organizations to commercialize any approved product candidates in the United States, in which event, our ability to generate product revenues may be limited. To the extent we rely on third parties to commercialize any products for which we obtain regulatory approval, we may receive less revenues than if we commercialized these products ourselves, which could materially harm our prospects. In addition, we would have less control over the sales efforts of any other third parties involved in our commercialization efforts, and could be held liable if they failed to comply with applicable legal or regulatory requirements.

We have no prior experience in the marketing, sale, and distribution of biopharmaceutical products, and there are significant risks involved in building and managing a commercial infrastructure. The establishment and development of commercial capabilities, including compliance plans, to market any products we may develop will be expensive and time consuming and could delay any product launch, and we may not be able to successfully develop this capability. We will have to compete with other biopharmaceutical and biotechnology companies, including oncology-focused companies, to recruit, hire, train, manage, and retain marketing and sales personnel, which is expensive and time consuming and could delay any product launch. Developing our sales capabilities may also divert resources and management attention away from product development. In the event we are unable to develop a marketing and sales infrastructure, we may not be able to commercialize vidutolimod or any future product candidates in the United States or elsewhere, which could limit our ability to generate product revenues and materially harm our business, financial condition, results of operations, stock price and prospects. Factors that may inhibit our efforts to commercialize vidutolimod or any future product candidates include:

- the inability to recruit, train, manage, and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe vidutolimod or any future product candidates;
- our inability to effectively oversee a geographically dispersed sales and marketing team;
- the costs associated with training sales and marketing personnel on legal and regulatory compliance matters and monitoring their actions;

- an inability to secure adequate coverage and reimbursement by government and private health plans;
- the clinical indications for which the products are approved and the claims that we may make for the products;
- limitations or warnings, including distribution or use restrictions, contained in the product's approved labeling;
- any distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities or to which we agree as part of a mandatory REMS or voluntary risk management plan;
- liability for sales or marketing personnel who fail to comply with the applicable legal and regulatory requirements;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization or engaging a contract sales organization.

If vidutolimod or any future product candidates do not achieve broad market acceptance, the revenues that we generate from their sales may be limited, and we may never become profitable.

We have never commercialized a product candidate for any indication. Even if vidutolimod and future product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors, and others in the medical community. If any product candidates for which we obtain regulatory approval do not gain an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. Market acceptance of vidutolimod and future product candidates by the medical community, patients, and third-party payors will depend on a number of factors, some of which are beyond our control. For example, physicians are often reluctant to switch their patients and patients may be reluctant to switch from existing therapies even when new and potentially more effective or safer treatments enter the market.

Efforts to educate the medical community and third-party payors on the benefits of vidutolimod and our novel approach to cancer treatment, and future product candidates, may require significant resources and may not be successful. If vidutolimod or any future product candidates are approved but do not achieve an adequate level of market acceptance, we could be prevented from or significantly delayed in achieving profitability. The degree of market acceptance of vidutolimod and future product candidates will depend on a number of factors, including:

- the efficacy of our vidutolimod and our VLP modality, and future product candidates alone or in combination with checkpoint inhibitor immunotherapies or other therapies;
- the commercial success of the checkpoint blockade drugs with which vidutolimod or future products are or may be co-administered;
- the prevalence and severity of adverse events associated with vidutolimod and future product candidates or those products with which they are co-administered;
- the clinical indications for which the products are approved and the approved claims that we may make for the products;
- limitations or warnings contained in the product's FDA-approved labeling or those of comparable foreign regulatory authorities, including potential limitations or warnings for vidutolimod and future product candidates that may be more restrictive than other competitive products;
- changes in the standard of care for the targeted indications for vidutolimod and future product candidates, which could reduce the marketing impact of any claims that we could make following FDA approval or approval by comparable foreign regulatory authorities, if obtained;
- the relative convenience and ease of administration of vidutolimod and future product candidates and any products with which they are co-administered;

- the cost of treatment compared with the economic and clinical benefit of alternative treatments or therapies;
- the availability of adequate coverage or reimbursement by third parties, such as insurance companies and other healthcare payors, and by government healthcare programs, including Medicare and Medicaid;
- the price concessions required by third-party payors to obtain coverage;
- the extent and strength of our marketing and distribution of vidutolimod and future product candidates;
- the safety, efficacy, and other potential advantages over, and availability of, alternative treatments already used or that may later be approved;
- distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities with respect to vidutolimod and future product candidates or to which we agree as part of a REMS or voluntary risk management plan;
- the timing of market introduction of vidutolimod and future product candidates, as well as competitive products;
- our ability to offer vidutolimod and future product candidates for sale at competitive prices;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the extent and strength of our third-party manufacturer and supplier support;
- the actions of companies that market any products with which vidutolimod and future product candidates are co-administered;
- the approval of other new products;
- adverse publicity about vidutolimod and future product candidates or any products with which they are co-administered, or favorable publicity about competitive products; and
- potential product liability claims.

The size of the potential markets for vidutolimod or any future product candidates is difficult to estimate and, if any of our assumptions are inaccurate, the actual markets for vidutolimod or any future product candidates may be smaller than our estimates.

The potential market opportunities for vidutolimod or any future product candidates are difficult to estimate and will depend in large part on the drugs with which vidutolimod or any future product candidates are co-administered and the success of competing therapies and therapeutic approaches. Our estimates of the potential market opportunities in melanoma, HNSCC and other indications are predicated on many assumptions, which may include industry knowledge and publications, third-party research reports, and other surveys. Although we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain, and their reasonableness has not been assessed by an independent source. If any of the assumptions proves to be inaccurate, the actual markets and patient populations eligible for vidutolimod and future product candidates could be smaller than our estimates of the potential market opportunities.

Negative developments in the field of immuno-oncology could damage public perception of vidutolimod or any future product candidates and negatively affect our business.

The commercial success of vidutolimod or any future product candidates will depend in part on public acceptance of the use of cancer immunotherapies. Adverse events in clinical trials of vidutolimod or any future product candidates or adverse outcomes, including actual or perceived lack of efficacy, or adverse events in clinical trials of others developing similar products and the resulting publicity, as well as any other negative developments in the field of immuno-oncology that may occur in the future, including in connection with competitor therapies, could result in a decrease in demand for vidutolimod or any future product candidates that we may develop. These events could also result in the suspension, discontinuation, or clinical hold of or modification to our clinical trials. If public perception is influenced by claims that the use of cancer immunotherapies is unsafe, whether related to our therapies

or those of our competitors, vidutolimod and future product candidates may not be accepted by the general public or the medical community and potential clinical trial subjects may be discouraged from enrolling in our clinical trials. As a result, we may not be able to continue or may be delayed in conducting our development programs. Future negative developments in the field of immuno-oncology or the biopharmaceutical industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of vidutolimod or any future product candidates. Any increased scrutiny could delay or increase the costs of obtaining marketing approval for vidutolimod or any future product candidates.

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

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

- decreased demand for any of vidutolimod and future product candidates that we may develop;
- injury to our reputation and significant negative media attention;
- regulatory investigations that could require costly recalls or product modifications;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- the diversion of management's attention away from managing our business; and
- the inability to commercialize vidutolimod and future product candidates that we may develop.

Although we maintain product liability insurance coverage, it may not be adequate to cover all liabilities that we may incur. We anticipate that we will need to increase our insurance coverage when we begin clinical trials and if we successfully commercialize any product candidate. Insurance coverage is increasingly expensive. We may not be able to maintain product liability insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

Even if we are able to commercialize vidutolimod or any future product candidates, such drugs may become subject to unfavorable pricing regulations or third-party coverage and reimbursement policies, which would harm our business.

The regulations that govern regulatory approvals, pricing and reimbursement for new drugs vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we might obtain marketing approval for a product candidate in a particular country, but then be subject to price regulations that delay our commercial launch of the product candidate, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product candidate in that country. Adverse pricing limitations may hinder our ability to recoup our investment in vidutolimod or any future product candidates, even if vidutolimod and future product candidates obtain marketing approval.

Our ability to commercialize vidutolimod and future product candidates successfully also will depend in part on the extent to which coverage and reimbursement for vidutolimod and future product candidates and related treatments will be available from third-party payors. In the United States and markets in other countries, patients generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Our ability to successfully commercialize our product candidates will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third-party payors, such as private health insurers and health maintenance organizations, decide

which medications they will pay for and establish reimbursement levels. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Factors payors consider in determining reimbursement are based on whether the product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular drugs. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for drugs. For products administered under the supervision of a physician, such as vidutolimod, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. We cannot be sure that coverage will be available for any product candidate that we commercialize and, if coverage is available, the level of reimbursement. Reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA or similar regulatory authorities outside the United States. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacturing, sale and distribution. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Our inability to promptly obtain coverage and profitable payment rates from both government-funded and private payors for any approved drugs that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize drugs and our overall financial condition.

Risks related to COVID-19 or other public health crises

A pandemic, epidemic, or outbreak of an infectious disease, such as the COVID-19 pandemic, may materially and adversely affect our business, including our preclinical studies, clinical trials, third parties on whom we rely, our supply chain, our ability to raise capital and our financial results.

We are subject to risks related to public health crises such as the COVID-19 pandemic. The pandemic and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred, supply chains have been disrupted, facilities and production have been suspended, and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The extent to which the COVID-19 pandemic, or ongoing measures in response to the pandemic, may further impact our preclinical studies or clinical trial operations, as well as our supply chain, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the pandemic, the severity and spread of new strains or variants of the virus, the pace and success of vaccination efforts or the effectiveness of other actions to contain and treat COVID-19 or its variants. The COVID-19 pandemic may also affect or continue to affect employees of third-party contract research organizations (“CROs”) located in affected geographies that we rely upon to carry out our clinical trials. For example, certain of our clinical trials that commenced in 2020 were adversely affected by the COVID-19 pandemic as a result of delays in enrolling patients. As COVID-19 or its variants continue to spread, despite current vaccination efforts, around the globe, we may experience additional disruptions that could severely impact our business and clinical trials, including:

- 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;
- 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 or absenteeism due to the COVID-19 pandemic that reduces site resources;
- 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;
- risk that participants enrolled in our clinical trials will contract COVID-19 or variants thereof while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events or patient withdrawals from our trials;
- limitations in employee resources that would otherwise be focused on conducting our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people;
- delays in receiving authorizations from local regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in global shipping that may affect the transport of clinical trial materials, such as investigational drug product used in our clinical trials;
- changes in local regulations as part of a response to the COVID-19 pandemic, which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- interruptions or delays in preclinical studies due to restricted or limited operations at research and development laboratory facilities;
- delays in necessary interactions with local regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government employees; and
- refusal of the FDA to accept data from clinical trials in affected geographies outside the United States.

Any future negative impact the evolving COVID-19 pandemic has on patient enrollment or treatment or the development of vidutolimod and future product candidates could cause additional, and potentially costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize vidutolimod and future product candidates, if approved, increase our operating expenses, and have a material adverse effect on our financial results. Additionally, three vaccines for COVID-19 were granted Emergency Use Authorization by the FDA in late 2020 and early 2021, and more may be authorized in the future. The resultant demand for vaccines and potential for manufacturing facilities and materials to be commandeered under the Defense Production Act of 1950, or equivalent foreign legislation, may make it more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials, which could lead to delays in these trials. The COVID-19 pandemic has also caused significant disruptions to the U.S. and global economies. This increased volatility and economic dislocation may make it more difficult for us to raise capital on favorable terms, or at all.

Although we have experienced impacts of the COVID-19 pandemic on our business and operations, we cannot currently predict the scope and severity of any additional impacts. If we or any of the third parties with whom we engage were to experience additional shutdowns or other business disruptions, our ability to conduct our business in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business and our results of operations and financial condition. To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also heighten many of the other risks described in this “Risk Factors” section, such as those relating to the timing and completion of our clinical trials and our ability to obtain future financing.

Risks related to government regulation

Even if our development efforts are successful, we may not obtain regulatory approval of vidutolimod or any future product candidates in the United States or other jurisdictions, which would prevent us from commercializing vidutolimod and future product candidates. Even if we obtain regulatory approval for vidutolimod and future product candidates, any such approval may be subject to limitations, including with respect to the approved indications or patient populations, which could impair our ability to successfully commercialize vidutolimod or any future product candidates.

We are not permitted to market or promote or sell vidutolimod or any future product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each therapeutic indication to establish the product candidate's safety and efficacy for that indication. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities and clinical trial sites by, the regulatory authorities. If we do not receive approval from the FDA and comparable foreign regulatory authorities for any of vidutolimod and future product candidates, we will not be able to commercialize such product candidates in the United States or in other jurisdictions. If significant delays in obtaining approval for and commercializing vidutolimod and future product candidates occur in any jurisdictions, our business, financial condition, results of operations, stock price and prospects will be materially harmed. Even if vidutolimod and future product candidates are approved, they may:

- be subject to limitations on the indicated uses or patient populations for which they may be marketed, distribution restrictions, or other conditions of approval;
- contain significant safety warnings, including boxed warnings, contraindications, and precautions;
- not be approved with label statements necessary or desirable for successful commercialization; or
- contain requirements for costly post-market testing and surveillance, or other requirements, including the submission of a REMS to monitor the safety or efficacy of the products.

We have not previously submitted a BLA to the FDA, or a similar marketing application to comparable foreign regulatory authorities, for vidutolimod or any product candidate, and we can provide no assurance that we will ultimately be successful in obtaining regulatory approval for claims that are necessary or desirable for successful marketing, if at all.

The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we are not able to obtain, or experience delays in obtaining, required regulatory approvals, we will not be able to commercialize vidutolimod and future product candidates as expected, and our ability to generate revenue may be materially impaired.

The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. 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. These regulatory requirements may require us to amend our clinical trial protocols, conduct additional preclinical studies or clinical trials that may require regulatory or IRB approval, or otherwise cause delays in obtaining approval or rejection of an application. Any delay in obtaining or failure to obtain required approvals could materially adversely affect our ability to generate revenue from the particular product candidate, which may materially harm our business, financial condition, results of operations, stock price and prospects.

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 studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. The number and types of preclinical studies and clinical trials that will be required for regulatory approval also varies depending on the product candidate, the disease or condition that the product candidate is designed to address, and the regulations applicable to any particular product candidate. 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, and there may be varying interpretations of data obtained from preclinical studies or clinical trials, any of which may cause delays or limitations in the approval or a decision not to approve an application. It is possible that vidutolimod and future product candidates will never obtain the appropriate regulatory approvals necessary for us to commence product sales.

If we experience delays in obtaining approval, if we fail to obtain approval of vidutolimod or any future product candidate or if the label for a product candidate does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate, the commercial prospects for such product candidate may be harmed and our ability to generate revenues from that product candidate may be materially impaired.

Vidutolimod or future product candidates may cause undesirable side effects or have other properties that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any. Serious adverse events or undesirable side effects caused by vidutolimod and future product candidates could cause us, IRBs, and other reviewing entities 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. For example, if concerns are raised regarding the safety of a new therapeutic as a result of undesirable side effects identified during clinical or preclinical testing, the FDA or comparable foreign regulatory authority may order us to cease further development, decline to approve the product candidate or issue a letter requesting additional data or information prior to making a final decision regarding whether or not to approve the product candidate. The FDA or comparable foreign regulatory authorities, or IRBs and other reviewing entities, may also require, or we may voluntarily develop, strategies for managing adverse events during clinical development, which could include restrictions on our enrollment criteria, the use of stopping criteria, adjustments to a study's design, or the monitoring of safety data by a data monitoring committee, among other strategies. For example, patients enrolled in our ongoing clinical trials of vidutolimod have experienced mild to moderate adverse events, consisting mainly of flu-like symptoms and injection site reactions. In response to these adverse events, we have implemented prophylactic measures, including intravenous fluids, antiemetics, and antipryetics. The FDA's or a comparable foreign regulatory authority's requests for additional data or information could also result in substantial delays in the approval of vidutolimod and future product candidates.

Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of a product candidate may only be uncovered when a significantly larger number of patients are exposed to the product candidate or when patients are exposed for a longer period of time.

Undesirable side effects caused by vidutolimod or any future product candidates could also result in denial of regulatory approval by the FDA or comparable foreign regulatory authorities for any or all targeted indications or the inclusion of unfavorable information in our product labeling, such as limitations on the indicated uses for which the products may be marketed or distributed, a label with significant safety warnings, including boxed warnings, contraindications, and precautions, a label without statements necessary or desirable for successful commercialization, or may result in requirements for costly post-marketing testing and surveillance, or other requirements, including REMS, to monitor the safety or efficacy of the products, and in turn prevent us from commercializing and generating revenues from the sale of vidutolimod and future product candidates. Any such limitations or restrictions could similarly impact any supplemental marketing approvals we may obtain for vidutolimod. Undesirable side effects may limit the potential market for any approved products or could result in restrictions on manufacturing processes, the discontinuation of the sales and marketing of the product, or withdrawal of product approvals. We could also be sued and held liable for harm caused to patients, or become subject to fines, injunctions or the imposition of civil or criminal penalties.

If vidutolimod and future product candidates are associated with serious adverse events or undesirable side effects or have properties that are unexpected, we may need to abandon development or limit development of that product candidate to certain 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. The therapeutic-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 materially harm our business, financial condition, results of operations, stock price and prospects.

Regulatory approval by the FDA or comparable foreign regulatory authorities is limited to those specific indications and conditions for which approval has been granted, and we may be subject to substantial fines, criminal penalties, injunctions, or other enforcement actions if we are determined to be promoting the use of our products for unapproved or "off-label" uses, or in a manner inconsistent with the approved labeling, resulting in damage to our reputation and business.

We must comply with requirements concerning advertising and promotion for any product candidates for which we obtain marketing approval. Promotional communications with respect to therapeutics are subject to a variety of legal and regulatory restrictions and continuing review by the FDA, Department of Justice, Department of Health and Human Services' Office of Inspector General, state attorneys general, members of Congress, and the public. When the FDA or comparable foreign regulatory authorities issue regulatory approval for a product candidate, the regulatory approval is limited to those specific uses and indications for which a product is

approved. If we are not able to obtain FDA approval for desired uses or indications for vidutolimod and future product candidates, we may not market or promote them for those indications and uses, referred to as off-label uses, and our business, financial condition, results of operations, stock price and prospects will be materially harmed. We also must sufficiently substantiate any claims that we make for any products, including claims comparing those products to other companies' products, and must abide by the FDA's strict requirements regarding the content of promotion and advertising.

Physicians may choose to prescribe products for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved by the regulatory authorities. Regulatory authorities in the United States generally do not restrict or regulate the behavior of physicians in their choice of treatment within the practice of medicine. Regulatory authorities do, however, restrict communications by biopharmaceutical companies concerning off-label use.

If we are found to have impermissibly promoted any of vidutolimod and future product candidates, we may become subject to significant liability and government fines. The FDA and other agencies actively enforce the laws and regulations regarding product promotion, particularly those prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted a product may be subject to significant sanctions. The federal government has levied large civil and criminal fines against companies for alleged improper promotion and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

In the United States, engaging in the impermissible promotion of any products, following approval, for off-label uses can also subject us to false claims and other litigation under federal and state statutes. These include fraud and abuse and consumer protection laws, which can lead to civil and criminal penalties and fines, agreements with governmental authorities that materially restrict the manner in which we promote or distribute therapeutic products and conduct our business. These restrictions could include corporate integrity agreements, suspension or exclusion from participation in federal and state healthcare programs, and suspension and debarment from government contracts and refusal of orders under existing government contracts. These False Claims Act lawsuits against manufacturers of drugs and biologics have increased significantly in volume and breadth, leading to several substantial civil and criminal settlements pertaining to certain sales practices and promoting off-label uses. In addition, False Claims Act lawsuits may expose manufacturers to follow-on claims by private payers based on fraudulent marketing practices. This growth in litigation has increased the risk that a biopharmaceutical company will have to defend a false claim action, pay settlement fines or restitution, as well as criminal and civil penalties, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid, or other federal and state healthcare programs. If we do not lawfully promote our approved products, if any, we may become subject to such litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

In the United States, the promotion of biopharmaceutical products is subject to additional FDA requirements and restrictions on promotional statements. If, after vidutolimod or any future product candidates obtains marketing approval, the FDA determines that our promotional activities violate its regulations and policies pertaining to product promotion, it could request that we modify our promotional materials or subject us to regulatory or other enforcement actions, including issuance of warning letters or untitled letters, suspension or withdrawal of an approved product from the market, requests for recalls, payment of civil fines, disgorgement of money, imposition of operating restrictions, injunctions or criminal prosecution, and other enforcement actions. Similarly, industry codes in foreign jurisdictions may prohibit companies from engaging in certain promotional activities, and regulatory agencies in various countries may enforce violations of such codes with civil penalties. If we become subject to regulatory and enforcement actions, our business, financial condition, results of operations, stock price and prospects will be materially harmed.

We have received orphan drug designation for vidutolimod, and we may in the future seek orphan drug status for additional indications for vidutolimod or for our future product candidates, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug status, including market exclusivity, which may cause our revenue, if any, to be reduced.

We have received Orphan Drug Designation for vidutolimod for Stage IIb-IV melanoma in the U.S., and we may seek Orphan Drug Designation for future product candidates. Regulatory authorities in some jurisdictions, including the U.S. and the European Union, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the U.S., or a patient population of greater than 200,000 individuals in the United States, but for which there is no reasonable expectation that the cost of developing the drug or biologic will be recovered from sales in the United States.

In the United States, orphan designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product with an Orphan Drug Designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for the same drug for that time period.

The applicable period is seven years in the U.S. and ten years in the European Union. The exclusivity period in the European Union can be reduced to six years if a drug no longer meets the criteria for Orphan Drug Designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan Drug exclusivity may be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we obtain Orphan Drug exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because competing drugs containing a different active ingredient can be approved for the same condition. In addition, even after an orphan drug is approved, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process.

We have received Fast Track designation by the FDA for vidutolimod for certain designations and may seek such designation for any future product candidates, but such designation may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that vidutolimod and future product candidates will receive marketing approval.

If a drug is intended for the treatment of a serious or life-threatening condition and nonclinical or clinical data demonstrate the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA Fast Track designation for a particular indication. In July 2020, the FDA granted Fast Track designation for vidutolimod in combination with a PD-1 blocking antibody (nivolumab or pembrolizumab) in both anti-PD-1 refractory melanoma and first-line metastatic melanoma.

We may seek Fast Track designation for our future product candidates, but there is no assurance that the FDA will grant this designation to any of our product candidates. Marketing applications filed by sponsors of products receiving Fast Track designation may qualify for priority review under the policies and procedures offered by the FDA, but the Fast Track designation alone does not assure qualification for priority review. The FDA has broad discretion whether or not to grant Fast Track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even though vidutolimod has received Fast Track designation, and any future product candidates may receive Fast Track designation, we may not experience a faster development, regulatory review or approval process compared to conventional FDA procedures, and receiving a Fast Track designation does not provide assurance of ultimate FDA approval or that approval will be granted in any particular time frame. In addition, the FDA may withdraw Fast Track designation at any time if it believes that the designation is no longer supported by data from our clinical development program or that the relevant criteria are no longer met.

We may attempt to secure approval from the FDA through the use of the accelerated approval pathway by the FDA. If we are unable to obtain such approval, we may be required to conduct additional preclinical studies or clinical trials beyond those that we 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 currently intend to seek approval of vidutolimod for the treatment of refractory melanoma and first-line melanoma, and may seek approval of future product candidates, under the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it is designed to treat a serious or life-threatening disease or condition and generally provides a meaningful advantage 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 the sponsor fails to conduct such studies in a timely manner, or if such post-approval studies fail to verify the drug's predicted clinical benefit, the FDA may withdraw its approval of the drug on an expedited basis.

Prior to seeking accelerated approval for vidutolimod or future product candidates, we would 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 a BLA 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 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. Specifically, during an end-of-Phase 1 meeting held in March 2020 to discuss our plans for a registration path for vidutolimod in melanoma, the FDA indicated that one single-arm Phase 2 trial may be unlikely to support accelerated approval of a BLA for vidutolimod for the treatment of anti-PD-1 refractory patients with metastatic or unresectable melanoma in combination with pembrolizumab, and recommended that we conduct a randomized trial in the proposed patient population to evaluate the contribution of each component to the potential treatment effect of the combination. 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.

Obtaining and maintaining regulatory approval of vidutolimod or any future product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of vidutolimod or any future product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of vidutolimod or any future product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. 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 of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, 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.

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and 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 fail to comply with the regulatory requirements in international markets or receive applicable marketing approvals, our target markets will be reduced and our ability to realize the full market potential of vidutolimod or any future product candidates will be harmed.

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

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

Since March 2020 when foreign and domestic inspections were largely placed on hold, the FDA has been working to resume routine surveillance, bioresearch monitoring and pre-approval inspections on a prioritized basis. The FDA has developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections. As of May 2021, certain inspections, such as foreign preapproval, surveillance, and for-cause inspections that are not deemed mission-critical, remain temporarily postponed. In April 2021, the FDA issued guidance for industry formally announcing plans to employ remote interactive evaluations, using risk management methods, to meet user fee commitments and goal dates and in May 2021 announced plans to continue progress toward resuming standard operational levels. Should the FDA determine that an inspection is necessary for approval and an inspection cannot be completed during the review cycle due to restrictions on travel and the FDA does not determine a remote interactive evaluation to be adequate, the FDA has stated that it generally intends to issue a complete response letter or defer action on the application until an inspection can be completed. In 2020 and 2021, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. Additionally, as of May 26, 2021, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals and conducting mission critical domestic and foreign inspections to ensure compliance of manufacturing facilities with FDA quality standards. However, the FDA may not be able to maintain this pace and delays or setbacks are possible in the future. 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. In 2020 and 2021, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications.

Even if vidutolimod or any future product candidates receive regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense and limit how we manufacture and market our products.

Any product candidate for which we may obtain marketing approval will be subject to extensive and ongoing requirements of and review by the FDA and comparable foreign regulatory authorities, including requirements related to the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, export, import, advertising, marketing, and promotional activities for such product. These requirements further include submissions of safety and other post-marketing information, including manufacturing deviations and reports, registration and listing requirements, the payment of annual fees, continued compliance with current good manufacturing practices ("cGMPs"), requirements relating to manufacturing, quality control, quality assurance, and corresponding maintenance of records and documents, and good clinical practices ("GCPs") for any clinical trials that we conduct post-approval.

The FDA and comparable foreign regulatory authorities will continue to closely monitor the safety profile of any product even after approval. If the FDA or comparable foreign regulatory authorities become aware of new safety information after approval of any of vidutolimod and future product candidates, they may withdraw approval, issue public safety alerts, require labeling changes or establishment of a REMS or similar strategy, impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. Any such restrictions could limit sales of the product.

We and any of our suppliers or collaborators, including our contract manufacturers, could be subject to periodic unannounced inspections by the FDA to monitor and ensure compliance with cGMPs and other FDA regulatory requirements. Application holders must further notify the FDA, and depending on the nature of the change, obtain FDA pre-approval for product and manufacturing changes. For certain commercial prescription drug and biologic products, manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States.

In addition, later discovery of previously unknown adverse events or that the product is less effective than previously thought or other problems with any products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements both before and after approval, may yield various negative results, including:

- restrictions on manufacturing, distribution, or marketing of such products;
- restrictions on the labeling, including required additional warnings, such as boxed warnings, contraindications, precautions, and restrictions on the approved indication or use;
- modifications to promotional pieces;

- issuance of corrective information;
- requirements to conduct post-marketing studies or other clinical trials;
- clinical holds or termination of clinical trials;
- requirements to establish or modify a REMS or similar strategy;
- changes to the way the product is administered to patients;
- liability for harm caused to patients or subjects;
- reputational harm;
- the product becoming less competitive;
- warning or untitled letters;
- suspension of marketing or withdrawal of the products from the market;
- regulatory authority issuance of safety alerts, Dear Healthcare Provider letters, press releases, or other communications containing warnings or other safety information about the product;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recalls of products;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure or detention;
- FDA debarment, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from federal healthcare programs, consent decrees, or corporate integrity agreements; or
- injunctions or the imposition of civil or criminal penalties, including imprisonment.

Any of these events could prevent us from achieving or maintaining market acceptance of any particular product or could substantially increase the costs and expenses of commercializing such product, which in turn could delay or prevent us from generating significant revenues from its marketing and sale. Any of these events could further have other material and adverse effects on our operations and business and could adversely impact our business, financial condition, results of operations, stock price and prospects.

Further, the FDA's policies or those of comparable foreign regulatory authorities may change and could impose extensive and ongoing regulatory requirements and obligations on any product candidate for which we obtain marketing approval. 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 be subject to regulatory enforcement action, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

Healthcare legislative reform measures may have a material adverse effect on our business and results of operations.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could prevent or delay marketing approval of vidutolimod and future product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell a product for which we obtain marketing approval. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the Affordable Care Act (the "ACA") was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the U.S. pharmaceutical industry. The ACA, among other things, subjects biological products to potential competition by lower-cost biosimilars, addresses 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, increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations, establishes annual fees and taxes on manufacturers of certain branded prescription drugs, and creates a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (increased pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden issued an Executive Order to initiate a special enrollment period from February 15, 2021 through August 15, 2021 for purposes of obtaining health insurance coverage through the ACA marketplace. The Executive Order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administrations or other efforts, if any, to challenge repeal or replace the ACA, will impact our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted that may impact our business if we are able to commercialize any product candidates. In August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers up to 2% per fiscal year, and, due to subsequent legislative amendments, including the Coronavirus Aid, Relief and Economic Security Act ("CARES Act") will remain in effect through 2030 unless additional Congressional action is taken. Pursuant to the CARES Act, which was signed into law on March 27, 2020 to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, and subsequent legislation, these reductions have been suspended from May 1, 2020 through December 31, 2021. Proposed legislation, if passed, would extend this suspension until the end of the pandemic. In addition, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. However, it is unclear whether the Biden administration will challenge, reverse, revoke or otherwise modify these executive and administrative actions after January 20, 2021.

There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget for fiscal year 2021 included a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. At a federal level, the President Biden signed an Executive Order on July 9, 2021 affirming its policy (i) to support legislative reforms that would lower prescription drug prices, including by allowing Medicare to negotiate drug prices and by imposing inflation caps; and (ii) to support the enactment of a public health insurance option. Among other things, the Executive Order also directs HHS to submit a report to combat excessive pricing of prescription drugs, to enhance the domestic drug supply chain, to reduce the price that the Federal government pays for drugs, and to address price gouging in the industry; and directs the FDA to work with states to develop prescription drug importation plans pursuant to the Medicare Modernization Act of 2003 and FDA's related implementing regulations. FDA released such implementing regulations on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020 CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biologicals based on the lowest price drug manufacturers

receive in Organization for Economic Cooperation and Development countries with a similar gross domestic product per capita. The MFN Model regulations mandate participation by identified Part B providers and would have applied to all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. However, in response to a lawsuit filed by several industry groups, on December 28, the U.S. District Court for the Northern District of California issued a nationwide preliminary injunction enjoining government defendants from implementing the MFN Rule pending completion of notice-and-comment procedures under the Administrative Procedure Act. On January 13, 2021, in a separate lawsuit brought by industry groups in the U.S. District of Maryland, the government defendants entered a joint motion to stay litigation on the condition that the government would not appeal the preliminary injunction granted in the U.S. District Court for the Northern District of California and that performance for any final regulation stemming from the MFN Interim Final Rule shall not commence earlier than 60 days after publication of that regulation in the Federal Register. Further, authorities in Canada have passed rules designed to safeguard the Canadian drug supply from shortages. If implemented, importation of drugs from Canada and the MFN Model may materially and adversely affect the price we receive for any of our product candidates. Additionally, on December 2, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. on December 2, 2020, HHS published a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. . Further, implementation of this change and new safe harbors for point-of-sale reductions in price for prescription pharmaceutical products and pharmacy benefit manager service fees are currently under review by the Biden administration and may be amended or repealed. Although a number of these and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, both the Biden administration and Congress have indicated that it will continue to seek new legislative measures to control drug costs.

On July 9, 2021, President Biden issued an executive order directing the FDA to work with states and tribes to safely import prescription drugs from Canada and to continue to clarify and improve the approval framework for generic drugs and biosimilars, including the standards for interchangeability of biological products, facilitate the development and approval of biosimilar and interchangeable products, clarify existing requirements and procedures related to the review and submission of BLAs, and identify and address any efforts to impede generic drug and biosimilar competition.

Further, on May 30, 2018, 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 pharmaceutical manufacturer to make its product candidates available to eligible patients as a result of the Right to Try Act. We review each individual request for access through the Cures Act, the Right to Try Act and similar state laws, and may or may not provide access depending upon the facts of each request. Checkmate has adopted an Expanded Access Policy which is available on our website.

At the state level, individual state governments are increasingly becoming aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other health care programs. These measures could reduce the ultimate demand for our products, if approved, or put pressure on our product pricing.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for vidutolimod and future product candidates or additional pricing pressures.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition.

There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future, including repeal, replacement or significant revisions to the ACA. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and impose price controls may adversely affect:

- the demand for vidutolimod and future product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability.

Our relationships with patients and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Although we do not currently have any drugs on the market, once we begin commercializing vidutolimod and future product candidates, if approved, we will be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal government and the states and foreign governments in which we conduct our business. Healthcare providers, physicians and third-party payors will play a primary role in the recommendation and prescription of vidutolimod and future product candidates for which we obtain marketing approval. Our future arrangements with 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 vidutolimod and future product candidates for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward 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 federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal civil and criminal false claims laws and civil monetary penalty laws, such as the federal False Claims Act, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false of fraudulent claim for purposes of the False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the 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;

- the federal physician payment transparency requirements, sometimes referred to as the "Sunshine Act" under the ACA require manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report to HHS information related to physician (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) payments and other transfers of value and the ownership and investment interests of such physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made in the previous year to certain nonphysician providers such as physician assistants and nurse practitioners;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (the "HITECH Act") and its implementing regulations, which also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- analogous state laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and may be broader in scope than their federal equivalents; some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures; and
- state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts, and analogous foreign laws and regulations.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge and may not comply under one or more of such laws, regulations, and guidance. Law enforcement authorities are increasingly focused on enforcing fraud and abuse laws, and it is possible that some of our practices may be challenged under these laws. Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. We have entered into certain advisory board and consulting agreements with physicians, including some who are compensated in the form of stock or stock options who may influence the ordering or use of our product candidates, if approved, in the future. It is possible that governmental authorities will conclude that our business practices do 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, including anticipated activities to be conducted by our sales team, were to be found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other 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 future growth may depend, in part, on our ability to penetrate foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability may depend, in part, on our ability to commercialize vidutolimod and future product candidates in foreign markets for which we may rely on collaborations with third parties. We are not permitted to market or promote any of vidutolimod and future product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market, and we may never receive such regulatory approval for vidutolimod or any future product candidates. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of vidutolimod and future product candidates, and we cannot predict success in these jurisdictions. If we obtain approval of vidutolimod and future product candidates and ultimately commercialize vidutolimod and future product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

- our customers' ability to obtain reimbursement for vidutolimod and future product candidates in foreign markets;
- our inability to directly control commercial activities because we are relying on third parties;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements;

- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- the existence of additional potentially relevant third-party intellectual property rights;
- foreign currency exchange rate fluctuations; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

Foreign sales of vidutolimod and future product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs. For example, in some countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a drug. To obtain reimbursement or pricing approval in some countries, we, or our future collaborators, may be required to conduct a clinical trial that compares the cost effectiveness of our drug to other available therapies. If reimbursement of our drugs is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

Risks related to intellectual property

If we are unable to obtain, maintain and protect our intellectual property rights for our technology and our product candidates, or if our intellectual property rights are inadequate, our competitive position could be harmed.

Our commercial success will depend in part on our ability to obtain and maintain patent and other intellectual property protection in the United States and other countries with respect to our VLP and other technology, vidutolimod and future product candidates. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. We seek to protect our proprietary position by filing and prosecuting patent applications in the United States and abroad related to our technology and vidutolimod and future product candidates.

The patent positions of biotechnology and pharmaceutical companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our licensed patents and any patents we own in the future are highly uncertain. The steps we have taken to protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside of the United States.

Further, the examination process may require us to narrow the claims for our pending patent applications, which may limit the scope of patent protection that may be obtained if these applications issue. The scope of a patent may also be reinterpreted after issuance. The rights that may be granted under our future issued patents may not provide us with the proprietary protection or competitive advantages we are seeking. If we are unable to obtain and maintain patent protection for our technology or for vidutolimod or any future product candidates, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize products similar or superior to ours, and our ability to successfully commercialize vidutolimod or any future product candidates and future technologies may be adversely affected. It is also possible that we will fail to identify patentable aspects of inventions made in the course of our development and commercialization activities before it is too late to obtain patent protection on them.

In addition, the patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, collaborators, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. It is also possible that we will fail to identify patentable aspects of our research and development efforts in time to obtain patent protection.

For the core technology related to vidutolimod and its component parts, we are prosecuting seven families of patent applications which we own including composition of matter, methods of use, combination therapies, drug delivery, dose volume, aggregation, packaging and pDC recruitment claims. Further, we have an exclusive license for 10 families of patents and patent applications including composition of matter, manufacturing methods, aggregation, packaging and synthesis claims. Some patents have issued in the United States and internationally and additional patent applications are pending in the United States and internationally (either in foreign jurisdictions or under the Patent Cooperation Treaty ("PCT")). As of April 30, 2020, we own or exclusively license the rights to 13 issued US patents. The 15 families include a total of 141 issued or granted patents worldwide. Any future provisional patent applications are not eligible to become issued patents until, among other things, we file a non-provisional patent application within 12 months of filing of one or more of our related provisional patent applications. If we do not timely file any non-provisional patent applications, we may lose our priority date with respect to our provisional patent applications and any patent protection on the inventions disclosed in our provisional patent applications. Although we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any of our future patent applications will result in the issuance of patents that effectively protect our technology or vidutolimod or any future product candidates, or if any of our future issued patents will effectively prevent others from commercializing competitive products. 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 until they are issued as a patent. Therefore, we cannot be certain that we were the first to make the inventions claimed in our pending patent applications, or that we were the first to file for patent protection of such inventions.

Our pending applications cannot be enforced against third parties practicing the inventions claimed in such applications unless and until a patent issues from such applications. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we license from third parties or own in the future may be challenged in the courts or patent offices in the United States and abroad, including through opposition proceedings, derivation proceedings, inter partes review, interference proceedings or litigation. Such proceedings may result in the loss of patent protection, the narrowing of claims in such patents or the invalidity or unenforceability of such patents, which could limit our ability to stop others from using or commercializing similar or identical products, or limit the duration of the patent protection for our technology. Protecting against the unauthorized use of our patented inventions, trademarks and other intellectual property rights is expensive, time consuming, difficult and in some cases may not be possible. In some cases, it may be difficult or impossible to detect third-party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult. If we are unable to obtain, maintain, and protect our intellectual property our competitive advantage could be harmed, and it could result in a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

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

We are a party to the Kuros License Agreement and we expect to enter into additional license agreements in the future. The Kuros License Agreement imposes, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. In spite of our efforts, Kuros and any future licensors may allege that we have materially breached our obligations under the relevant license agreement and may therefore attempt to terminate the license agreements, thereby removing or limiting our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties might have the freedom to seek regulatory approval of, and to market, products identical to ours and we may be required to cease our development and commercialization of our lead products or other product candidates that we may identify. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

Moreover, disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;

- the extent to which our product candidates, technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our third-party vendors; and
- the priority of invention of patented technology.

In addition, the agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial conditions, results of operations, and prospects.

If we are unable to protect the confidentiality of our proprietary information and know-how, the value of our technology and products could be adversely affected.

In addition to seeking patent protection, we also rely on other proprietary rights, including protection of trade secrets, know-how and confidential and proprietary information. To maintain the confidentiality of our trade secrets and proprietary information, we enter into confidentiality agreements with our employees, consultants, collaborators and other third parties who have access to our trade secrets. Our agreements with employees also provide that any inventions conceived by the individual in the course of rendering services to us shall be our exclusive property. However, we may not obtain these agreements in all circumstances, and individuals with whom we have these agreements may not comply with their terms. 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. In addition, in the event of unauthorized use or disclosure of our trade secrets or proprietary information, these agreements, even if obtained, may not provide meaningful protection, particularly for our trade secrets or other confidential information. To the extent that our employees, consultants or contractors use technology or know-how owned by third parties in their work for us, disputes may arise between us and those third parties as to the rights in related inventions.

Adequate remedies may not exist in the event of unauthorized use or disclosure of our confidential information including a breach of our confidentiality agreements. 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 in and outside of the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. The disclosure of our trade secrets or the independent development of our trade secrets by a competitor or other third party would impair our competitive position and may materially harm our business, financial condition, results of operations, stock price and prospects.

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

Filing, prosecuting and defending patents on our technology 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 and practices 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 or manufacture their own products, and may export otherwise infringing products to territories where we have patent protection but where enforcement is not as strong as that in the United States. These products may compete with our products and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the granting or enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to obtain patent rights or stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally in those countries. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to protect and enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property we develop or license.

In addition, the laws of certain foreign countries may not protect our rights to the same extent as the laws of the United States, and those foreign laws may also be subject to change. For example, methods of treatment and manufacturing processes may not be patentable in certain jurisdictions, and the requirements for patentability may differ in certain countries. Furthermore, biosimilar product manufacturers or other competitors may challenge the scope, validity and enforceability of our patents, requiring us to engage in complex, lengthy and costly litigation or proceedings.

Moreover, many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. 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 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 and results of operations may be adversely affected.

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

The U.S. Patent and Trademark Office (the “USPTO”) and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payments and other similar provisions during the patent application process and to maintain patents after they are issued. For example, periodic maintenance fees, renewal fees, annuity fees and various other government fees on issued patents and patent applications often must be paid to the USPTO and foreign patent agencies over the lifetime of our licensed patents or any patents we own in the future. In certain circumstances, we may rely on future licensing partners to take the necessary action to comply with these requirements with respect to licensed intellectual property. Although an unintentional lapse can be cured for a period of time 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 obtain and maintain the patents and patent applications covering our products or procedures, we may not be able to stop a competitor from marketing products that are the same as or similar to vidutolimod or any future product candidates, which could have a material adverse effect on our business.

Changes to the patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect vidutolimod and future 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 both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (the “Leahy-Smith Act”), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. They also include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application

will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications 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, stock price and prospects.

The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Patent terms may be inadequate to protect our competitive position with respect to vidutolimod and future product candidates for an adequate amount of time.

Given the amount of time required for the development, testing and regulatory review of new product candidates, such as vidutolimod and future product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. In the United States, the Drug Price Competition and Patent Term Restoration Act of 1984 permits a patent term extension of up to five years beyond the normal expiration of the patent, but no longer than 14 years from the product's approval date, which is limited to the approved indication (or any additional indications approved during the period of extension). However, the applicable authorities, including the USPTO in the United States, and any equivalent regulatory authorities in other countries, may not agree with our assessment of whether such extensions are available, and may refuse to grant extensions to our patents, or may grant more limited extensions than we request. If this occurs, our competitors may be able to take advantage of our investment in development and clinical trials by referencing our clinical and preclinical data and launch their products earlier than might otherwise be the case, which could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

Vidutolimod and future product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

Vidutolimod is a biological product candidate. We believe that any of our product candidates approved in the United States as a biological product under a BLA should qualify for the 12-year period of regulatory exclusivity. The enactment of the Biologics Price Competition and Innovation Act of 2009 ("BPCIA") as part of the ACA, created an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The abbreviated regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an existing brand product. Under the BPCIA, an application for a biosimilar product cannot be approved by the FDA until 12 years after the original branded product was approved under a BLA. Certain changes, however, and supplements to an approved BLA, and subsequent applications filed by the same sponsor, manufacturer, licensor, predecessor in interest, or other related entity do not qualify for the 12-year exclusivity period. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty. While it is uncertain when such processes intended to implement the BPCIA may be fully adopted by the FDA, any such processes could have a material adverse effect on the future commercial prospects for our biological products.

However, there is also a risk that this exclusivity could be changed in the future. For example, this exclusivity could be shortened due to congressional action or through other actions, including future proposed budgets, international trade agreements and other arrangements or proposals. The extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. It is also possible that payers will give reimbursement preference to biosimilars over reference biologics, even absent a determination of interchangeability.

To the extent that we do not receive any anticipated periods of regulatory exclusivity for vidutolimod and future product candidates or the FDA or foreign regulatory authorities approve any biosimilar, interchangeable, or other competing products to vidutolimod and future product candidates, it could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

Intellectual property rights do not necessarily address all potential threats.

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

- we, or our current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate our technology without infringing our owned or in-licensed intellectual property rights;
- it is possible that our pending patent applications or those we may own or in-license in the future will not lead to issued patents;
- issued patents that we hold rights to may be held invalid or unenforceable, including 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 cannot ensure that any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect our product candidates;
- we cannot ensure that any patents issued to us or our licensors will provide a basis for an exclusive market for our commercially viable product candidates or will provide us with any competitive advantages;
- we cannot ensure that our commercial activities or product candidates will not infringe upon the patents of others;
- we cannot ensure that we will be able to successfully commercialize our product candidates on a substantial scale, if approved, before the relevant patents that we own or license expire;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

Third parties may in the future initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could harm our business.

Our commercial success depends on our ability and the ability of our current or future collaborators to develop, manufacture, market and sell vidutolimod and future product candidates, and to use our related proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. The biotechnology and pharmaceutical industries are characterized by extensive litigation regarding patents and other intellectual property rights. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to vidutolimod and future product candidates, including interference proceedings, post-grant review, inter partes review and derivation proceedings before the USPTO. Third parties may assert infringement or other intellectual property claims against us based on existing patents or patents that may be granted in the future. If we are found to infringe a third party's intellectual property rights, and we are unsuccessful in demonstrating that such intellectual property rights are invalid or unenforceable, we could be required to obtain a license from such third party to continue developing, manufacturing and commercializing vidutolimod and future product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us, and it could require us to make substantial licensing and royalty payments. We also could be forced, including by court order, to cease developing, manufacturing, and commercializing vidutolimod or any future product candidates. In addition, in any such proceeding or litigation, we could be found liable for significant monetary damages, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent or other intellectual property right. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, stock price and prospects. Any claims by third parties that we have misappropriated their confidential information or trade secrets could have a similar material adverse effect on our business.

In addition, we are developing vidutolimod in combination with certain PD-1 blocking antibodies, including avelumab, pembrolizumab and nivolumab and cemiplimab, which are covered by patents or licenses held by Merck and Pfizer, or Merck US, BMS and Regeneron, respectively, to which we do not have a license other than for use in connection with the applicable clinical trial. We also may develop any future product candidates in combination with products developed by additional companies that are covered by patents or licenses held by those entities to which we do not have a license. In the event that a labeling instruction is required in product packaging recommending that combination, we could be accused of, or held liable for, infringement of the third-party patents covering the product candidate or product recommended for administration with vidutolimod or any future product candidates. In such a case, we could be required to obtain a license from the other company or institution to use the required or desired package labeling, which may not be available on commercially reasonable terms, or at all.

We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time-consuming and unsuccessful and have a material adverse effect on the success of our business.

Competitors may infringe any licensed patents or any patent we own or misappropriate or otherwise violate our intellectual property rights. We may also be required to defend against claims of infringement and our licensed patents and any patents we own may become involved in priority or other intellectual property related disputes. To counter infringement or unauthorized use, litigation may be necessary in the future to enforce or defend our intellectual property rights, to protect our trade secrets or to determine the validity and scope of our own intellectual property rights or the proprietary rights of others. Also, third parties may initiate legal proceedings against us to assert that we are infringing their intellectual property rights or to challenge the validity or scope of our owned or licensed intellectual property rights. These proceedings can be expensive and time consuming. Many of our current and potential competitors have the ability to dedicate substantially greater resources to conduct intellectual property related litigations or proceedings than we can. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating our intellectual property. Litigation and other intellectual property related proceedings could result in substantial costs and diversion of management resources, which could harm our business and financial results. In addition, in an infringement proceeding, a court may decide that a patent owned by or licensed to us is invalid or unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or other intellectual property related proceeding could put one or more of our patents at risk of being invalidated, held unenforceable or interpreted narrowly.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation in the United States, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments in any such proceedings. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Any of the foregoing may have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

We may be subject to claims by third parties asserting that our collaborators, employees or we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees, including our senior management team, were previously employed at, or consulted for, universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Our collaborators' employees may currently be or previously have been employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Some of these persons, including each member of our senior management team, executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment or consulting agreements, that assigned ownership of intellectual property relating to work performed under such agreements to the contracting third party. Although we try to ensure that our employees do not use, claim as theirs, or misappropriate the intellectual property, proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used, claimed as theirs, misappropriated or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products. Such a license may not be available on commercially reasonable terms, or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management. Any of the foregoing may have a material adverse effect on our business, financial condition, results of operations, stock price and prospects.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed confidential information of third parties or are in breach of non-competition or non-solicitation agreements with our competitors.

We could be subject to claims that we or our employees, including senior management, have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors or others. Although we try to ensure that our employees and consultants do not use the intellectual property, proprietary information, know-how or trade secrets of others in their work for us, we may be subject to claims that we caused an employee to breach the terms of their non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor or other party. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defenses to these claims fail, in addition to requiring us to pay monetary damages, a court could prohibit us from using technologies or features that are essential to vidutolimod and future product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers, competitors or other parties. An inability to incorporate such technologies or features would have a material adverse effect on our business, and may prevent us from successfully commercializing vidutolimod and future product candidates. In addition, we may lose valuable intellectual property rights or personnel as a result of such claims. Moreover, any such litigation or the threat thereof may adversely affect our ability to hire employees or consultants. A loss of key personnel or their work product could hamper or prevent our ability to develop and commercialize vidutolimod and future product candidates, which could have an adverse effect on our business, financial condition, results of operations, stock price and prospects.

If we obtain any issued patents covering our technology, such patents could be found invalid or unenforceable if challenged in court or before the USPTO or comparable foreign regulatory authority.

If we or one of our licensing partners initiate legal proceedings against a third party to enforce a patent covering any of our technology, the defendant could counterclaim that the patent covering vidutolimod and future product candidates is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Grounds for a validity challenge could be, among other things, an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be, among other things, an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, inter partes review, post-grant review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions, such as opposition proceedings. Such proceedings could result in revocation, cancellation or amendment to our patents in such a way that they no longer cover and protect vidutolimod and future product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. For example, with respect to the validity of our licensed patents or any patents we obtain in the future, we cannot be certain that there is no invalidating prior art of which we, our or our licensing partner’s patent counsel, and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on vidutolimod and future product candidates. Such a loss of patent protection could have a material adverse impact on our business.

Risks related to manufacturing and our reliance on third parties

We currently rely on third-party CMOs, based both in the United States and abroad, for the production of clinical supply of vidutolimod and may continue to rely on CMOs for the production of commercial supply of vidutolimod, if approved. This reliance on CMOs increases the risk that we will not have sufficient quantities of such materials, product candidates, or any therapies that we may develop and commercialize, or that such supply will not be available to us at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.

We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. Instead, we expect to rely on third parties for the manufacture of our product candidates and related raw materials for future pre-clinical and clinical development, as well as for commercial manufacture if any of our product candidates receive marketing approval. We have entered into an arrangement with a number of third-party CMOs as part of our clinical development for vidutolimod. These CMOs provide drug substance intermediate and drug product that is subsequently labeled, packaged and distributed to our CROs. We may also enter into agreements with additional companies for the supply of substances for use in the development of vidutolimod or any future product candidates or for the manufacture of such product candidates.

We or our third-party suppliers or manufacturers may encounter shortages in the raw materials or active pharmaceutical ingredient ("API") necessary to produce vidutolimod and future product candidates we may develop in the quantities needed for our clinical trials or, if vidutolimod or any future product candidates we may develop are approved, in sufficient quantities for commercialization or to meet an increase in demand, as a result of capacity constraints or delays or disruptions in the market for the raw materials or API, including shortages caused by the purchase of such raw materials or API by our competitors or others. Even if raw materials or API are available, we may be unable to obtain sufficient quantities at an acceptable cost or quality. The failure by us or our third-party suppliers or manufacturers to obtain the raw materials or API necessary to manufacture sufficient quantities of vidutolimod or any future product candidates we may develop could delay, prevent or impair our development efforts and may have a material adverse effect on our business.

The facilities used by third-party manufacturers to manufacture vidutolimod or any future product candidates must be authorized by the FDA pursuant to inspections that will be conducted after we submit a BLA to the FDA. We do not control the manufacturing process of, and are completely dependent on, third-party manufacturers for compliance with cGMP requirements for manufacture of drug products and other laws and regulations. If these third-party 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 maintain regulatory approval for their manufacturing facilities. Some of our contract manufacturers may not have produced a commercially-approved product and therefore may not have obtained the requisite FDA approvals to do so. In addition, we have no control over the ability of third-party 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 regulatory approval for or market our product candidates, if approved.

Finding new CMOs or third-party suppliers involves additional cost and requires our management's time and focus. In addition, there is typically a transition period when a new CMO commences work. Although we generally have not, and do not intend to, begin a clinical trial unless we believe we have on hand, or will be able to obtain, a sufficient supply of our product candidates to complete the clinical trial, any significant delay in the supply of our product candidates or the raw materials needed to produce our product candidates, could considerably delay conducting our clinical trials and potential regulatory approval of our product candidates. Additionally, any changes implemented by a new CMO could delay completion of clinical trials, require the conduct of bridging clinical trials or studies, require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of vidutolimod and future product candidates and jeopardize our ability to commence product sales and generate revenue.

If any CMO with whom we contract fails to perform its obligations, we may be forced to manufacture the materials ourselves, for which we may not have the capabilities or resources, or enter into an agreement with a different CMO, which we may not be able to do on reasonable terms, if at all. In either scenario, our clinical trials supply could be delayed significantly as we establish alternative supply sources. In some cases, the technical skills required to manufacture our products or product candidates may be unique or proprietary to the original CMO and we may have difficulty, or there may be contractual restrictions prohibiting us from, transferring such skills to a back-up or alternate supplier, or we may be unable to transfer such skills at all. In addition, if we are required to change CMOs for any reason, we will be required to verify that the new CMO maintains facilities and procedures that comply with quality standards and with all applicable regulations. We will also need to verify, such as through a manufacturing comparability study, that any new manufacturing process will produce our product candidate according to the specifications previously submitted to or approved by the FDA or another regulatory authority. The delays associated with the verification of a new CMO could negatively affect our ability to develop product candidates or commercialize our products in a timely manner or within budget. Furthermore, a CMO may possess technology related to the manufacture of our product candidate that such CMO owns independently. This would increase our reliance on such CMO or require us to obtain a license from such CMO in order to have another CMO manufacture our product candidates. In addition, in the case of CMOs that supply our product candidates, changes in manufacturers often involve changes in manufacturing procedures and processes, which could require that we conduct bridging studies between our prior clinical supply used in our clinical trials and that of any new manufacturer. We may be unsuccessful in demonstrating the comparability of clinical supplies which could require the conduct of additional clinical trials.

As part of their manufacture of our product candidates, our CMOs and third-party suppliers are expected to comply with and respect the intellectual property and proprietary rights of others. If a CMO or third-party supplier fails to acquire the proper licenses or otherwise infringes, misappropriates or otherwise violates the intellectual property or proprietary rights of others in the course of providing services to us, we may have to find alternative CMOs or third-party suppliers or defend against applicable claims, either of which would significantly impact our ability to develop, obtain regulatory approval for or commercialize 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 clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, we may be unable to establish any agreements with third-party manufacturers or to do so on acceptable terms.

Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- failure of third-party manufacturers to comply with regulatory requirements and maintain quality assurance;
- breach of the manufacturing agreement by the third party;
- failure to manufacture our product according to our specifications;
- failure to manufacture our product according to our schedule or at all;
- production difficulties caused by unforeseen events that may delay the availability of one or more of the necessary raw materials or delay the manufacture of vidutolimod or any future product candidates for use in clinical trials or for commercial supply, including as a result of the COVID-19 pandemic;
- misappropriation of our proprietary information, including our trade secrets and know-how; and
- termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us.

Vidutolimod and any other product candidates that we may develop may compete with other product candidates and products for access to manufacturing facilities. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval, and any related remedial measures may be costly or time-consuming to implement. We do not currently have arrangements in place for redundant supply or a second source for all required raw materials used in the manufacture of our product candidates. If our current third-party manufacturers cannot perform as agreed, we may be required to replace such manufacturers and we may be unable to replace them on a timely basis or at all. Our current and anticipated future dependence upon others for the manufacture of vidutolimod or any other future product candidates or products may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

We rely, and expect to continue to rely, on third parties to conduct, supervise, and monitor our preclinical studies and clinical trials. If those third parties do not perform satisfactorily, including failing to meet deadlines for the completion of such trials or failing to comply with regulatory requirements, we may be unable to obtain regulatory approval for vidutolimod or any future product candidates.

We rely on third-party CROs, study sites, and others to conduct, supervise, and monitor our preclinical studies and clinical trials for vidutolimod and future product candidates. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions, and clinical investigators, to conduct our preclinical studies and clinical trials. Although we have agreements governing their activities, we have limited influence over their actual performance and control only certain aspects of their activities. The failure of these third parties to successfully carry out their contractual duties or meet expected deadlines, including as a result of the impact of the COVID-19 pandemic, could substantially harm our business because we may be delayed in completing or unable to complete the studies required to support future approval of vidutolimod and future product candidates, or we may not obtain marketing approval for, or commercialize, vidutolimod and future product candidates in a timely manner or at all. Moreover, these agreements might terminate for a variety of reasons, including a failure to perform by the third parties. If we need to enter into alternative arrangements our product development activities would be delayed and our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Our reliance on these third parties for development activities reduces our control over these activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory, and scientific standards and our reliance on third parties does not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our trials is conducted in accordance with the general investigational plan and protocols for the trial. We must also ensure that our preclinical trials are conducted in accordance with the FDA's Good Laboratory Practice regulations, as appropriate. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with GCPs for

conducting, recording, and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial participants are protected. Regulatory authorities enforce these requirements through periodic inspections of trial sponsors, clinical investigators, and trial sites. If we or any of our third parties fail to comply with applicable GCPs or other regulatory requirements, we or they may be subject to enforcement or other legal actions, the data generated in our trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional studies.

In addition, we will be required to report certain financial interests of our third-party investigators if these relationships exceed certain financial thresholds or meet other criteria. The FDA or comparable foreign regulatory authorities may question the integrity of the data from those clinical trials conducted by investigators who may have conflicts of interest.

We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our trials complies with the applicable regulatory requirements. In addition, our clinical trials must be conducted with product candidates that were produced under cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. We also are required to register certain clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in enforcement actions and adverse publicity.

The third parties with which we work may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting trials or other therapeutic development activities that could harm our competitive position. In addition, such third parties are not our employees, and except for remedies available to us under our agreements with such third parties we cannot control whether or not they devote sufficient time and resources to our ongoing clinical, non-clinical, and preclinical programs. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, if these parties are adversely impacted by the COVID-19 pandemic limiting or materially affecting their ability to carry out their contractual duties, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our protocols, regulatory requirements or for other reasons, our trials may be repeated, extended, delayed, or terminated; we may not be able to obtain, or may be delayed in obtaining, marketing approvals for vidutolimod and future product candidates; we may not be able to, or may be delayed in our efforts to, successfully commercialize vidutolimod and future product candidates; or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for vidutolimod and future product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative providers or to do so on commercially reasonable terms. Switching or adding additional third parties involves additional cost and requires management’s time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines.

We also rely on other third parties to store and distribute our products for the clinical trials that we conduct. Any performance failure on the part of our distributors could delay clinical development, marketing approval, or commercialization of vidutolimod and future product candidates, which could result in additional losses and deprive us of potential product revenue.

Our collaboration agreements with any future third-parties may not be successful, which could adversely affect our ability to develop and commercialize vidutolimod or any future product candidates.

We may in the future seek collaboration arrangements with other parties for the development or commercialization of vidutolimod or any future product candidates. The success of existing or any future collaboration arrangements may depend on the efforts and activities of our collaborators. Collaborators generally have significant discretion in determining the efforts and resources that they will apply to these arrangements. Disagreements between parties to a collaboration arrangement regarding clinical development and commercialization matters can lead to delays in the development process or commercializing the applicable product candidate and, in some cases, termination of the collaboration arrangement. These disagreements can be difficult to resolve if neither of the parties has final decision making authority.

Collaborations with biopharmaceutical companies and other third parties often are terminated or allowed to expire by the other party. Any such termination or expiration could adversely affect us financially and could harm our business reputation.

Any future collaborations we might enter into may pose a number of risks, including the following:

- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create 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 fail to make timely regulatory submissions for a product candidate;
- collaborators may control the public release of information regarding the developments, and we may not be able to make announcements or data presentations on a schedule favorable to us;
- collaborators may not comply with all applicable regulatory requirements or may fail to report safety data in accordance with all applicable regulatory requirements, which could subject them or us to regulatory enforcement actions;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our products or 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;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of vidutolimod and future product candidates;
- a collaborator with marketing and distribution rights to vidutolimod or any future product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such product candidate or product;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates or might result in litigation or arbitration, any of which would be time consuming and expensive;
- collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation; and
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability.

If any collaborations we might enter into in the future do not result in the successful development and commercialization of products or if one of our collaborators subsequently terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under such potential future collaboration. If we do not receive the funding we expect under the agreements, our development of vidutolimod and future product candidates could be delayed and we may need additional resources to develop vidutolimod and future product candidates and our product platform.

Additionally, if any future collaborator of ours is involved in a business combination, the collaborator might deemphasize or terminate development or commercialization of any product candidate licensed to it by us. If one of our collaborators terminates its agreement with us, we may find it more difficult to attract new collaborators and our reputation in the business and financial communities could be adversely affected.

We face significant competition in seeking appropriate collaborators. Our ability to reach a definitive agreement for any 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.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms, or at all, 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 fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms, or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop vidutolimod and future product candidates or bring them to market or continue to develop our product platform and our business may be materially and adversely affected.

If we materially breach or default on our current or future license agreements, the licensor party to such agreement may have the right to terminate the license agreement, which termination may materially harm our business.

Our commercial success will depend in part on the maintenance of our license agreements. Currently, we are a party to the Kuros License Agreement, and we expect to enter into additional license agreements in the future. The Kuros License Agreement imposes, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. For example, under the Kuros License Agreement, we are required to use commercially reasonable diligence to develop and commercialize a product and to satisfy specified payment obligations. If we fail to comply with our obligations under the Kuros License Agreement or any future license agreements with any party, or we are subject to a bankruptcy, the licensor may have the right to terminate the license, in which event we would not be able to market products covered by the license. The Kuros License Agreement further provides Kuros with a right to terminate the license agreements for our material breach or default under the agreement, including the failure to make any required milestone or other payments. Should Kuros exercise such a termination right, we would lose our right to the intellectual property under the license agreement, and such loss may materially harm our business. Moreover, the termination of the Kuros License Agreement or any reduction in our collaboration with Kuros may delay or impair our development efforts.

Risks related to our operations

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

We are highly dependent on the principal members of our management, scientific and clinical team. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

Recruiting and retaining qualified scientific, clinical, manufacturing and sales and marketing personnel will also be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval of and commercialize drugs. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. Failure to succeed in clinical trials may make it more challenging to recruit and retain qualified scientific personnel.

We will need to develop and expand our company, and we may encounter difficulties in managing this development and expansion, which could disrupt our operations.

As of June 30, 2021, we had 25 full-time employees, and we expect to increase our number of employees and the scope of our operations. To manage our anticipated development and expansion, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Also, our management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these development activities. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert financial resources from other projects, such as the development of vidutolimod and future product candidates. If our management is unable to effectively manage our expected development and expansion, our expenses may increase more than expected, our ability to generate or increase our revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize vidutolimod and future product candidates, if approved, and to compete effectively will depend, in part, on our ability to effectively manage the future development and expansion of our company.

If we engage in future acquisitions or strategic partnerships, our capital requirements may increase, our stockholders may be diluted, we may incur debt or assume contingent liabilities, and we may be subject to other risks.

We may evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies, or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- the issuance of our equity securities;
- assimilation of operations, intellectual property and products of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing product programs and initiatives in pursuing such a strategic merger or acquisition;
- retention of key employees, the loss of key personnel, and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party, their regulatory compliance status, and their existing products or product candidates and marketing approvals; and
- our inability to generate revenue from acquired technology or products sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

In addition, if we undertake acquisitions, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. Moreover, we may not be able to locate suitable acquisition opportunities and this inability could impair our ability to grow or obtain access to technology or products that may be important to the development of our business. Any of the foregoing may materially harm our business, financial condition, results of operations, stock price and prospects.

If we fail to maintain proper and effective internal controls over financial reporting our ability to produce accurate and timely financial statements could be impaired.

We are required to maintain internal controls over financial reporting. Commencing with the end of this fiscal year, we must perform system and process design evaluation and testing of the effectiveness of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Form 10-K filing for that year, as required by Section 404 of the Sarbanes-Oxley Act of 2002 ("Sarbanes-Oxley Act"). This will require that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts. We have not yet been required to test our internal controls within a specified period and, as a result, we may experience difficulty in meeting these reporting requirements in a timely manner. In addition, in connection with the audits of our financial statements as of and for the years ended December 31, 2018 and 2019, we identified a material weakness in our internal control over financial reporting. See "—*We previously identified a material weakness in our internal control over financial reporting. If our internal control over financial reporting is not effective, we may not be able to accurately report our financial results or file our*

periodic reports in a timely manner, which may cause adverse effects on our business and may cause investors to lose confidence in our reported financial information and may lead to a decline in our stock price." In addition, our independent registered public accounting firm will be required to provide an attestation report on our internal control over financial reporting. However, while we remain an emerging growth company, we will not be required to provide the attestation report.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner or we are unable to maintain proper and effective internal controls over financial reporting we may not be able to produce timely and accurate financial statements. As a result, our investors could lose confidence in our reported financial information, the market price of our stock could decline and we could be subject to sanctions or investigations by the SEC or other regulatory authorities.

We believe that any internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. We may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make a required related party transaction disclosure. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

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

As a public company, we are subject to the periodic reporting requirements of the Exchange Act. We must design our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. Decision-making can be faulty and breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make a required related party transaction disclosure. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

We previously identified a material weakness in our internal control over financial reporting. If our internal control over financial reporting is not effective, we may not be able to accurately report our financial results or file our periodic reports in a timely manner, which may cause adverse effects on our business and may cause investors to lose confidence in our reported financial information and may lead to a decline in our stock price.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports in a timely manner. In connection with the audit of our financial statement for the years ended December 31, 2019, we concluded that there was a material weakness in our internal control over financial reporting. As of December 31, 2020, we concluded that this material weakness had been remediated, but there can be no assurance that we will not identify future material weaknesses or reportable conditions.

The material weaknesses we identified related to the maintenance of an effective control environment commensurate with our financial reporting requirements. Specifically, we lacked sufficient personnel to maintain effective segregation of duties in the processing and recording of financial transactions.

To remediate this weakness, we expanded our finance organization to allow for the segregation of duties in the processing and recording of financial transaction by hiring a full-time chief financial officer and accounting manager to augment our accounting staff and to provide more resources for control environment. We also redesigned our processes and related controls to maintain effective segregation of duties in the processing and recording of financial transactions.

If we identify any future significant deficiencies or material weaknesses, the accuracy and timing of our financial reporting may be adversely affected, a material misstatement in our financial statements could occur, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports, which may adversely affect our business and our stock price may decline as a result.

Nevertheless, we will be required to expend significant time and resources to further improve our internal controls over financial reporting, including by further expanding our finance and accounting staff to meet the demands that are placed upon us as a public company, including the requirements of the Sarbanes-Oxley Act. If we fail to adequately staff our accounting and finance function, or fail to maintain adequate internal control over financial reporting, any new or recurring material weaknesses could prevent our management from concluding our internal control over financial reporting is effective and impair our ability to prevent material misstatements in our financial statements, which could cause our business to suffer.

Risks related to our common stock

The price of our common stock may be volatile and fluctuate substantially.

Our stock price is and is likely to continue to be highly volatile. The stock market in general and the market for biopharmaceutical companies in particular have experienced periods of extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, a holder may not be able to sell our common stock at or above the price at which such holder acquired shares of our common stock. The market price for our common stock may be influenced by many factors, including:

- the success of competitive drugs or technologies;
- results of clinical trials of vidutolimod and future product candidates or those of our competitors, including interim or topline results;
- regulatory or legal developments in the United States and other countries;
- the regulatory status of our product candidates;
- failure of any of our product candidates, if approved, to achieve commercial success;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of vidutolimod and future product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license future product candidates or drugs;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- the impact of the ongoing COVID-19 pandemic on us or on the U.S. and global economies and global equity markets;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

Anti-takeover provisions under our charter documents and Delaware law could delay or prevent a change of control, which could limit the market price of our common stock and may prevent or frustrate attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could delay or prevent a change of control of our company or changes in our board of directors that our stockholders might consider favorable. Some of these provisions include:

- a board of directors divided into three classes serving staggered three-year terms, such that not all members of the board will be elected at one time;
- a prohibition on stockholder action through written consent, which requires that all stockholder actions be taken at a meeting of our stockholders;
- a requirement that special meetings of stockholders be called only by the board of directors acting pursuant to a resolution approved by the affirmative vote of a majority of the directors then in office;
- advance notice requirements for stockholder proposals and nominations for election to our board of directors;
- a requirement that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of not less than two-thirds of all outstanding shares of our voting stock then entitled to vote in the election of directors;
- a requirement of approval of not less than two-thirds of all outstanding shares of our voting stock to amend any bylaws by stockholder action or to amend specific provisions of our certificate of incorporation; and
- the authority of the board of directors to issue preferred stock on terms determined by the board of directors without stockholder approval and which preferred stock may include rights superior to the rights of the holders of common stock.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer, or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for you and other stockholders to elect directors of your choosing or cause us to take other corporate actions you desire. Any delay or prevention of a change of control transaction or changes in our board of directors could cause the market price of our common stock to decline.

Our amended and restated bylaws designate a certain court as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers, or employees.

Pursuant to our amended and restated bylaws, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the sole and exclusive forum for any state law claims for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim of breach of fiduciary duty owed by any of our directors, officers, employees or agents to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation and our amended and restated bylaws, (iv) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or by-laws or (v) any action asserting a claim that is governed by the internal affairs doctrine, in each case subject to the Court of Chancery having personal jurisdiction over the indispensable parties named as defendants therein (the "Delaware Forum Provision"). The Delaware Forum Provision will not apply to any causes of action arising under the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Unless we consent in writing to the selection of an alternate forum, the United Stated District Court for the District of Massachusetts shall be the sole and exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act (the "Federal Forum Provision"), as our principal office is located in Cambridge, Massachusetts. In addition, our amended and restated bylaws provide that any person or entity purchasing or otherwise acquiring any interest in our shares of common stock is deemed to have notice of and consented to the Delaware Forum Provision and the Federal Forum Provision; provided, however, that stockholders cannot and will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

The Delaware Forum Provision and the Federal Forum Provision may impose additional litigation costs on stockholders who assert the provision is not enforceable and may impose more general additional litigation costs in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware or the Commonwealth of Massachusetts. In addition, these forum selection clauses in our bylaws may limit our stockholders' ability to bring a claim in a judicial forum that they find favorable for disputes with us or our directors, officers or employees, which may discourage such lawsuits against us and our directors, officers and employees even though an action, if successful, might benefit our stockholders. Moreover, while the Delaware Supreme Court ruled in March 2020 that federal forum selection provisions purporting to require claims under the Securities Act be brought in federal court were "facially valid" under Delaware law, there is uncertainty as to whether other courts will enforce our Federal Forum Provision. If the Federal Forum Provision is found to be unenforceable, we may incur additional costs associated with resolving such matters. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert that the provision is not enforceable or invalid. The Federal Forum Provision may also impose additional litigation costs on stockholders who assert the provision is not enforceable or invalid. The Court of Chancery of the State of Delaware may also reach different judgments or results than would other courts, including courts where a stockholder considering an action may be located or would otherwise choose to bring the action, and such judgments may be more or less favorable to us than our stockholders.

General risk factors

We will continue to incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to compliance initiatives.

As a newly public company, we have been and will continue to incur significant legal, accounting, and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, which require, among other things, that we file with the Securities and Exchange Commission ("SEC") annual, quarterly, and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules adopted by the SEC and Nasdaq to implement provisions of the Sarbanes-Oxley Act, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. Further, in July 2010, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Dodd-Frank Act") was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that required the SEC to adopt additional rules and regulations in these areas, such as "say on pay" and proxy access. The Jumpstart Our Business Startups Act ("JOBS Act") permits emerging growth companies and smaller reporting companies like us to implement many of these requirements over a longer period and up to five years from the pricing of our initial public offering ("IPO"). We intend to take advantage of this extended time period for compliance, but cannot guarantee that we will not be required to implement these requirements sooner than budgeted or planned and thereby incur unexpected expenses. Stockholder activism, the current political and economic environment, and the high levels of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, and results of operations. The increased costs will increase our net loss and may require us to reduce costs in other areas of our business. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees, or as executive officers.

If securities analysts do not continue to publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock relies in part on the research and reports that industry or financial analysts publish about us or our business. If one or more of the analysts covering our business downgrade their evaluations of our stock, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. If our existing stockholders, members of our board of directors or shareholders affiliated with our board of directors sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, the trading price of our common stock could decline. Certain holders of our common stock have rights, subject to conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Registration of these shares under the Securities Act of 1933, as amended (the "Securities Act") would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

We are an emerging growth company and a smaller reporting company, and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies will make our 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 may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and stockholder approval of any golden parachute payments not previously approved. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year (a) following the fifth anniversary of the closing of our IPO, (b) in which we have total annual gross revenue of at least $1.07 billion or (c) in which we are deemed to be a large accelerated filer, which requires the market value of our common stock that is held by non-affiliates to exceed $700 million as of the prior June 30th , and (ii) the date on which we have issued more than $1 billion in non-convertible debt during the prior three-year period.

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 have elected to not "opt out" of this exemption from complying with new or revised accounting standards and, therefore, we will adopt new or revised accounting standards at the time private companies adopt the new or revised accounting standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

Because we do not anticipate paying any cash dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Changes in tax law could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future.

It cannot be predicted whether, when, in what form or with what effective dates new tax laws may be enacted, or regulations and rulings may be promulgated or issued under existing or new tax laws, which could result in an increase in our or our shareholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof.

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

As of December 31, 2020, we had U.S. federal NOL carryforwards of $114.2 million including $81.6 million which have an indefinite carryforward period and $32.6 million which expire at various dates through 2038. As of December 31, 2020, we had state net operating loss carryforwards of $94.6 million which expire at various dates between 2037 and 2040. As of December 31, 2020, we had federal and state research and development tax credit carryforwards of approximately $6.5 million available to reduce future tax liabilities, which begin to expire in 2031.

Under Sections 382 and 383 of the Code, and certain corresponding provisions of state law, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOL carryforwards or credits to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. We have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result subsequent shifts in our stock ownership, some of which are outside our control. If finalized, Treasury regulations currently proposed under Section 382 of the Code may further limit our ability to utilize our pre-change NOL carryforwards or credits if we undergo a future ownership change. The amount of NOLs generated in taxable years beginning after December 31, 2020 that we are permitted to deduct in any taxable year is limited to 80% of our taxable income in such, where taxable income is determined without regard to such NOL deduction itself. Our NOLs or credits may also be impaired under state law. Accordingly, due to these limitations, we may not be able to utilize a material portion of our NOLs or credits. Furthermore, our ability to utilize our NOLs or credits is conditioned upon our attaining profitability and generating U.S. federal and state taxable income. We have incurred significant net losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future; and therefore, we do not know whether or when we will generate the U.S. federal or state taxable income necessary to utilize our NOLs or credits.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price.

Global financial markets have in the past experienced, extreme volatility and disruptions, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy and ability to raise capital may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other third-parties may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

In addition, the stock markets have experienced extreme price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies, including recently in connection with the ongoing COVID-19 pandemic, which resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. These fluctuations have often been unrelated or disproportionate to the operating performance of those companies. Although the markets recovered, market and industry factors, including potentially worsening economic conditions and other adverse effects or developments relating to the ongoing COVID-19 pandemic, political, regulatory and other market conditions, may negatively affect the market price of shares of our common stock, regardless of our actual operating performance.

As of June 30, 2021, our cash, cash equivalents and available-for-sale investments were $95.6 million. While we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents since June 30, 2021, no assurance can be given that further deterioration of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or our ability to meet our financing objectives. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

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

Any unplanned event, such as earthquake, flood, fire, explosion, extreme weather, medical epidemic, pandemic, power shortage, telecommunication failure or other natural or manmade accidents or incidents, including the COVID-19 pandemic, could severely disrupt our operations, and have a material adverse effect on our business, results of operations, financial condition and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. We plan to put disaster recovery and business continuity plans in place; however, these may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, could have a material adverse effect on our business.

Our internal computer systems, or those of our third-party CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of vidutolimod and future product candidates' development programs.

Despite our implementation of security measures, our internal computer systems, and those of our CROs, CMOs, IT suppliers and other contractors and consultants are vulnerable to damage from computer viruses, cyber-attacks and other unauthorized access, natural disasters, terrorism, war, and telecommunication and electrical failures. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs for vidutolimod and future product candidates. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of personal, confidential or proprietary information, we could incur liability and the further development of any of vidutolimod and future product candidates could be delayed.

We may be unable to adequately protect our information systems from cyberattacks, which could result in the disclosure of confidential or proprietary information, including personal data, damage our reputation, and subject us to significant financial and legal exposure.

We rely on information technology systems that we or our third-party providers operate to process, transmit and store electronic information in our day-to-day operations. In connection with our product discovery efforts, we may collect and use a variety of personal data, such as names, mailing addresses, email addresses, phone numbers and clinical trial information. A successful cyberattack could result in the theft or destruction of intellectual property, data, or other misappropriation of assets, or otherwise compromise our confidential or proprietary information and disrupt our operations. Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include wrongful conduct by hostile foreign governments, industrial espionage, wire fraud and other forms of cyber fraud, the deployment of harmful malware, denial-of-service, social engineering fraud or other means to threaten data security, confidentiality, integrity and availability. A successful cyberattack could cause serious negative consequences for us, including, without limitation, the disruption of operations, the misappropriation of confidential business information, including financial information, trade secrets, financial loss and the disclosure of corporate strategic plans. Although we devote resources to protect our information systems, we realize that cyberattacks are a threat, and there can be no assurance that our efforts will prevent information security breaches that would result in business, legal, financial or reputational harm to us, or would have a material adverse effect on our results of operations and financial condition. Any failure to prevent or mitigate security breaches or improper access to, use of, or disclosure of our clinical data or patients' personal data could result in significant liability under state (e.g., state breach notification laws), federal (e.g., HIPAA, as amended by the HITECH Act), and international law (e.g., the GDPR) and may cause a material adverse impact to our reputation, affect our ability to conduct new studies and potentially disrupt our business.

We rely on our third-party providers to implement effective security measures and identify and correct for any such failures, deficiencies or breaches. If we or our third-party providers fail to maintain or protect our information technology systems and data integrity effectively or fail to anticipate, plan for or manage significant disruptions to our information technology systems, we or our third-party providers could have difficulty preventing, detecting and controlling such cyber-attacks and any such attacks could result in the losses described above as well as disputes with physicians, patients and our third-party contractors, regulatory sanctions or penalties, increases in operating expenses, expenses or lost revenues or other adverse consequences, any of which could have a material adverse effect on our business, results of operations, financial condition, prospects and cash flows. Any failure by such third parties to prevent or mitigate security breaches or improper access to or disclosure of such information could have similarly adverse consequences for us. If we are unable to prevent or mitigate the impact of such security or data privacy breaches, we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business. By way of example, the California Consumer Privacy Act ("CCPA"), which went into effect on January 1, 2020, creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. 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 many similar laws have been proposed at the federal level

and in other states. By way of example regarding foreign laws and regulations with respect to data privacy and security, the GDPR went into effect in the European Union in May 2018 and introduces strict requirements for processing the personal data of EU data subjects. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater.

Our employees, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct or disclosure of unauthorized activities to us that violate the regulations of the FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities; healthcare fraud and abuse laws and regulations in the United States and abroad; or laws that require the reporting of financial information or data accurately. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials or creating fraudulent data in our pre-clinical studies or clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We adopted a code of conduct applicable to all of our employees, but it is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Our third-party manufacturers and suppliers use biological materials and may use hazardous materials, and any claims relating to improper handling, storage or disposal of these materials could be time consuming or costly and could have a material adverse effect on the success of our business.

Our third-party manufacturers and suppliers may use hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety or the environment. The operations of our third-party manufacturers and suppliers also produce hazardous waste products. We and our third-party manufacturers 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. We cannot entirely eliminate the risk of contamination or injury from these materials or wastes. 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.

Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of biological, hazardous or radioactive materials. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with civil or criminal fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended.

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.

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

Use of Proceeds from our Public Offering of Common Stock

On August 11, 2020, we closed our initial public offering ("IPO"), in which we issued and sold 5,000,000 shares of common stock, at a public offering price of $15.00 per share.

There has been no material change in the planned use of IPO proceeds from that described in the Prospectus filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, on August 7, 2020.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

The exhibits filed or furnished as part of this Quarterly Report on Form 10-Q are set forth below.

Exhibit Number	Description
10.1†	Supply and Non-Exclusive License Agreement, effective as of May 6, 2021, by and between Checkmate Pharmaceuticals, Inc. and Regeneron Pharmaceuticals, Inc.
31.1*	Certification of the Principal Executive Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
31.2*	Certification of the Principal Financial Officer pursuant to Rule 13a-14(a) or 15d-14(a) of the Securities Exchange Act of 1934.
32.1*(1)	Certification of the Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	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 with applicable taxonomy extension information contained in Exhibits 101.*)

* Filed herewith

† Portions of this exhibit (indicated by asterisk) have been omitted in accordance with Item 601(b)(10) of Regulation S-K

(1) The certifications on Exhibit 32 hereto are deemed to be furnished with this Quarterly Report on Form 10-Q and will not be deemed “filed” for purposes of Section 18 of the Exchange Act or otherwise subject to the liability of that Section. Such certifications will not be deemed incorporated by reference into any filing under the Securities Act or the Exchange Act.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: August 12, 2021

CHECKMATE PHARMACEUTICALS, INC.

By: /s/ Barry Labinger
Barry Labinger
President, Chief Executive Officer and Director
(Principal Executive Officer)

By: /s/ Robert Dolski
Robert Dolski
Chief Financial Officer
(Principal Financial Officer)

SUPPLY AND NON-EXCLUSIVE LICENSE AGREEMENT

This **Supply and Non-Exclusive License Agreement** ("**Agreement**"), made as of this 6th day of May 2021 (the "**Effective Date**"), is by and between **Regeneron Pharmaceuticals, Inc.** ("**Regeneron**"), having a place of business at 777 Old Saw Mill River Road, Tarrytown, NY 10591-6707 and Checkmate Pharmaceuticals**.** ("**Sponsor**"), having a place of business at 245 Main Street, 2nd Floor, Cambridge MA 02142. Regeneron and Sponsor are each referred to herein individually as "**Party**" and collectively "**Parties**".

RECITALS

WHEREAS, Sponsor is developing the Sponsor Product;

WHEREAS, Regeneron is developing the Regeneron Product;

WHEREAS, Sponsor desires to sponsor and perform one or more clinical trials for the treatment of patients with various types of cancer, in which the Sponsor Product and the Regeneron Product would be dosed concurrently or in combination, as more particularly described in the Protocol for such clinical trial; and

WHEREAS, Regeneron desires to supply the Regeneron Product for the performance of each such clinical trial.

NOW, THEREFORE, in consideration of the premises and of the following mutual promises, covenants and conditions, the Parties, intending to be legally bound, mutually agree as follows:

1. DEFINITIONS. For all purposes of this Agreement, the capitalized terms defined in this Article 1 and throughout this Agreement shall have the meanings herein specified.

1.1. "**Affiliate**" means, with respect to either Party, a firm, corporation or other entity which directly or indirectly owns or controls said Party, or is owned or controlled by said Party, or is under common ownership or control with said Party. The word "**control**" means (i) the direct or indirect ownership of fifty percent (50%) or more of the outstanding voting securities of a legal entity, or (ii) possession, directly or indirectly, of the power to direct the management or policies of a legal entity, whether through the ownership of voting securities, contract rights, voting rights, corporate governance or otherwise.

1.2. "**Agreement**" means this agreement, as amended by the Parties from time to time, and as set forth in the preamble, together with all appendices attached or deemed attached hereto.

1.3. "**Applicable Law**" means applicable federal, state, local, national and supra-national laws, statutes, rules and regulations of a Governmental Authority, including any rules, regulations, guidelines or other requirements of any Regulatory Authority, that may be in effect from time to time during the Term and applicable to a particular activity hereunder, including: export control and economic sanctions regulations which prohibit the shipment of United States origin products and technology to certain restricted countries, entities and individuals; all applicable data protection requirements such as those specified in the EU Data Protection Directive (if applicable) and the regulations issued under the United States Health Insurance Portability and Accountability Act of 1996 ("**HIPAA**"); and laws and regulations governing payments to healthcare providers.

1.4. "**Business Day**" means any day other than a Saturday, Sunday or any public holiday in the country where the applicable obligations are to be performed.

1.5. "**cGMP**" means the current Good Manufacturing Practices officially published and interpreted by EMA, FDA and other applicable Regulatory Authorities that may be in effect from time to time and are applicable to the Manufacture of the Products.

1.6. "**Clinical Supply Quality Agreement**" means a clinical quality agreement entered into by the Parties for a particular Study in accordance with Section 9.11.

1.7. "**CMC**" means, with respect to a Product, the information contained in (or that would be contained in) the chemistry, manufacturing and controls section of an IND or application for Regulatory Approval for such Product in the United States, or the equivalent section of corresponding regulatory filings made outside the United States. For the avoidance of doubt, the information described in the preceding sentence is CMC information regardless of what document it is contained in or the form in which it is disclosed.

1.8. "**Combination**" means the use of the Sponsor Product and the Regeneron Product in concomitant or sequential administration.

1.9. "**Combination Invention**" means any Invention, the practice of which necessarily requires both (1) the presence or direct use of the Sponsor Product, or a TLR9 Agonist or the practice of any Sponsor Intellectual Property, on the one hand, and (2) the presence or direct use of the Regeneron Product or a PD-1 Antagonist or practice of any Regeneron Intellectual Property, on the other hand, in each case (1) and (2) when such Invention is Controlled by Sponsor, by Regeneron, or by both Sponsor and Regeneron.

1.10. "**Combination Patent Applications**" has the meaning set forth in Section 11.3.

1.11. "**Combination Patents**" has the meaning set forth in Section 11.3.

1.12. "**Confidential Information**" means any confidential and proprietary information or Know-How furnished or otherwise made available to one Party by the other Party pursuant to this Agreement or generated in the performance of this Agreement, except to the extent that it can be established by the receiving Party that such information or Know-How: (a) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the other Party as demonstrated by competent business records; (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party; (c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement; (d) was disclosed to the receiving Party by a Third Party who had no obligation to the disclosing Party not to disclose such information to others; or (e) was independently developed by the receiving Party without use of or access or reference to the disclosing Party's Confidential Information, as demonstrated by competent business records.

1.13. "Control" and "Controlled by" means, with respect to any Patent, Data or other Intellectual Property right, possession by a Party or its Affiliates (whether by ownership, license grant or other means) of the legal right to assign, grant the right to access or use, or to grant a license or a sublicense to, such Patent, data or other Intellectual Property right as provided for herein without violating the terms of any agreement or other arrangement between such Party (or any of its Affiliates) and any Third Party.

1.14. "**Delivery**" has the meaning set forth in Section 9.3 with respect to delivery of the Regeneron Product, and Section 9.4 with respect to the Sponsor Product.

1.15. "**Effective Date**" has the meaning set forth in the preamble.

1.16. "**EMA**" means the European Medicines Agency and any successor agency(ies) or authority having substantially the same function.

1.17. "**Exclusions List**" has the meaning set forth in the definition of Violation.

1.18. "**FDA**" means the United States Food and Drug Administration and any successor agency(ies) or authority having substantially the same function.

1.19. "**FFDCA**" means the United States Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., as amended from time to time, together with any rules, regulations and requirements promulgated thereunder (including all additions, supplements, extensions, and modifications thereto).

1.20. "**Force Majeure**" has the meaning set forth in Section 14.4.

1.21. "**Forecast**" has the meaning set forth in Section 9.2.

1.22. "**GCP**" means the Good Clinical Practices officially published by EMA, FDA and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) that may be in effect from time to time and are applicable to the testing of the Products.

1.23. "**Government Official**" means: (a) any officer or employee of a government or any department, agency or instrument of a government; (b) any Person acting in an official capacity for or on behalf of a government or any department, agency, or instrument of a government; (c) any officer or employee of a company or business owned in whole or part by a government; (d) any officer or employee of a public international or multilateral organization such as the World Bank, United Nations or the World Health Organization; who, when such Government Official is acting in an official capacity, or in an official decision making role, has responsibility for performing regulatory inspections, government authorizations or licenses, or otherwise has the capacity to make decisions for or on behalf of a government or any department, agency, or instrument of a government with the potential to affect the business of either of the Parties.

1.24. "**Governmental Authority**" means any court, agency, department, authority or other instrumentality of any national, supra-national, state, county, city or other political subdivision.

1.25. "**HIPAA**" has the meaning set forth in the definition of Applicable Law.

1.26. "**Invention**" means any development, modification, invention, derivative work or improvement, in each case whether or not patentable, including any Know How, and whether or not protectable as Intellectual Property, which is discovered, conceived, reduced to practice or developed or otherwise made by or on behalf of either Party or any of their Representatives in the performance of a Study Plan hereunder or otherwise generated in the performance of this Agreement.

1.27. "**IND**" means an application filed with a Regulatory Authority for authorization to commence clinical trials, including (a) an Investigational New Drug Application as defined in the FFDCA or any successor application or procedure filed with the FDA, (b) any equivalent of a United States IND in other countries or regulatory jurisdictions, (e.g., clinical trial application (CTA)), and (c) all supplements, amendments, variations, extensions and renewals thereof that may be filed with respect to the foregoing.

1.28. "**Intellectual Property**" means any and all of the following rights whether protected, created or arising under Applicable Law in the United States or any other jurisdiction: ideas, inventions, conceptions, Know-How, data, compositions, results, databases, documentation, reports, materials, writings, and other information, including Patents, trade secrets, registered designs, design rights, copyrights (including rights in computer software and database rights), whether registered or not, and all legal means of establishing rights in and to and the aforesaid rights or property similar to any of the foregoing, in any part of the world, together with the rights to apply for the registration of any such right. For the avoidance of doubt, Intellectual Property for purposes of this Agreement expressly excludes all Trademark rights.

1.29. "**IRB/EC**" has the meaning set forth in Section 4.1.

1.30. "**Joint Patent Application**" has the meaning set forth in Section 11.3.

1.31. "**Joint Patents**" has the meaning set forth in Section 11.3.

1.32. "**Jointly Owned Invention**" has the meaning set forth in Section 11.3.

1.33. "**Know-How**" means any proprietary information, innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, including manufacturing, use, process, structural, operational and other data and information, whether or not written or otherwise fixed in any form or medium, regardless of the media on which contained and whether or not patentable or copyrightable, that is not generally known or otherwise in the public domain.

1.34. "**Liability**" has the meaning set forth in Section 14.1.1.

1.35. "**Manufacture**," "**Manufactured**," or "**Manufacturing**" means all stages of the manufacture of a Product, including planning, purchasing, manufacture, processing, compounding, storage, filling, packaging, waste disposal, labeling, leafleting, testing, quality assurance, sample retention, stability testing, release, dispatch and supply, as applicable.

1.36. "**New Clinical Trial**" has the meaning set forth in Section 6.1.

1.37. "**Non-Conformance**" means, with respect to any Product, such Product deviates from (a) the applicable specifications for such Product (including, in the case of the Regeneron Product, the Specifications) or (b) any Applicable Law, including cGMP or health, safety or environmental protections.

1.38. "**Party**" has the meaning set forth in the preamble.

1.39. "**Patents**" means patents, patent disclosures and applications (including all patents issuing thereon), statutory invention registrations, division, continuations, continuations-in-part, substitute applications of the foregoing and any extensions, reissues, restorations and reexaminations thereof, and all patent rights provided by international treaties or conventions, whether created or arising under the laws of the United States or any other jurisdiction.

1.40. "**PD-1 Antagonist**" means any molecule that selectively binds to and interferes with or otherwise blocks signaling of the programmed cell death 1 receptor (PD-1) pathway, other than the Regeneron Product.

1.41. "**Person**" means any individual, sole proprietorship, partnership, corporation, business trust, joint stock company, trust, unincorporated organization, association, limited liability company, institution, public benefit corporation, joint venture, entity or governmental entity.

1.42. "**Pharmacovigilance Agreement**" means a pharmacovigilance agreement entered into by the Parties for a particular Study with respect to the exchange of safety information related to the Regeneron Product (alone or in the Combination) as set forth in Section4.5.

1.43. TLR9 Agonist means any molecule that activates Toll Like Receptor 9 pathway, other than the Sponsor Product.

1.44. "**Product**" means the Sponsor Product or the Regeneron Product.

1.45. "**Project Manager**" has the meaning set forth in Section 2.5.

1.46. "**Protocol**" means a written protocol created pursuant to Section 5.1 for a particular Study, that describes such Study and sets forth specific activities to be performed as part of such Study, as such protocol may be amended from time to time by the SCC.

1.47. "**Protocol Synopsis**" means a written summary of the procedural method and design of the applicable Study.

1.48. "**Regeneron**" has the meaning set forth in the preamble.

1.49. "**Regeneron Indemnitees**" has the meaning set forth in Section 14.1.1.

1.50. "**Regeneron Invention**" means any Invention, the practice of which necessarily requires the presence or direct use of the Regeneron Product or a PD-1 Antagonist or which requires the practice of any Regeneron Intellectual Property, and which is not a Combination Invention.

1.51. "Regeneron Intellectual Property" means Intellectual Property Controlled by Regeneron as of the Effective Date or during the Term pertaining to the Regeneron Product or a PD-1 Antagonist, including all such Intellectual Property of Regeneron that is provided to Sponsor under this Agreement or is reasonably necessary for the conduct of a Study in accordance with this Agreement.

1.52. "**Regeneron Product**" means LIBTAYO® (cemiplimab) provided by Regeneron hereunder. [Redacted]

1.53. "**Regulatory Approvals**" means, with respect to a Product and a country, any and all permissions (other than the Manufacturing approvals) required to be obtained from Regulatory Authorities and any other competent authority for the development, registration, importation, use (including use in clinical trials), distribution, sale or marketing of such Product in such country, including any pricing or reimbursement approvals.

1.54. "**Regulatory Authority**" means any applicable supra-national, federal, national, regional, state, provincial, or local governmental or regulatory authority, agency, department, bureau, commission, council or other entity (e.g., the FDA and EMA) regulating or otherwise exercising authority with respect to activities contemplated in this Agreement, including the development and commercialization of Products in the Territory.

1.55. "**Representatives**" means, with respect to a Party, its Affiliates or any employees, directors, contractors, agents or consultants of such Party or its Affiliates.

1.56. "**Restricted Period**" means, with respect to a particular Study and Study Field, [Redacted]

1.57. [Redacted]

1.58. "**SCC Dispute**" has the meaning set forth in Section 2.4.

1.59. "**Sponsor**" has the meaning set forth in the preamble.

1.60. "**Sponsor Indemnitees**" has the meaning set forth in Section 14.1.2.

1.61. "Sponsor Intellectual Property" means Intellectual Property Controlled by Sponsor as of the Effective Date or during the Term pertaining to Sponsor Product and including all Intellectual Property of Sponsor that is provided to Regeneron under this Agreement or is reasonably necessary for the conduct of a Study in accordance with this Agreement.

1.62. "**Sponsor Invention**" means any Invention, the practice of which necessarily requires the presence or direct use of the Sponsor Product or a TLR9 Agonist, or which requires the practice of any Sponsor Intellectual Property, and which is not a Combination Invention

1.63. "**Sponsor Product**" means CMP-001. [Redacted]

1.64. "**Specifications**" means, with respect to Regeneron Product, the set of specifications for such Product as set forth in the applicable Clinical Supply Quality Agreement.

1.65. "**Study**" means each clinical trial to be conducted by Sponsor under this Agreement pursuant to an executed Study Plan involving the concomitant or sequenced administration of the Combination for the treatment of patients in the applicable Study Field, as more particularly described in the applicable Protocol.

1.66. "**Study Completion**" has the meaning set forth in Section 3.9.

1.67. "**Study Coordination Committee**" or "**SCC**" has the meaning set forth in Section 2.1.

1.68. "**Study Data**" means, with respect to a particular Study, all data (including raw data) and results (including Study Results) generated in the performance of the Study Plan for such Study and including results obtained from testing or analysis of biological samples as part of a Study pursuant to the Protocol, if applicable, and any relevant monotherapy data generated in the course of the Study pertaining to the Sponsor Product within the Study Field.

1.69. "**Study Field**" means, with respect to a particular Study, the specific type(s) of cancer identified in the Study Plan.

1.70. "**Study Plan**" means, with respect to a particular Study for a particular cancer and patient population, the plan, as it may be amended from time to time upon mutual written agreement of the Parties, for the clinical evaluation of the Combination in such Study for which Regeneron Product is used. The initial Study Plan for the first Study is attached hereto, as Appendix B.

1.71. "**Study Results**" has the meaning set forth in Section 3.9.

1.72. "**Term**" has the meaning set forth in Section 7.1.

1.73. "**Territory**" means worldwide.

1.74. "**Third Party**" means any Person other than Sponsor, Regeneron or their respective Affiliates.

1.75. "Trademark" means any trademark, trade name, service mark, service name, brand, trade dress, logo, slogan, tag line or other indicia or origin of ownership, whether registered or unregistered, including the goodwill and activities associated with each of the foregoing.

1.76. "**Transfer**" shall mean any sale, license, transfer, other disposal or the granting of any option to do any of the foregoing.

1.77. "**Violation**" means that a Party or any of its officers or directors or any other personnel (or other permitted agents of a Party performing activities hereunder) has been: (1) convicted of any of the felonies identified among the exclusion authorities listed on the U.S. Department of Health and Human Services, Office of Inspector General (OIG) website, including 42 U.S.C. 1320a-7(a) (http://oig.hhs.gov/exclusions/authorities.asp); (2) identified in the OIG List of Excluded Individuals/Entities (LEIE) database (http://exclusions.oig.hhs.gov/) or listed as having an active exclusion in the System for Award Management (http://www.sam.gov); (3) listed by any US Federal agency as being suspended, debarred, excluded or otherwise ineligible to participate in Federal procurement or non-procurement programs, including under 21 U.S.C. 335a (http://www.fda.gov/ora/compliance_ref/debar/) (each of (1), (2) and (3) collectively the "**Exclusions Lists**"); or (4) otherwise ineligible under Applicable Law (including United States law or any foreign equivalent) or any government programs for the performance of the Study or any other activities under this Agreement.

2. STUDY COORDINATION.

2.1. Formation. As soon as practical after the Effective Date (but in all cases within thirty (30) days thereafter), the Parties shall form a study coordination committee (the **"Study Coordination Committee"** or "**SCC**"), made up of an equal number of representatives of Regeneron and Sponsor. SCC members will be agreed by both Parties, such agreement not to be unreasonably withheld or delayed.

2.2. Meetings. The SCC shall meet as soon as practicable after the Effective Date (with respect to the initial Study) or the effective date of each Study Plan (for each other Study) and then once each calendar quarter, or at such other frequency as is mutually determined by the Parties, until the Study Results for the applicable Study have been provided to Regeneron.

2.3. Role. The SCC shall have the responsibility of coordinating and overseeing the conduct of each Study (and other related activities set forth in the applicable Study Plan, including regulatory activities) and shall enable the exchange of information between the Parties. In particular, the SCC is empowered to:

(i) serve as a forum for discussing Study activities;

(ii) review and approve the initial Study Plan for each Study and any amendments to the applicable Study Plan; For Clarity, Regeneron's approval shall only be required for decisions relating to the Combination or the Regeneron Product.

(iii) review and approve the applicable Protocol for each Study and any amendments thereto;

(iv) serve as a forum for discussing strategies to obtain Regulatory Approvals necessary to conduct the applicable Study and for coordinating all regulatory activities (including communications with Regulatory Authorities) for the applicable Study;

(v) serve as a forum for discussing strategies for any diagnostic product to be included in the applicable Study (including the selection of any third party to develop or provide any such diagnostic product for the applicable Study);

(vi) serve as a forum for discussing matters relating to supply and Manufacturing, including Forecasts, specifications, Delivery and Non-Conformances;

(vii) establish and oversee joint sub-teams agreed by the Parties to oversee particular projects or activities within the purview of the SCC; and

(viii) perform such other functions as are set forth herein, or as the Parties may mutually agree in writing.

2.4. Decision Making. The SCC will attempt to reach decisions by consensus, with the Sponsor representatives having collectively one vote and the Regeneron representatives having collectively one vote. If consensus is not achieved on any matter within thirty (30) days ("**SCC Dispute**"), the matter will be escalated to the Sponsor CEO and the Regeneron Executive Vice President, Global Clinical Development, provided however that (1) in the event that the matter relates solely to the Regeneron Product (including the dose and dosing regimen for the Regeneron Product) or any diagnostic for the Regeneron Product alone, Regeneron shall have final decision making authority and (2) in the event that the matter relates solely to the Sponsor Product (including the dose and dosing regimen for the Sponsor Product) or any diagnostic for the Sponsor Product alone, Sponsor shall have final decision making authority. If such SCC Dispute is not addressed by clause (1) or (2) of the previous sentence, the dispute shall be resolved as provided for in Article 19.

2.5. Project Manager. Each Party shall designate a project manager (the "**Project Manager**") who shall be responsible for implementing and coordinating activities, and facilitating the exchange of information between the Parties, with respect to a given Study. The Project Managers shall endeavor to ensure clear and responsive communication between the Parties and the effective exchange of information and shall serve as the primary point of contact for any issues arising under this Agreement. The Project Managers shall have the right to attend all SCC meetings and may bring to the attention of the SCC any matters or issues either of them reasonably believes should be discussed and shall have such other responsibilities as the Parties may mutually agree in writing. Prior to any meeting of the SCC, the Sponsor Project Manager shall provide an update in writing to the Regeneron Project Manager, which update shall contain information about overall Study progress, recruitment status, interim analysis (if results are available), final analysis and other information relevant to the conduct of the applicable Study and the applicable Study Data.

3. CONDUCT OF THE STUDY.

3.1. General; Study Plans. The Parties shall perform the initial Study in accordance with this Agreement, including the Study Plan for such Study, which is attached hereto. For each other Study that the Parties agree to perform under this Agreement, the Parties are to complete and execute a Study Plan, which, among other items, shall include the Protocol Synopsis or the draft Protocol attached hereto as Appendix A, for such Study and the obligations and activities to be performed by each Party in connection with such Study (including regulatory activities). Each Study Plan, once mutually agreed, shall be signed by an authorized representative of each Party and, once fully executed, shall be deemed incorporated into this Agreement by this reference. Sponsor shall act as the sponsor of each Study and shall hold each IND relating to each Study. Sponsor shall be solely responsible for designing each Study and for the Protocol therefor, provided that the SCC shall review and approve the Protocol pursuant to Section 2.3 and subject to each Party's decision-making rights as set forth in Section 5.2.

3.2. Compliance. Subject to Section 5.2, Sponsor shall be responsible for operational execution and management of, and will use commercially reasonable efforts to conduct, each Study. Sponsor shall ensure that each Study is performed in accordance with this Agreement, the Protocol for such Study, and all Applicable Laws, including GCP, and shall ensure that its Affiliates and subcontractors performing activities under this Agreement do the same.

3.3. No Violation. Neither Party shall knowingly employ or subcontract with any Person that is in Violation. Each Party hereby certifies that it has not employed or otherwise used in any capacity and will not employ or otherwise use in any capacity the services of any Person in Violation in performing any portion of any Study or other activities under this Agreement, and that each Party has, as of the Effective Date, screened itself, and its officers and directors, against the Exclusions Lists and that it has informed the other Party whether it or any of its officers or directors is in Violation. Each Party shall notify the other Party in writing immediately if any such Violation comes to its attention with respect to any Person performing activities under this Agreement, and shall, with respect to any such Person in Violation, promptly remove such Person from performing activities or acting in any function or capacity related to any Study or otherwise related to activities under this Agreement.

3.4. Records and Reports. Sponsor shall maintain reports and all related documentation in good scientific manner and in compliance with Applicable Law in connection with each Study. Sponsor shall provide to Regeneron all Study information and documentation reasonably requested by Regeneron to enable Regeneron to (i) comply with any of its legal, regulatory and/or contractual obligations, or any request by any Regulatory Authority, related to the Regeneron Product or (ii) determine whether the applicable Study has been performed in accordance with this Agreement.

3.5. Consent. Sponsor shall ensure that all patient authorizations and consents required under HIPAA, the General Data Protection Regulation (Regulation (EU) 2016/679) (if applicable) or any other similar Applicable Law in connection with each Study are obtained, are valid and permit the sharing of Study Data with Regeneron.

3.6. Study Data Ownership and Copies. [Redacted]

3.7. Restrictions on Use. [Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

3.8. Samples. [Redacted]

[Redacted]

3.9. Report. Within six (6) months following Study Completion of a given Study in the Study Field, Sponsor shall provide Regeneron with a preliminary draft of the final clinical study report and the tables and listings for such Study ("**Study Results**"), in electronic form. Sponsor shall consider in good faith any comments made by Regeneron to such report, and shall not include any statements pertaining to the Regeneron Product (or its use in the Combination) that Regeneron objects to in writing within thirty (30) days' of receipt of the draft report, Sponsor shall provide Regeneron with the final version of the clinical study report within a reasonable time following Sponsor's receipt of Regeneron's comments, but in no event later than the date that is three (3) months after such receipt (or, if Regeneron does not provide comments, after the expiration of the thirty (30) day period following Regeneron's receipt of the draft clinical study report). "**Study Completion**" for each Study shall occur upon final database lock of such Study.

3.10. License Grants.

3.10.1. Subject to the terms of this Agreement, with respect to each Study, Regeneron hereby grants to Sponsor a non-exclusive, worldwide, non-transferable, royalty-free, limited license under Regeneron Intellectual Property for the Term of this Agreement, solely to the extent necessary to discharge Sponsor's obligations under this Agreement with respect to the conduct of its activities under the Study Plan for such Study.

3.10.2. Subject to the terms of this Agreement, with respect to each Study, Sponsor hereby grants to Regeneron a non-exclusive, worldwide, non-transferable, royalty-free, limited license under Sponsor Intellectual Property for the Term of this Agreement, solely to the extent necessary to discharge Regeneron's obligations under this Agreement with respect to the conduct of its activities under the Study Plan for such Study.

3.11. Subcontractors; Study Sites, Investigators, and Agreement. Each Party may delegate its activities under a given Study Plan to its own Affiliates without the other Party's consent. Each Party shall have the right to subcontract any portion of its obligations hereunder to Third Party subcontractors without the other Party's consent. Each Party shall remain solely and fully liable for the performance of its Affiliates and subcontractors. Subject to the applicable Clinical Supply Quality Agreement, either Party may, without consulting the other Party, subcontract Manufacturing with regards to either the Sponsor Product or the Regeneron Product, as applicable, to be provided for such Study. Each Party shall ensure that each of its Affiliates and subcontractors performs its obligations in a manner no less restrictive than the terms of this Agreement, including the Appendices attached hereto, and to the extent consistent with pre-existing Third Party agreements; the

Parties agree that Sponsor shall have no obligation to amend any existing Third Party agreements. Each Party shall obtain and maintain copies of documents relating to the obligations performed by such Affiliates and use commercially reasonable efforts to obtain and have maintained documents relating to the obligations performed by such subcontractors and that are required to be provided to the other Party under this Agreement. Sponsor shall ensure that all clinical trial agreements with Study sites do not conflict with the terms of this Agreement.

4. REGULATORY AND SAFETY.

4.1. Approvals. Sponsor shall ensure that all directions from any Regulatory Authority or institutional review board or ethics committee ("**IRB/EC**") with jurisdiction over a Study are followed. Further, Sponsor shall ensure that all IRB/EC approvals, customs clearances, and Regulatory Approvals for each Study from any Regulatory Authority and/or IRB/EC with jurisdiction over such Study are obtained prior to initiating performance of such Study. Sponsor will be responsible for filing the IND for each Study.

4.2. Interactions with Regulatory Authorities. Regeneron shall have the right (but no obligation) to participate in any discussions between Sponsor and any Regulatory Authority regarding matters related specifically to the Regeneron Product in the Study, and, to the extent reasonably practicable, Sponsor shall provide sufficient advance notice (at least five (5) Business Days, unless a shorter response period is required by the applicable Regulatory Authority, in which case such notice shall be provided to Regeneron as soon as reasonably practicable) to Regeneron of any such discussions. If Sponsor receives any correspondence, comments or other inquiries from a Regulatory Authority that pertain to the Combination or the Regeneron Product, Sponsor shall promptly provide such correspondence, comments or inquiries to Regeneron at least five (5) Business Days before any response is due, unless a shorter response period is required by the applicable Regulatory Authority, in which case such correspondence, comments or inquiries shall be provided to Regeneron as soon as reasonably practicable. For all correspondence, comments or inquiries from a Regulatory Authority that pertain to the Combination, but not solely to the Regeneron Product, Regeneron may provide, and Sponsor will consider in good faith, Regeneron's reasonable comments provided within such five (5) Business Day (or if applicable, shorter) period. If such correspondence, comments or other inquiries pertain solely to the Regeneron Product, Regeneron will promptly review and respond within five (5) Business Days (or such shorter period as may be required), and Sponsor will forward such response to the Regulatory Authority on Regeneron's behalf. With respect to any correspondence, comments or other inquiries from a Regulatory Authority regarding a Study that pertain specifically to the Regeneron Product, Regeneron shall also be permitted to respond directly to such Regulatory Authority if Regeneron's response includes proprietary subject matter regarding Regeneron's Product that is not to be shared with the Sponsor. Subject to the conditions set forth in the foregoing sentence, if Regeneron elects to respond directly to such Regulatory Authority, Regeneron shall be responsible for providing its response within the deadline prescribed by such Regulatory Authority (if none, Regeneron shall nonetheless provide such response promptly).

4.3. Right of Reference. [Redacted]

4.4. Physician Payment Reporting. To the extent that Regeneron is required by Applicable Law to report payments made by Sponsor and its subcontractors to physicians or teaching hospitals, Sponsor shall provide on a timely basis, in consultation with Regeneron, all information necessary to comply with Applicable Law.

4.5. Adverse Event Reporting. Sponsor will be solely responsible for compliance with all Applicable Law pertaining to safety reporting for each Study and related activities. As soon as reasonably practical after the Effective Date, but, in any event, prior to the first dosing of the first patient with the Regeneron Product in the first Study, the Parties will agree upon and execute a Pharmacovigilance Agreement. For all other Studies, the Parties will execute a Pharmacovigilance Agreement as soon as reasonably practicable following the execution of the Study Plan for such Study, but, in any event, prior to the first dosing of the first patient with a Product in the applicable Study. Each Pharmacovigilance Agreement will establish appropriate processes and timelines for exchanging relevant safety data to fulfill local and international regulatory reporting obligations and to facilitate appropriate safety monitoring of the Regeneron Product (alone or in the Combination) in the applicable Study, and shall include safety data exchange procedures governing the coordination, collection, reporting, and exchange of information concerning any adverse experiences, pregnancy reports, and any other safety information arising from or related to the use of the Regeneron Product (alone or in the Combination) in the applicable Study. Such procedures shall be in accordance with, and enable the Parties and their Affiliates to fulfill, all local and international regulatory reporting obligations to Regulatory Authorities and the clinical investigators.

5. PROTOCOL AND RELATED DOCUMENTS.

5.1. Protocol. A Protocol Synopsis or agreed draft Protocol for the initial Study has been agreed to by the Parties as of the Effective Date and a draft Protocol is attached hereto as Appendix A. Within sixty (60) days after the Effective Date, but, in any event, no later than sixty (60) days prior to any meeting with FDA to discuss the draft Protocol for the initial Study if not attached to Appendix A, the Parties shall agree upon a Protocol for such Study, with reference to the draft Protocol attached hereto as Appendix A, subject to each Party's decision-making rights as set forth in Section 5.2. For each other Study, the Sponsor shall prepare and provide to Regeneron a Protocol and, if mutually agreed to by the Parties pursuant to Section 2.3, such Protocol shall be included in the applicable Study Plan executed by the Parties. Any changes to the Protocol (whether or not material) shall require mutual written consent subject to each Party's decision-making rights as set forth in Section 5.2.

5.2 **Decision Making.** Notwithstanding anything to the contrary in this Agreement including the agreed draft Protocol included in Appendix A, each Party, in its sole discretion, will determine the dose and dosing regimen for such Party's Product and its use in the Combination for any new Study Plan or Protocol not attached to the Agreement as of the Effective Date and will have the final decision on all matters relating to such Party's Product and its use in the Combination (including any changes to the Protocol that would require such Party to provide additional Product) and any information regarding such Party's Product included in the Protocol. In addition, each Party will determine matters relating to any diagnostic to be used for its Product.

5.3 **Consent Form.** Sponsor shall prepare the patient informed consent form for each Study (it being understood that the portion of the informed consent form relating to the Regeneron Product will be provided by Regeneron). Sponsor shall ensure that any such patient informed consent form complies with GCP requirements and Applicable Laws.

5.4 **Financial Disclosure Information.** Sponsor shall (a) track and collect financial disclosure information from all "clinical investigators" involved in each Study and (b) prepare and submit the certification and/or disclosure of the same in accordance with all Applicable Law, including, but not limited to, Part 54 of Title 21 of the United States Code of Federal Regulations (Financial Disclosure by Clinical Investigators) and related FDA Guidance Documents. Sponsor shall track and collect from all "clinical investigators" involved in each Study one (1) "combined" certification and/or disclosure form for both Regeneron and Sponsor. For purposes of this Section 5.3, the term "clinical investigators" shall have the meaning set forth in Part 54.2(d) of Title 21 of the United States Code of Federal Regulations.

6. CERTAIN COVENANTS.

6.1 Clinical Trials. [Redacted]

[Redacted]

6.2 Notifications of Potential Transfers in the Study Field. [Redacted]

6.3 No further obligations. Nothing in this Agreement obligates either Party to any further agreement or collaboration related to the products or studies in this Agreement.

7. TERM AND TERMINATION.

7.1 Term. The term of this Agreement shall commence on the Effective Date and shall continue in full force and effect until completion of all of the obligations of the Parties hereunder for all Studies, or until terminated by either Party pursuant to this Article 7 (the "**Term**"). The Parties shall be entitled to enter into Study Plans during the period of time commencing on the Effective Date and expiring on the fifth (5th) anniversary of the Effective Date.

7.2 **Unsafe Use of Regeneron Product.** In the event that (a) Regeneron in good faith believes that the Regeneron Product is being used in a manner that represents an unjustified risk to the safety of patients in the Study Field, and Sponsor fails to incorporate changes into the Protocol requested in writing by Regeneron to address such issue, or (b) the Regeneron Product is not being used as described in the Protocol, Regeneron has the right to immediately terminate this Agreement (or any Study being performed under this Agreement) and the supply of the Regeneron Product upon written notice to Sponsor.

7.3 Certain Additional Termination Rights. Either Party may terminate a Study Plan in the event that (1) patient screening for the Study does not commence within twelve (12) months after (a) the Effective Date, with respect to the initial Study, or (b) the execution of the applicable Study Plan, with respect to each other Study or (2) initial patient recruitment for Stage 1 (as defined in the Study Plan) of a Study Plan is not completed within 18 months of (a) the first study subject dosed, with respect to each Study under this Agreement. Sponsor may terminate any Study and related Study Plan if the Parties do not agree to any Protocol or amendment related to such Study within 60 Business Days of the Effective Date. If either Party terminates a Study Plan under this Section 7.3, Sponsor shall return to Regeneron any Regeneron Product it received in connection with such Study Plan. If such Product has past its expiration date, Sponsor shall reimburse Regeneron for such unusable Product if the failure to enroll patients is due to Sponsor's failure to use commercially reasonable efforts to enroll trial in a timely matter.

7.4 Termination for Material Breach. Either Party may terminate this Agreement if the other Party commits a material breach of this Agreement, and such material breach remains uncured thirty (30) days after receipt of written notice thereof from the non-breaching Party; provided that if such material breach cannot reasonably be cured within thirty (30) days, the breaching Party shall be given a reasonable period of time to cure such breach not to exceed one-hundred and twenty (120) days; provided further, that if such material breach is incapable of cure, then the notifying Party may terminate this Agreement effective after the expiration of such thirty (30)- day period. Notwithstanding the foregoing, if any such material breach relates solely to a particular Study and does not reasonably relate to or affect the breaching Party's performance of (or ability to perform) any other Study, then the non-breaching Party shall only have the right under this Section 7.4. to terminate such Study to which the breach relates. If Regeneron terminates for material breach by Sponsor, then Sponsor shall reimburse Regeneron for Regeneron Product it received in connection with the terminated Study to which the breach relates.

7.5 Pharmacovigilance Agreement. Either Party may terminate a particular Study under this Agreement immediately upon written notice to the other Party if (a) the Parties do not execute a Pharmacovigilance Agreement for such Study within the timeframe set forth in Section 4.5 or (b) the terminating Party determines in good faith that such Study may unreasonably adversely affect patient safety.

7.6 Mutual Termination for Regulatory Action; Other Reasons. Either Party may terminate a particular Study (in whole or in part on a country-by-country basis) immediately upon written notice to the other Party in the event that any Regulatory Authority takes any action, or raises any objection, that prohibits the terminating Party from supplying its Product for purposes of such Study. Additionally, either Party shall have the right to terminate a particular Study immediately upon written notice to the other Party in the event that it determines, in its sole discretion, to discontinue development and/or commercialization of its Product within the Study Field for such Study, for medical, scientific or legal reasons. Notwithstanding the foregoing, Regeneron shall continue to supply the Regeneron Product for any already activated sites at the time of termination for patients which have already been enrolled in such trial for the duration of such individual treatment.

7.7 Mutual Termination for Corruption. Either Party shall be entitled to terminate this Agreement immediately upon written notice to the other Party, if such other Party fails to perform its obligations in accordance with Section 13.5. The non-terminating Party shall have no claim against the terminating Party for compensation for any loss of whatever nature by virtue of the termination of this Agreement in accordance with this Section 7.7. To the extent (and only to the extent) that the laws of the Territory provide for any such compensation to be paid to the non-terminating Party upon the termination of this Agreement, the non-terminating Party hereby expressly agrees (to the extent possible under the laws of the Territory) to waive or to repay to the Party terminating this Agreement any such compensation.

7.8 Survival. The provisions of Sections 3.4-3.9, 4, 7.3-7.4, this Section 7.8, 7.9 and Articles 1 (to the extent definitions are used in other surviving provisions), 10-23 shall survive the expiration or termination of this Agreement.

7.9 Effects of Termination.

7.9.1 No Prejudice. Termination of this Agreement shall be without prejudice to any claim or right of action of either Party against the other Party for any prior breach of this Agreement.

7.9.2 Return of Regeneron Product. Except as otherwise set forth in this Section 7, in the event that this Agreement or any Study is terminated, or in the event Sponsor remains in possession (including through any Affiliate or subcontractor) of Regeneron Product at the end of the Term, Sponsor shall, at Regeneron's sole discretion, promptly either return or destroy all such unused Regeneron Product pursuant to Regeneron's instructions subject to Section 7.9.4 below. If Regeneron requests that Sponsor destroy the unused Regeneron Product, as the case may be, Sponsor shall provide written certification of such destruction. In the event Sponsor terminates this Agreement pursuant to Section 7.4 except as otherwise agreed, all such return of unused Regeneron Product shall be at Regeneron's sole cost and expense and in all other instances shall be at Sponsor's sole cost and expense.

7.9.3 Confidential Information. Upon termination of this Agreement, each Party and its Affiliates shall promptly return to the other Party or destroy any Confidential Information of the other Party (other than Study Data and Inventions in which such Party has an ownership interest) furnished to the receiving Party by the other Party, except that the receiving Party shall have the right to retain one copy for record keeping purposes and such retained copy shall be maintained in accordance with the non-disclosure and non-use restrictions set forth in Article 10.

7.9.4 Wind-Down. Upon receipt by either Party of a termination notice of this Agreement, subject to the terms of this Article 7, Sponsor shall submit a wind-down plan to Regeneron setting forth the tasks reasonably necessary or required in connection with the orderly termination of the Study and the proper plan for managing the patients enrolled in the Study, including any actions reasonably required to safely close out the Study or required by Applicable Laws. [Redacted]

8. COSTS OF STUDY PLAN. [Redacted]

9. SUPPLY AND USE OF THE PRODUCTS.

9.1 Supply. Sponsor and Regeneron will each use commercially reasonable efforts to supply, or cause to be supplied, sufficient quantities of Sponsor Product and Regeneron Product, respectively, to satisfy the requirements of the Study Plan for each Study. Each Party shall also provide to the other Party a contact person for coordination of Product supply under this Agreement. Each Party shall supply its Product in accordance with the terms of this Agreement. Each Party shall notify the other Party as promptly as possible in the event of any Manufacturing delay that is likely to adversely affect supply of a Product as contemplated by this Agreement, and Sponsor and Regeneron shall cooperate to seek to promptly resolve such issue. Notwithstanding the foregoing, or anything to the contrary herein, in the event that either Party is not supplying its Product in accordance with the terms of this Agreement, or is not allocating its Product under procedures agreed to under Section 9.9, then the other Party shall have no obligation to supply its Product, or may allocate proportionally. This Agreement does not create any obligation on the part of Regeneron to provide the Regeneron Product for any activities other than as set forth in a Study Plan, nor does it create any obligation on the part of Sponsor to provide the Sponsor Product for any activities other than those set forth in a Study Plan.

9.2 Forecast. For each Study, the Study Plan shall include a forecast of quantities and delivery dates for the requirements of the Regeneron Product to be supplied under this Agreement for such Study (each a "**Forecast**"). If there is any change in the quantity of Regeneron Product required for a Study, Sponsor shall promptly notify Regeneron of such change upon becoming aware of the same. Promptly following receipt of any requested change to any Forecast, Regeneron shall notify Sponsor of its ability to supply the requirements of the modified Forecast. The Parties shall discuss the changes to the Forecast and Regeneron's ability to meet any such changes. In the event Regeneron notifies Sponsor that it is able to meet such requirements, then such modified Forecast shall be deemed accepted by Regeneron. If Regeneron notifies Sponsor that it is not able to meet such requirements, then Regeneron, at its option, may prepare and provide Sponsor with a time schedule for additional Manufacturing of the Regeneron Product to satisfy such requirements. Otherwise, the previous Forecast shall apply.

9.3 Delivery; Storage. Regeneron will deliver the Regeneron Product DAP (INCOTERMS 2010) to Sponsor's, or its designee's, location as specified by Sponsor and agreed to by Regeneron ("**Delivery**" with respect to such Regeneron Product). Risk of loss for the Regeneron Product shall transfer from Regeneron to Sponsor at Delivery. All costs associated with the subsequent transportation, warehousing and distribution of Regeneron Product, including all importation or customs taxes or duties, shall be borne by Sponsor. Sponsor will: (a) take delivery of the Regeneron Product supplied hereunder; (b) perform the acceptance procedures allocated to it under the Clinical Supply Quality Agreement; (c) subsequently label and pack (in accordance with Section9.6), and promptly ship the Regeneron Product to the Study sites, in compliance with cGMP, GCP and other Applicable Law and the Clinical Supply Quality Agreement; and (d) provide, at the reasonable request of Regeneron, the following information: any applicable chain of custody forms, in transport temperature recorder(s), records and receipt verification documentation, such other transport or storage documentation as may be reasonably requested by Regeneron, and usage and inventory reconciliation documentation related to the Regeneron Product.

9.4 Sponsor Product. As between the Parties, Sponsor is solely responsible, at its own cost, for supplying (including all Manufacturing, acceptance and release testing) the Sponsor Product for each Study Plan, and the subsequent handling, storage, transportation, warehousing and distribution of the Sponsor Product supplied hereunder and shall use commercially reasonable efforts to perform such activities. Sponsor shall ensure that all such activities are conducted in

compliance with cGMP, GCP and other Applicable Law and that the Sponsor Product meets Sponsor's specifications. For purposes of this Agreement, the "**Delivery**" of a given quantity of the Sponsor Product shall be deemed to occur when such quantity is packaged for shipment to a Study site or other site as set forth herein.

9.5 Representations and Warranties. [Redacted]

9.6 Labeling and Packaging. Regeneron shall provide the Regeneron Product to Sponsor in the form of unlabeled vials, and Sponsor shall be responsible for labeling, packaging and leafleting such Regeneron Product in accordance with the terms and conditions of the applicable Clinical Supply Quality Agreement and otherwise in accordance with all Applicable Law, including applicable cGMP, GCP, and health, safety and environmental protections. Sponsor shall be responsible for labeling, packaging and leafleting of the Sponsor Product in accordance with all Applicable Law, including applicable cGMP, GCP, and health, safety and environmental protections.

9.7 Use, Handling and Storage. Sponsor shall (a) use the Regeneron Product solely for purposes of performing the Study for which such Regeneron Product was provided; (b) not use the Regeneron Product in any manner that is inconsistent with this Agreement or for any commercial purpose; and (c) use, store, transport, handle and dispose of the Regeneron Product in compliance with Applicable Law and the applicable Clinical Supply Quality Agreement, as well as all instructions of Regeneron. Sponsor shall not reverse engineer, reverse compile, disassemble or otherwise attempt to derive the composition or underlying information, structure or ideas of the Regeneron Product, and in particular shall not analyze the Regeneron Product by physical, chemical or biochemical means except as necessary to perform its obligations under the applicable Clinical Supply Quality Agreement.

9.8 Release. A certificate of analysis shall accompany each shipment of the Regeneron Product to Sponsor. Sponsor shall be responsible for any failure of the Regeneron Product to meet the Specifications to the extent caused by shipping, storage or handling conditions after Delivery to Sponsor hereunder. Sponsor shall, upon receipt of Regeneron Product and within the time defined in the applicable Clinical Supply Quality Agreement, perform the acceptance (including testing, if any) procedures allocated to it under such Clinical Supply Quality Agreement. Sponsor shall be solely responsible for taking all steps necessary to determine that Regeneron Product or Sponsor Product, as applicable, is suitable for release before making such Regeneron Product or Sponsor Product, as applicable, available for human use, consistent with the Clinical Supply Quality Agreement.

9.9 Shortage; Allocation. In the event of a shortage of a Product such that a Party reasonably believes that it will not be able to fulfill its supply obligations hereunder with respect to its Product, such Party will provide prompt written notice to the other Party thereof (including the quantity of its Product that such Party reasonably determines it will be able to supply) and, upon request, the Parties will promptly discuss such situation (including how the quantities of Product that such Party is able to supply hereunder will be allocated within the applicable Study). In such event, the Party experiencing such shortage shall use its commercially reasonable efforts to remedy the situation giving rise to such shortage as soon as practicable and to take action to minimize the impact of the shortage on the applicable Study.

9.10 Records. Sponsor will keep complete and accurate written records pertaining to its use and disposition of Regeneron Product (including its storage, shipping (cold chain) and chain of custody activities) and, upon the request of Regeneron made with reasonable notice, will make such records open to review by Regeneron for the purpose of conducting investigations for the determination of Regeneron Product safety and/or efficacy and Sponsor's compliance with this Agreement with respect to the Regeneron Product. Such requests for review by Regeneron shall not be made more than once per calendar year unless Regeneron has a reasonable basis for seeking more frequent review. Each Party shall maintain complete and accurate records pertaining to its Manufacture of its Product supplied hereunder, and, upon request of the other Party, will make such records open to review by such other Party for the purpose of confirming such Party's compliance with this Agreement with respect to its Manufacturing obligations hereunder. Such requests for review by the other Party shall not be made more than once per calendar year unless such Party has a reasonable basis for seeking more frequent review.

9.11 Quality. The Parties (or their Affiliates) shall enter into a Clinical Supply Quality Agreement for each Study with respect to the quality assurance of the Regeneron Product supplied by Regeneron hereunder for such Study. The Parties will execute the Clinical Supply Quality Agreement for the initial Study as soon as reasonably practicable following the Effective Date, but in any event, prior to the initiation of the shipment of Regeneron Product for a Study. For all other Studies, the Parties will execute the Clinical Supply Quality Agreement as soon as reasonably practicable following the execution of the Study Plan for such Study, but in any event, prior to the initiation of the shipment of Regeneron Product for such Study. Quality matters related to the Manufacture of Regeneron Product for a particular Study shall be governed by the terms of the Clinical Supply Quality Agreement for such Study, in addition to the relevant quality terms of this Agreement, provided that if there is a conflict between the terms of the applicable Clinical Supply Quality Agreement and the terms of this Agreement with respect to a particular Study, the terms of the Clinical Supply Quality Agreement shall govern with respect to any technical or quality matters and otherwise the terms of this Agreement shall govern.

Each Party shall implement and perform operating procedures and controls for sampling, stability and other testing of its Product, and for validation, documentation and release of its Product and such other quality assurance and quality control procedures as are required by cGMPs and the applicable Clinical Supply Quality Agreement. Audit and inspection rights, recalls, rejection and non-conformances, in each case, with respect to the Regeneron Product and Sponsor Product, are governed by the terms of the applicable Clinical Supply Quality Agreement.

9.12 Placebo. Where applicable, Sponsor shall be responsible for the Manufacture and supply of placebo, comparator products and diagnostic products, in each case, as applicable and to the extent set forth in the applicable Study Plan; provided that, except as otherwise set forth in a Study Plan, Regeneron shall be responsible for the Manufacture and supply of placebo and diagnostic products for the Regeneron Product. The provisions of this Article 9 applicable to the supply of Product shall also apply to any such placebo or comparator product.

9.13 Supporting Documentation. After release of Regeneron Product by Regeneron (as described in the applicable Clinical Supply Quality Agreement) and concurrent with shipment of Regeneron Product to Sponsor, Regeneron shall provide Sponsor with such certificates and documentation as are described in the applicable Clinical Supply Quality Agreement, which documentation will support release of such Regeneron Product for human use.

9.14 Non-Conformance Determination. In the event that Sponsor becomes aware that the Regeneron Product may have a Non-Conformance, Sponsor shall promptly notify Regeneron by [Redacted]. The Parties shall investigate any Non-Conformance and any discrepancy between them shall be escalated to the head of quality of each Party (or such person's designee) for resolution.

9.15 Replacement. In the event that any proposed or actual shipment of the Regeneron Product (or portion thereof) shall be agreed to have a Non-Conformance at the time of Delivery to Sponsor, then unless otherwise agreed to by the Parties, Regeneron shall replace such Regeneron Product as is found to have a Non-Conformance (with respect to the Regeneron Product that has not yet been administered in the course of performing the applicable Study). [Redacted]

9.16 Non-Conformance of Sponsor Product. Sponsor shall be responsible for, and Regeneron shall have no obligations or liability with respect to, any amounts of Sponsor's Product supplied hereunder that is found to have a Non-Conformance. Sponsor shall replace, using diligent efforts, any of Sponsor's Product as is found to have a Non-Conformance (with respect to Sponsor Product that has not yet been administered in the course of performing the applicable Study). [Redacted]

[Redacted]

10. CONFIDENTIALITY.

10.1 Confidential Information. Sponsor and Regeneron agree to hold in confidence any Confidential Information provided or made available by the other Party, and neither Party shall use Confidential Information of the other Party except to fulfill such Party's obligations or exercise such Party's rights under this Agreement. Without limiting the foregoing, Regeneron may not use Confidential Information disclosed by or on behalf of Sponsor relating to the Sponsor Product other than for purposes of performance of a Study Plan or in exercising its rights as set forth in this Agreement. Sponsor may not use Confidential Information disclosed by or on behalf of Regeneron relating to the Regeneron Product other than for purposes of the performance of a Study Plan or in exercising its rights as set forth in this Agreement. Neither Party shall, without the prior written permission of the other Party, disclose any Confidential Information of the other Party to any Third Party except to the extent disclosure (a) is required by Applicable Law; (b) is pursuant to the terms of this Agreement; or (c) is necessary for the conduct of a Study Plan, and (d) provided that the disclosing Party shall otherwise provide reasonable advance notice to the other Party before making such disclosure. For the avoidance of doubt, Sponsor may, without Regeneron's consent, disclose Confidential Information to clinical trial sites and clinical trial investigators performing a Study, the data safety monitoring and advisory board relating to a Study, and Regulatory Authorities such as the FDA, EMA or other health authorities working with Sponsor on a Study, in each case to the extent necessary for the performance of the applicable Study and provided that such persons (other than governmental entities) are bound by an obligation of confidentiality at least as stringent as the obligations contained herein. Notwithstanding the foregoing, (i) [Redacted] and (ii) Sponsor may share Confidential Information of Regeneron as set forth in Section 3.7.8.

10.2 Ownership of Certain Confidential Information. Study Data regarding the safety or efficacy of the Regeneron Product alone shall be the Confidential Information of Regeneron and Study Data regarding the safety or efficacy of the Sponsor Product alone shall be the Confidential Information of Sponsor. Study Data regarding the Combination (including the safety of the Combination and/or efficacy in any Study Field) shall be the Confidential Information of both Parties; [Redacted]. The terms and conditions hereof are deemed to constitute both Parties' Confidential Information provided that each Party may disclose such terms and conditions to actual or potential investors, acquirors, licensees and collaborators on a need-to-know basis under the same confidentiality requirements set forth in this Section 10 that apply to each of the Parties

under this Agreement. Inventions that constitute Confidential Information and are jointly owned by the Parties, shall constitute the Confidential Information of both Parties and each Party shall have the right to use such Confidential Information consistent with this Article 10 and Articles 11, 12 and 13. Inventions that constitute Confidential Information and are solely owned by one Party shall constitute the Confidential Information of that Party and each Party shall have the right to use such Confidential Information consistent with this Article 10 and Articles 11, 12 and 13.

10.3 Personally Identifiable Data. All Confidential Information containing personal identifiable data shall be handled in accordance with all applicable data protection and privacy laws, rules and regulations applicable to such Party.

11. INTELLECTUAL PROPERTY.

11.1 Sponsor Inventions. As between Regeneron and Sponsor, Sponsor shall own all right, title and interest in and to Sponsor Inventions and all Intellectual Property rights thereto are the exclusive property of Sponsor, [Redacted]

11.2 Regeneron Inventions. As between Regeneron and Sponsor, Regeneron shall own all right, title and interest in and to Regeneron Inventions and all Intellectual Property rights thereto are the exclusive property of Regeneron, [Redacted]s.

11.3 Combination Inventions. All right, title and interest in and to all Combination Inventions shall belong jointly to Sponsor and Regeneron. [Redacted]

[Redacted]

[Redacted]

[Redacted]

11.4 Enforcement; Control. Each Party shall promptly provide the other Party with written notice reasonably detailing any known or alleged infringement or misappropriation by a Third Party of Combination Patents or Joint Patents, as well as any declaratory judgment or similar action alleging the invalidity, unenforceability or non-infringement of Combination Patents or Joint Patents. [Redacted]

11.5 Patent Applications. [Redacted]

11.6 REPRINTS; RIGHTS OF CROSS-REFERENCE. Consistent with applicable copyright and other laws, each Party may use, refer to, and disseminate reprints of scientific, medical and other published articles and materials from journals, conferences and/or symposia relating to a Study Plan, which disclose the name of a Party, provided such use does not constitute an endorsement of any commercial product or service by the other Party.

12. PUBLICATIONS.

12.1 Publicity. Unless **otherwise** required by Applicable Law (including regulations under any stock exchange on which either Party or its Affiliates is listed), other than the agreed press release set forth on Appendix C hereto, neither Party shall make any public announcement concerning this Agreement or any Study that includes Regeneron Product (including the initial posting to www.clinicaltrials.gov.) or otherwise communicate with any news media without the prior written

consent of the other Party. Without limiting the previous sentence, to the extent a Party desires to make such public announcement beyond that set forth on Appendix C hereto, such Party shall provide the other Party with a draft thereof at least ten (10) Business Days prior to the date on which such Party would like to make the public announcement, unless such ten day prior notice is not possible in order to comply with Applicable Laws (including regulations under any stock exchange on which either Party or its Affiliates is listed); further provided however, that, in such case such Party shall provide the other Party with as much advance notice as reasonably practicable**.**

12.2 Registration. Sponsor will register each Study with the Clinical Trials Registry located at www.clinicaltrials.gov as required by Applicable Law.

12.3 Publications. Sponsor shall have the first right to publish Study Data and Study Results subject to Section 13.4 and shall use commercially reasonable efforts to publish or present scientific papers regarding the Study Plan and Study Results in accordance with accepted scientific practice. Regeneron agrees not to publish Study Data or Study Results for any Study prior to the timely publication of Study Data and/or Study Results from such Study by Sponsor.

12.4 Review. The Parties agree that prior to submission of any Study Data or Study Results for publication or presentation or any other dissemination of any such results, including oral dissemination, the publishing Party shall invite the other to comment on the content of the material to be published or presented according to the following procedure:

(i) At least thirty (30) days prior to submission for publication of any paper, letter or any other publication, or fifteen (15) U.S business days prior to submission for presentation of any abstract, poster, talk or any other presentation, the publishing Party shall provide to the other Party the full details of the proposed publication or presentation in an electronic version (cd rom or email attachment). Upon written request from the other Party, the publishing Party agrees not to submit data for publication/presentation for an additional sixty (60) days in order to allow for actions to be taken to preserve rights for patent protection.

(ii) The publishing Party shall give reasonable consideration to any request by the other Party made within the periods mentioned in clause (i) of this Section 12.4 to modify the publication.

(iii) The publishing Party shall remove all Confidential Information of the other Party (but shall not remove jointly owned Study Data) before finalizing the publication.

12.5 Acknowledgement. Each Party agrees to identify the other Party and acknowledge its support in any press release and any other publication or presentation of the Study Data or Study Results of any Study.

13. REPRESENTATIONS AND WARRANTIES; **DISCLAIMERS**.

13.1 Mutual Representations and Warranties. Each of Sponsor and Regeneron represents and warrants to the other that it has the full right and authority to enter into this Agreement.

13.2 Representations and Warranties of Sponsor. Sponsor hereby represents and warrants to Regeneron that: (a) Sponsor has the full right, power and authority to grant all of the rights and licenses granted to Regeneron under this Agreement; (b) it will not transfer to any Third Party except to subcontractors acting on behalf of Sponsor pursuant to this Agreement, or sell or make commercially available any Regeneron Product for any use; (c) it will not use Regeneron Product in any manner that is inconsistent with or in conflict with the rights granted herein without the prior written consent of Regeneron in each instance; and (d) that all of its Representatives that may generate Study Results or Inventions, are, or will be prior to generating Study Results or Inventions, contractually obligated to assign Study Results and Inventions to Sponsor, subject to such Study Sites having reserved rights to use such Study Results and Inventions solely for its non-commercial, internal, patient care, educational, and research purposes.

13.3 Representations and Warranties of Regeneron. Regeneron hereby represents and warrants to Sponsor that Regeneron has the full right, power and authority to grant all of the rights and licenses granted to Sponsor under this Agreement and that all of its Representatives are, or will be prior to generating Study Results or Inventions, contractually obligated to assign Inventions to Regeneron.

13.4 No Guarantee of Results. Sponsor does not undertake that any Study shall lead to any particular result, nor is the success of any Study guaranteed. Neither Party accepts any responsibility for any use that the other Party may make of Study Data nor for advice or information given in connection therewith.

13.5 Anti-Corruption.

(i) In performing their respective obligations hereunder, the Parties acknowledge that the corporate policies of Sponsor and Regeneron and their respective Affiliates require that each Party's business be conducted within the letter and spirit of the law. By signing this Agreement, each Party agrees to conduct the business contemplated herein in a manner which is consistent in all material respects with all Applicable Law, including the U.S. Foreign Corrupt Practices Act, good business ethics, and such Party's ethics and other corporate policies.

(ii) Each Party represents and warrants that it and its Representatives have not, and covenants that it and its Representatives will not, in connection with the performance of this Agreement, directly or indirectly, make, promise, authorize, ratify or offer to make, or take any action in furtherance of, any payment or transfer of anything of value for the purpose of (a) influencing, inducing or rewarding any act, omission or decision to secure an improper advantage, (b) improperly assisting it in obtaining or retaining business for it or the other Party or (c) public or commercial bribery.

(iii) Neither Party shall contact or otherwise knowingly meet with any Government Official for the purpose of discussing activities arising out of or in connection with this Agreement without the prior written approval of the other Party, except where such meeting is consistent with the purpose and terms of this Agreement and in compliance with Applicable Law.

Disclaimer. EXCEPT AS EXPRESSLY PROVIDED HEREIN, REGENERON MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO THE REGENERON PRODUCT, AND SPONSOR MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO THE SPONSOR PRODUCT.

14. INSURANCE; **INDEMNIFICATION**; **LIMITATION OF LIABILITY**.

14.1. Insurance. Each Party warrants that it maintains a policy or program of insurance or self-insurance at levels sufficient to support the indemnification obligations assumed herein. Without limiting the foregoing, Sponsor shall procure insurance for the performance of each Study and shall add Regeneron as an additional insured under each such policy with respect to the applicable Study. Upon request, a Party shall provide evidence of such insurance.

14.1.1 Indemnification. *By Sponsor.* [Redacted]

14.1.2 *By Regeneron.* [Redacted]

14.1.3 *[Redacted].* [Redacted]

14.1.4 *Notice of Claim.* The obligations of Regeneron and Sponsor under this Section 15.2 are conditioned upon the delivery of written notice to Regeneron or Sponsor, as the case might be, of any potential Liability, as the case may be, within a reasonable time after the indemnified Party becomes aware of such potential Liability. The indemnifying Party will have the right to assume the defense of any suit or claim related to the Liability if it has assumed responsibility for the suit or claim in writing. The indemnified Party may participate in (but not control) the defense thereof at its sole cost and expense. The indemnifying Party shall not agree to any settlement of such action, suit, proceeding or claim without the prior written consent of the indemnified Party, which shall not be unreasonably withheld. It shall be reasonable for the indemnifying Party to withhold consent if the settlement of such action, suit, proceeding or claim or consent to any judgment in respect thereof that does not include a complete and unconditional release of the indemnified Party from all Liability with respect thereto or if it imposes any Liability or obligation on the indemnified Party without the prior written consent of the indemnified Party.

14.1.5 [Redacted]

14.2 LIMITATION OF LIABILITY. OTHER THAN WITH RESPECT TO THE OBLIGATIONS OF EACH PARTY UNDER SECTION 15.2, IN NO EVENT SHALL EITHER PARTY (OR ANY OF ITS AFFILIATES OR SUBCONTRACTORS) BE LIABLE TO THE OTHER PARTY FOR, NOR SHALL ANY PARTY HAVE THE RIGHT TO RECOVER, ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES (INCLUDING LOST PROFITS OR DAMAGES FOR LOST OPPORTUNITIES), WHETHER IN CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE, ARISING OUT OF (x) THE MANUFACTURE OR USE OF ANY PRODUCT SUPPLIED HEREUNDER OR (y) ANY BREACH OF OR FAILURE TO PERFORM ANY OF THE PROVISIONS OF THIS AGREEMENT OR ANY REPRESENTATION, WARRANTY OR COVENANT CONTAINED IN OR MADE PURSUANT TO THIS AGREEMENT, EXCEPT THAT SUCH LIMITATION SHALL NOT APPLY TO DAMAGES PAID OR PAYABLE TO A THIRD PARTY BY AN INDEMNIFIED PARTY FOR WHICH THE INDEMNIFIED PARTY IS ENTITLED TO INDEMNIFICATION HEREUNDER.

14.3 USE OF NAME. Except as otherwise provided herein, neither Party shall have any right, express or implied, to use in any manner the name or other designation of the other Party or any other trade name, trademark or logo of the other Party for any purpose in connection with the performance of this Agreement.

14.4 FORCE MAJEURE. If in the performance of this Agreement, one of the Parties is prevented, hindered or delayed by reason of any cause beyond such Party's reasonable control (*e.g.*, war, riots, fire, strike, governmental laws), such Party shall be excused from performance to the extent that it is necessarily prevented, hindered or delayed ("**Force Majeure**"). The non-performing Party will notify the other Party of such Force Majeure within ten (10) days after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance will be of no greater scope and no longer duration than is necessary and the non-performing Party will use commercially reasonable efforts to remedy its inability to perform.

14.5 ENTIRE AGREEMENT; **MODIFICATION**. The Parties agree to the full and complete performance of the mutual covenants contained in this Agreement. This Agreement, together with each Clinical Supply Quality Agreement and each Pharmacovigilance Agreement, constitutes the sole, full and complete agreement by and between the Parties with respect to the subject matter of this Agreement, and all prior agreements, understandings, promises and representations, whether written or oral, with respect thereto are superseded by this Agreement. No amendments, changes, additions, deletions or modifications to or of this Agreement shall be valid unless reduced to writing and signed by the Parties hereto.

15. **ASSIGNMENT AND PERFORMANCE BY AFFILIATES**. Neither Party shall assign or transfer this Agreement without the prior written consent of the other Party; provided, however, that either Party may assign this Agreement without the other Party's consent to one or more of its Affiliates or to a Third Party that merges with, consolidates with or acquires all or substantially all of the business or assets or voting control of the assigning Party, and any and all rights and obligations of either Party may be exercised or performed by its Affiliates, provided that such Affiliates agree to be bound by this Agreement and the applicable Party shall remain responsible for and liable for all acts and omissions of such Party's Affiliate.

16. **INVALID PROVISION**. If any provision of this Agreement is held to be illegal, invalid or unenforceable, the remaining provisions shall remain in full force and effect and will not be affected by the illegal, invalid or unenforceable provision. In lieu of the illegal, invalid or unenforceable provision, the Parties shall negotiate in good faith to agree upon a reasonable provision that is legal, valid and enforceable to carry out as nearly as practicable the original intention of the entire Agreement.

17. **TIME OF THE ESSENCE**. Notwithstanding anything to the contrary in this Agreement, the Parties agree that time is of the essence for initiation of the initial Studies and that Sponsor shall be free to commence each such Study without Regeneron Product and that no approval, or consent, or consultation from or with Regeneron shall be required in any way related to such initial Studies and Regeneron shall have no rights in any Study Data or any Inventions developed in connection with such initial Study if Regeneron does not commence the supply of Regeneron Product within 60 days of the Effective Date.

18. **NO ADDITIONAL OBLIGATIONS**. Sponsor and Regeneron have no obligation to renew this Agreement or apply this Agreement to any clinical trial other than the Studies for which the Parties have agreed to a Study Plan and Protocol. Neither Party is under any obligation to enter into another type of agreement at this time or in the future.

19. DISPUTE RESOLUTION AND JURISDICTION.

- The Parties shall attempt in good faith to settle all disputes arising out of or in connection with this Agreement in an amicable manner. Any claim, dispute or controversy arising out of or relating to this Agreement, including the breach, termination or validity hereof or thereof, shall be governed by and construed in accordance with the substantive laws of the State of New York without giving effect to its choice of law principles. The Parties irrevocably and unconditionally submit to the exclusive jurisdiction of the United States District Court for the Southern District of New York (or the New York State Supreme Court in New York County if such federal district court lacks subject matter jurisdiction) solely and specifically for the purposes of any action or proceeding arising out of or in connection with this Agreement.
- Nothing contained in this Agreement shall deny either Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed or maintained notwithstanding any ongoing discussions between the Parties.

20. NOTICES. All notices or other communications that are required or permitted hereunder shall be in writing and delivered personally, sent by facsimile (and promptly confirmed by personal delivery or overnight courier), or sent by internationally-recognized overnight courier addressed as follows:

If to Sponsor, to:

[Redacted]

If to Regeneron, to:

[Redacted]

21. RELATIONSHIP OF THE PARTIES. The relationship between the Parties is and shall be that of independent contractors, and does not and shall not constitute a partnership, joint venture, agency or fiduciary relationship. Neither Party shall have the authority to make any statements, representations or commitments of any kind, or take any actions, which are binding on the other Party, except with the prior written consent of the other Party to do so. All persons employed by a Party will be the employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

22. **COUNTERPARTS AND DUE EXECUTION.** This Agreement and any amendment may be executed in two (2) or more counterparts (including by way of facsimile or electronic transmission), each of which shall be deemed an original, but all of which together shall constitute one and the same instrument, notwithstanding any electronic transmission, storage and printing of copies of this Agreement from computers or printers. When executed by the Parties, this Agreement shall constitute an original instrument, notwithstanding any electronic transmission, storage and printing of copies of this Agreement from computers or printers. For clarity, facsimile signatures, electronic signatures and signatures transmitted via PDF shall be treated as original signatures.

23. **CONSTRUCTION**. Except where the context otherwise requires, wherever used, the singular will include the plural, the plural the singular, the use of any gender will be applicable to all genders, and the word "or" is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including" as used herein shall be deemed to be followed by the phrase "without limitation" or like expression. The term "will" as used herein means shall. References to "Article," "Section" or "Appendix" are references to the numbered sections of this Agreement and the appendices attached to this Agreement, unless expressly stated otherwise. Except where the context otherwise requires, references to this "Agreement" shall include the appendices attached to this Agreement. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction will be applied against either Party hereto.

[Signature page follows]

IN WITNESS WHEREOF, the Parties have entered into this Agreement as of the Effective Date.

Regeneron Pharmaceuticals, Inc.		**Checkmate Pharmaceuticals, Inc.**	
By:	_____	By:	_____
Name:	_____	Name:	_____
Title:	_____	Title:	_____

[Signature Page to Supply and Non-Exclusive License Agreement]

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APPENDIX C

DRAFT PRESS RELEASE

Checkmate Pharmaceuticals Announces Clinical Supply Agreement with Regeneron to Evaluate Vidutolimod (CMP-001) in Combination with Libtayo® (cemiplimab)

CAMBRIDGE, Mass., May XX, 2021 – Checkmate Pharmaceuticals, Inc. (NASDAQ: CMPI) ("Checkmate"), a clinical stage biopharmaceutical company focused on developing its proprietary technology to harness the power of the immune system to combat cancer, today announced the development program expansion of vidutolimod (CMP-001) into non-melanoma skin cancers in combination with Libtayo® (cemiplimab) under a clinical supply agreement with Regeneron Pharmaceuticals, Inc. ("Regeneron"). Vidutolimod is an advanced generation Toll-like receptor 9 (TLR9) agonist, delivered as a biologic virus-like particle utilizing a CpG-A oligodeoxynucleotide as a key component. Cemiplimab is a PD-1 blocking antibody being jointly developed by Regeneron and Sanofi.

Checkmate and Regeneron will collaborate on a multi-indication, Phase 2, proof-of-concept clinical trial of vidutolimod in combination with cemiplimab in the following patient cohorts: (a) PD-1 treatment-naïve subjects with cutaneous squamous cell carcinoma (CSCC), (b) subjects with cutaneous squamous cell carcinoma (CSCC) that is refractory to PD-1 blockade, and (c) subjects with Merkel cell carcinoma (MCC) that is refractory to PD-1 blockade. Checkmate will be the sponsor of the clinical trial, and Regeneron will supply cemiplimab.

"We're pleased to collaborate with Regeneron as we expand evaluation of vidutolimod as a potent stimulator of innate immune activity to patients with life-threatening non-melanoma skin cancers such as CSCC and MCC," said Barry Labinger, President and Chief Executive Officer of Checkmate. "We look forward to advancing vidutolimod in combination with Libtayo to further unlock the capabilities and impact of immuno-oncology therapeutics."

About Checkmate Pharmaceuticals

Checkmate Pharmaceuticals is a clinical stage biotechnology company focused on developing its proprietary technology to harness the power of the immune system to combat cancer. Checkmate Pharmaceuticals' product candidate, vidutolimod (CMP-001), is an advanced generation Toll-like receptor 9 (TLR9) agonist, delivered as a biologic virus-like particle utilizing a CpG-A oligodeoxynucleotide as a key component, designed to trigger the body's innate immune system to attack tumors in combination with other therapies. Information regarding Checkmate Pharmaceuticals is available at www.checkmatepharma.com.

Availability of Other Information About Checkmate Pharmaceuticals

Investors and others should note that we communicate with our investors and the public using our website (www.checkmatepharma.com), our investor relations website (ir.checkmatepharma.com), and on social media (Twitter and LinkedIn), including but not limited to: investor presentations and investor fact sheets, U.S. Securities and Exchange Commission filings, press releases, public conference calls and webcasts. The information that Checkmate Pharmaceuticals posts on these channels and websites could be deemed to be material information. As a result, we encourage investors, the media, and others interested in us to review the information that is posted on these channels, including the investor relations website, on a regular basis. This list of channels may be updated from time to time on our investor relations website and may include additional social media channels. The contents of our website or these channels, or any other website that may be accessed from our website or these channels, shall not be deemed incorporated by reference in any filing under the Securities Act of 1933.

Forward Looking Statements

Various statements in this release are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including. Words such as, but not limited to, “anticipate,” “believe,” “can,” “could,” “expect,” “estimate,” “design,” “goal,” “intend,” “may,” “might,” “objective,” “plan,” “predict,” “project,” “target,” “likely,” “should,” “will,” and “would,” or the negative of these terms and similar expressions or words, identify forward-looking statements. Forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. These statements include those regarding our product candidate, including its development and therapeutic potential and the advancement of our clinical and preclinical pipeline; expectations regarding the results and analysis of data; and expectations regarding the timing, initiation, implementation and success of its planned and ongoing clinical trials for vidutolimod (CMP-001), and the benefits and related implications of current and future partnerships and/or collaborations. Forward-looking statements should not be read as a guarantee of future performance or results and may not be accurate indications of when such performance or results will be achieved. These forward-looking statements are subject to risks and uncertainties, including those related to the development of our product candidate, including any delays in our ongoing or planned preclinical or clinical trials, the results from clinical trials, including the fact that positive results from a trial may not necessarily be predictive of the results of future or ongoing clinical trials, the impact of the ongoing COVID-19 pandemic on our business, operations, clinical supply and plans, the risks inherent in the drug development process, the risks regarding the accuracy of our estimates of expenses and timing of development, our capital requirements and the need for additional financing, and obtaining, maintaining and protecting our intellectual property. These and additional risks are discussed in the sections titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our Annual Report on Form 10-K for the year ending December 31, 2020, as filed with the Securities and Exchange Commission pursuant to Rule

424(b) under the Securities Act 1933, as amended, which is available on the Securities and Exchange Commission's website at www.sec.gov, and as well as discussions of potential risks, uncertainties and other important factors in Checkmate's subsequent filings with the Securities and Exchange Commission. All information in this press release is as of the date of the release, and Checkmate undertakes no duty to update this information unless required by law.

Investor Contact
Rob Dolski
Chief Financial Officer
rdolski@checkmatepharma.com

Media Contact
Karen Sharma
MacDougall
781-235-3060
ksharma@macbiocom.com

Exhibit 31.1

Certification of Periodic Report under Section 302 of the Sarbanes-Oxley Act of 2002

I, Barry Labinger, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 2021 of Checkmate Pharmaceuticals, Inc.;

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

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

4. The registrant's other certifying officer 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 is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

    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: August 12, 2021

/s/ Barry Labinger
Barry Labinger
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Periodic Report under Section 302 of the Sarbanes-Oxley Act of 2002

I, Robert Dolski, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 2021 of Checkmate Pharmaceuticals, Inc.;

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

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

4. The registrant's other certifying officer 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 is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. (Paragraph omitted pursuant to SEC Release Nos. 33-8238/34-47986 and 33-8392/34-49313);

    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: August 12, 2021

/s/ Robert Dolski
Robert Dolski
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

Certification Of
Principal Executive Officer
Pursuant To 18 U.S.C. Section 1350,
As Adopted Pursuant To
Section 906 of The Sarbanes-Oxley Act Of 2002

In connection with the Quarterly Report on Form 10-Q of Checkmate Pharmaceuticals, Inc. (the "Company") for the period ended June 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of his knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition of the Company at the end of the period covered by the Report and results of operations of the Company for the period covered by the Report.

Date: August 12, 2021

/s/ Barry Labinger
Barry Labinger
President and Chief Executive Officer
(Principal Executive Officer)

/s/ Robert Dolski
Robert Dolski
Chief Financial Officer
(*Principal Financial Officer*)