### 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 \_\_\_\_\_

Commission File Number: 001-39401

to

# iTeos Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or other jurisdiction of incorporation or organization) 139 Main Street Cambridge, MA

(Address of principal executive offices)

84-3365066 (I.R.S. Employer Identification No.)

02142 (Zip Code)

Registrant's telephone number, including area code: (339) 217 0161

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, \$0.001 par value per share	ITOS	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  $\boxtimes$  No  $\square$ 

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  $\boxtimes$  No  $\square$ 

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 □
Non-accelerated filer ⊠

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  $\Box$  No  $\boxtimes$  As of August 6, 2021, the registrant had 35,209,755 shares of common stock, \$0.001 par value per share, outstanding.

#### Summary of the material risks associated with our business

Our business is subject to numerous risks and uncertainties that you should be aware of before making an investment decision, including those highlighted in the section entitled "Risk Factors". These risks include, but are not limited to, the following:

- We will not be able to commercialize our current product candidates and any future product candidates if our preclinical studies do not produce successful results or our clinical trials do not demonstrate the safety and efficacy of our current or future product candidates.
- As an organization, we have never conducted pivotal clinical trials, and we may be unable to do so for any product candidates we may develop.
- Positive results from early preclinical studies of our product candidates are not necessarily predictive of the results of later preclinical studies and any future clinical trials of our product candidates. If we cannot replicate the positive results from our earlier preclinical studies of our product candidates in our later preclinical studies and future clinical trials, we may be unable to successfully develop, obtain regulatory for and commercialize our product candidates.
- We may not be able to file INDs or IND amendments to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA or a comparable foreign regulatory may not permit us to proceed.
- 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.
- We rely on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.
- Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability. We have never generated any revenue from product sales and may never be profitable.
- If the current public health pandemic related to coronavirus (COVID-19) continues to worsen, our operations, business and financial results may be adversely impacted.
- If we are unable to obtain and maintain sufficient intellectual property protection for our current product candidates or any future product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected.
- Even if our development efforts are successful, we may not obtain regulatory approval for any of our current product candidates or any future product candidates in the United States or other jurisdictions, which would prevent us from commercializing our current product candidates and any future product candidates. Even if we obtain regulatory approval for our current product candidates and any 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 our current product candidates or any future product candidates.
- We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.
- 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.

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- We are an emerging growth company and a smaller reporting company, and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.
- The trading price of our common stock may be volatile. We may be at an increased risk of securities class action litigation.

The summary risk factors described above should be read together with the text of the full risk factors below, in the section entitled "Risk Factors" and the other information set forth in this Quarterly Report on 10-Q, including our condensed consolidated financial statements and the related notes, as well as in other documents that we file with the Securities and Exchange Commission (SEC). The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us, or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations and future growth prospects.

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#### PART I-FINANCIAL INFORMATION

#### iTeos Therapeutics, Inc. and subsidiaries Condensed consolidated balance sheets (unaudited)

(in thousands, except share amounts)	June 30, 2021	December 31, 2020		
Assets				
Current assets:				
Cash and cash equivalents	\$ 302,933	\$	336,326	
Grants receivable	4,232		133	
Research and development tax credits receivable	—		192	
Prepaid expenses and other current assets	2,603		2,893	
Total current assets	309,768		339,544	
Property and equipment, net	2,021		1,352	
Research and development tax credits receivable	3,297		3,286	
Restricted cash	139		128	
Right of use asset	3,048		-	
Other assets	412		248	
Total assets	\$ 318,685	\$	344,558	
Liabilities, redeemable convertible preferred stock and stockholders' equity	 <u> </u>		<u> </u>	
Current liabilities:				
Accounts payable	\$ 11,661	\$	3,026	
Accrued expenses and other current liabilities	7,570		7,486	
Deferred income	977		4,486	
Lease liability	555		_	
Total current liabilities	20,763		14,998	
Grants repayable	5,693		5,883	
Other noncurrent liabilities	230		480	
Lease liability, net of current portion	2,501		_	
Total liabilities	29,187		21,361	
Commitments and contingencies (Note 9)			· · · ·	
Stockholders' equity:				
Preferred stock, \$0.001 par value; 10,000,000 shares authorized; zero shares issued or outstanding at June 30, 2021 and December 31, 2020	_		_	
Common stock, \$0.001 par value, 150,000,000 shares authorized; 35,148,110 and 35,044,758 shares issued and outstanding at				
June 30, 2021 and December 31, 2020, respectively	35		35	
Additional paid-in capital	403,116		396,443	
Accumulated other comprehensive income	238		617	
Accumulated deficit	(113,891)		(73,898)	
Total stockholders' equity	 289,498		323,197	
Total liabilities, redeemable convertible preferred stock and stockholders' equity	\$ 318,685	\$	344,558	
The accompanying notes are an integral part of these condensed consolidated financial statements.				

### iTeos Therapeutics, Inc. and subsidiaries Condensed consolidated statements of operations and comprehensive loss (unaudited)

	Three Months Ended June 30,					Six Months Ended June 30,			
(in thousands, except share and per share amounts)		2021		2020		2021		2020	
Operating expenses:									
Research and development expenses	\$	14,238	\$	6,137	\$	25,881	\$	11,962	
General and administrative expenses		15,101		2,394		22,147		4,812	
Total operating expenses		29,339		8,531		48,028		16,774	
Loss from operations		(29,339)		(8,531)		(48,028)		(16,774)	
Other income and expenses:									
Grant income		2,701		1,081		7,616		2,670	
Fair value adjustment for preferred stock tranche rights liability		_				_		1,265	
Research and development tax credits		119		186		119		370	
Other income (expense), net		60		12		300		(30)	
Loss before income taxes		(26,459)		(7,252)		(39,993)		(12,499)	
Income tax benefit		_		50		_		50	
Net loss		(26,459)		(7,202)		(39,993)		(12,449)	
Cumulative dividends on Series A preferred stock		_		(106)		—		(213)	
Accretion of redeemable convertible preferred stock to redemption value		_		(2,994)		_		(4,189)	
Net loss attributable to common stockholders	\$	(26,459)	\$	(10,302)	\$	(39,993)	\$	(16,851)	
Basic and diluted net loss per common share	\$	(0.75)	\$	(29.49)	\$	(1.14)	\$	(55.63)	
Weighted-average common shares outstanding— basic and diluted		35,119,952		349,290		35,103,294		302,919	
		00,110,002		343,230		33,103,234		302,313	
Net loss	\$	(26,459)	\$	(7,202)	\$	(39,993)	\$	(12,449)	
Foreign currency translation adjustments		(74)		245		(379)		(72)	
Comprehensive loss	\$	(26,533)	\$	(6,957)	\$	(40,372)	\$	(12,521)	

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

iTeos Therapeutics, Inc. and subsidiariesw Condensed consolidated statements of redeemable convertible preferred stock and stockholders' equity (deficit) (unaudited)

In thousands except share amounts	Serie preferre		Serie preferre		Commo	n stock	Additional paid-in	Accumulated other comprehensive	Accumulated	Total stockholders' equity
	Shares	Amount	Shares	Amount	Shares	Amount	capital	loss	deficit	(deficit)
Balance at December 31, 2019	6,167,726	\$ 5,353	20,942,781	\$ 46,404	256,548	\$1	\$ —	\$ (224)	\$ (35,865)	\$ (36,088)
Issuance of Series B-2 Preferred Stock, net										
of there										
issuance costs of \$332	-	-	44,453,477	125,026	_	-	-	-	-	-
Settlement of preferred stock tranche right	—	—	—	—	—	—	4,135	—	—	4,135
Accretion of Series B and B-2 preferred stock										
to redemption value	—	_	_	1,195	—	_	(1,195)	_	_	(1,195)
Stock-based compensation	_	_	_	_	_	_	186	_	_	186
Currency translation adjustment	_	_	_	_	_	_	_	(317)	_	(317)
Net loss	_	_	_	_	_	_	_		(5,247)	(5,247)
Balance at March 31, 2020	6,167,726	5,353	65,396,258	172,625	256,548	1	3,126	(541)	(41,112)	(38,526)
Accretion of Series B and B-2 preferred stock										
to redemption value	_	_	_	2,994		_	(2,994)	_	_	(2,994)
'Stock-based compensation	_	_	_	_		_	350	_	_	350
Exercise of stock options into common stock	_	_	_	_	131,867	_	205	_	_	205
Currency translation adjustment	_	_	_	_	_	_	_	245	_	245
Net loss	_	_	_	_		_	_	_	(7,202)	(7,202)
Balance at June 30, 2020	6,167,726	\$ 5,353	65,396,258	\$ 175,619	388,415	\$1	\$ 687	\$ (296)	\$ (48,314)	\$ (47,922)
					I					

	Serie			ies B			Additional	Accumulated other		Total
In thousands except share amounts	preferre	d stock	preferre	ed stock	Commo	n stock	paid-in	comprehensive	Accumulated	stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	capital	income	deficit	equity
Balance at December 31, 2020	_	\$ —		\$ —	35,044,758	\$ 35	\$ 396,443	\$ 617	\$ (73,898)	\$ 323,197
Stock-based compensation	_	_	_	_	_	_	2,584	_	_	2,584
Common stock issued upon exercises of										
options	—	—	_	—	56,241	—	667	—	—	667
Currency translation adjustment	_	_	_	_	_	_	_	(305)	_	(305)
Net loss	_	_	_	_	_	_	_	_	(13,534)	(13,534)
Balance at March 31, 2021		-			35,100,999	35	399,694	312	(87,432)	312,609
Stock-based compensation	_	_	_	_	_	_	3,227	_	_	3,227
Common stock issued upon exercises of										
options	_	_	_	_	47,111	_	195	_	_	195
Currency translation adjustment	_	_	_	_	_	_	_	(74)	_	(74)
Net loss	_	_	_	_		_	_	_	(26,459)	(26,459)
Balance at June 30, 2021		\$ —		\$ —	35,148,110	\$ 35	\$ 403,116	\$ 238	\$ (113,891)	\$ 289,498

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

#### iTeos Therapeutics, Inc. and subsidiaries Condensed consolidated statements of cash flows (unaudited)

	Six Months Ended June 30,					
(in thousands)		2021		2020		
Cash flows from operating activities						
Net loss	\$	(39,993)	\$	(12,449)		
Adjustments to reconcile net loss to net cash used in operating activities:						
Depreciation and amortization		276		250		
Stock-based compensation		5,811		536		
Change in operating lease right-of-use assets		8		_		
Fair value adjustment for preferred stock tranche rights liability		—		(1,265)		
Deferred rent		—		(14)		
Changes in operating assets and liabilities:						
Grants receivable		(4,185)		4,962		
Research and development tax credits receivable		73		(238)		
Prepaid expenses and other current assets		81		(580)		
Accounts payable		8,265		1,055		
Accrued expenses and other liabilities		50		(886)		
Deferred income		(3,431)		(852)		
Net cash used in operating activities		(33,045)		(9,481)		
Cash flows from investing activities						
Purchase of property and equipment		(489)		(119)		
Purchase of other assets		(60)		(19)		
Net cash used in investing activities		(549)		(138)		
Cash flows from financing activities						
Proceeds from issuance of Series B-2 Preferred Stock		_		125,358		
Payment of issuance costs on Series B-2 Preferred Stock		_		(332)		
Proceeds from issuance of common stock upon exercise of options		862		205		
Payment of IPO costs		_		(1,311)		
Proceeds from grants repayable		_		2,713		
Net cash provided by financing activities		862		126,633		
Effects of exchange rate changes on cash, cash equivalents and restricted cash		(650)		(11)		
Net (decrease) increase in cash, cash equivalents and restricted cash		(33,382)		117,003		
Cash, cash equivalents and restricted cash at beginning of period		336,454		19,990		
Cash, cash equivalents and restricted cash at end of period	\$	303,072	\$	136,993		
Non-cash investing and financing activities						
Capital expenditure included in accounts payable	\$	459				
Accretion of Series B and B-2 Preferred Stock to redemption value			\$	4,189		
Settlement of preferred stock tranche right			\$	4,135		
Deferred IPO costs in accounts payable			\$	400		
Operating lease liabilities arising from obtaining right-of-use assets	\$	3,316		_		
Supplemental disclosure of cash flows		· · · ·				
Cash paid for taxes			\$	147		
			-			

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

#### iTeos Therapeutics, Inc. Notes to condensed consolidated financial statements (unaudited)

#### Note 1. Nature of business and basis of presentation

#### Description of business and corporate reorganization

iTeos Therapeutics, Inc. (iTeos Inc. or the Company), a Delaware corporation headquartered in Cambridge, Massachusetts (incorporated on October 4, 2019), is the successor to iTeos Belgium SA (iTeos Belgium) a company organized under the laws of Belgium in 2011 and headquartered in Charleroi, Belgium. The Company is a clinical stage biopharmaceutical company pioneering the discovery and development of a new generation of highly differentiated immuno-oncology therapeutics for patients. The Company leverages its deep understanding of the tumor microenvironment and cancer immunology and immunosuppressive pathways to design novel product candidates with the potential to fully restore the immune response against cancer. The Company's innovative pipeline includes two clinical-stage programs targeting novel, validated immuno-oncology pathways designed with optimized pharmacologic properties for improved clinical outcomes. The Company's initial antibody product candidate, EOS-448, is a high affinity, potent, anti-TIGIT antibody with a functional Fc domain, designed to enhance the anti-tumor response through a multifaceted immune modulatory mechanism. An open-label Phase 1/2a clinical trial of EOS-448 is ongoing in adult cancer patients with advanced solid tumors. The Company is also advancing inupadenant, a next-generation adenosine A2A receptor antagonist tailored to overcome cancer immunosuppression. iTeos is conducting an open-label multi-arm Phase 1/2a clinical trial of inupadenant in adult cancer patients with advanced solid tumors. The Company also has a preclinical pipeline targeting additional mechanisms.

On October 4, 2019, the Company completed a corporate reorganization in which iTeos Inc., iTeos Belgium, and the stockholders of iTeos Belgium entered into an Equity Contribution and Exchange Agreement (Share Exchange), pursuant to which all outstanding shares of preferred stock, common stock and profit certificates of iTeos Belgium were exchanged on a one-for-one basis for newly issued shares of iTeos Inc. iTeos Inc. was a newly-formed holding company, and as a result of the Share Exchange, iTeos Belgium became a wholly owned subsidiary of iTeos Inc. iTeos U.S., which was a wholly owned subsidiary of iTeos Belgium throughout 2019. On February 28, 2020, iTeos Inc. purchased iTeos U.S. from iTeos Belgium and then the entities effectively merged.

The Share Exchange was accounted for in accordance with the Financial Accounting Standards Board (FASB) Accounting Standard Codification (ASC) 805-50, *Business Combinations—Related Issues*. The Company evaluated the guidance in ASC 805-50 with respect to the transaction between entities under common control and concluded that since all shareholders of iTeos Inc. and iTeos Belgium have nearly identical ownership percentages and interests before and after the transaction, the Share Exchange lacks economic substance and represents a transaction between entities with common ownership and should be accounted for in a manner consistent with common control transactions and did not result in a change in control at the ultimate parent or the controlling shareholder level.

#### **Reverse Stock Split and Initial Public Offering**

On July 20, 2020, the Company effected a 1-for-3.3115 reverse stock split of the Company's common stock and adjusted the ratio at which the Company's preferred stock is convertible into common stock, as well as the number of shares under the 2019 Stock Option and Grant Plan and the Amended and Restated Certificate of Incorporation of iTeos Therapeutics, Inc., as well as the share amounts of stock grants under the plan and the number of options and exercise prices of options under the plan. All shares of common stock, stock options exercisable for shares of common stock, and per share information presented in the accompanying consolidated financial statements and notes thereto have been adjusted, where applicable, to reflect the reverse stock split on a retroactive basis for all periods presented. There was no change in the par value of the Company's common stock.

On July 28, 2020, the Company completed its initial public offering (IPO), in which the Company issued and sold 10,586,316 shares of its common stock, for aggregate gross proceeds of \$201.1 million and its shares started trading on The Nasdaq Global Select Market under the ticker symbol "ITOS." The Company received approximately \$184.0 million in net proceeds after deducting underwriting discounts and commissions and other estimated offering expenses payable by the Company. Upon closing of the IPO, all of the Company's outstanding shares of convertible preferred stock automatically converted into 22,460,076 shares of common stock.

On August 5, 2020, the underwriters purchased an additional 1,505,359 shares of common stock pursuant to their option to purchase additional shares for net proceeds of \$26.6 million after deducting underwriting discounts and commissions.

#### Liquidity and capital resources

Since inception, the Company's activities have consisted primarily of performing research and development to advance its product candidates. The Company is still in the development phase and has not been marketing any developed products to-date. Since inception, the Company has incurred recurring losses, including a net loss of \$40.0 million for the six months ended June 30, 2021. As of June 30, 2021, the Company had an accumulated deficit of \$113.9 million. The Company expects to continue to generate operating losses in the foreseeable future. As of August 11, 2021, the issuance date of the condensed consolidated financial statements for the six months ended June 30, 2021, the Company expected that its cash and cash equivalents would be sufficient to fund its operating expenses, capital expenditure requirements and debt service payments through at least 12 months from the issuance date of the condensed consolidated financial statements.

The Company may seek additional funding in order to reach its development and commercialization objectives. The Company may not be able to obtain funding on acceptable terms, or at all, and the Company may not be able to enter into collaborations or other arrangements. The terms of any funding may adversely affect the holdings or the rights of the Company's stockholders. If the Company is unable to obtain funding, the Company could 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.

The Company's future results of operations involve a number of risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, uncertainty regarding results of clinical trials and reaching milestones, uncertainty of regulatory approval of the Company's current or future product candidates, uncertainty of market acceptance of the Company's product candidates, if approved, competition from substitute products and larger companies, securing and protecting proprietary technology, strategic relationships and dependence on key individuals and sole source suppliers. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities and may not ultimately lead to a marketing approval and commercialization of a product.

The Company's product candidates require approvals from the U.S. Food and Drug Administration (FDA) and comparable foreign regulatory agencies prior to commercial sales in their respective jurisdictions. There can be no assurance that any product candidates will receive the necessary approvals. If the Company was denied approval, approval was delayed or the Company was unable to maintain approval for any product candidate, it could have a materially adverse impact on the Company. 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 will need to generate significant revenue to achieve profitability, and it may never do so.

#### COVID-19

With the ongoing concern related to the COVID-19 pandemic during 2020 and in the first six months of 2021, the Company has maintained and expanded its business continuity plans to address and mitigate the impact of the COVID-19 pandemic on its business. In March 2020, to protect the health of its employees, and their families and communities, the Company restricted access to its offices to personnel who performed critical activities that must be completed on-site, limited the number of such personnel that could be present at its facilities at any one time, and requested that most of its employees work remotely. In May 2020, as certain states eased restrictions, the Company established new protocols to better allow its full laboratory staff access to the Company's facilities. These protocols included several shifts working over a seven-day-week protocol. The Company expects to continue incurring additional costs to ensure it adheres to the best-practice safe hygiene guidelines issued by recognized health experts such as the U.S. Centers for Disease Control and Prevention (CDC), the European Center for Disease Prevention and Control (ECDC) and the World Health Organization (WHO), and to provide a safe working environment to its onsite employees.

The extent to which the COVID-19 pandemic impacts the Company's business, its corporate development objectives, results of operations and financial condition, and the value of and market for its common stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, the severity of COVID-19 or the effectiveness of actions taken globally to contain and treat COVID-19, such as travel restrictions, quarantines, social distancing and business closure requirements, but particularly in the geographies where we, our third party manufacturers, contract research organizations (CROs) or current and planned clinical trial sites operate. Disruptions to the global economy, disruption of global healthcare systems, and other



significant impacts of the COVID-19 pandemic could have a material adverse effect on the Company's business, financial condition, results of operations and growth prospects.

#### Basis of presentation

The accompanying condensed consolidated financial statements and accompanying notes have been prepared in accordance with generally accepted accounting principles in the United States of America (U.S. GAAP).

The unaudited interim condensed consolidated financial statements of the Company included herein have been prepared, without audit, pursuant to the rules and regulations of the Securities and Exchange Commission (SEC). Certain information and footnote disclosures normally included in financial statements prepared in accordance with U.S. GAAP have been condensed or omitted from this report, as is permitted by such rules and regulations. Accordingly, these condensed consolidated financial statements should be read in conjunction with the consolidated financial statements as of and for the years ended December 31, 2020 and 2019, and the notes thereto, which are included in the Company's Annual Report on Form 10-K (File No. 001-39401). The results for any interim period are not necessarily indicative of results for any future period.

In the opinion of management, the information furnished reflects all adjustments, all of which are of a normal and recurring nature, necessary for a fair presentation of the results for the reported interim periods. The Company considers events or transactions that occur after the balance sheet date but before the financial statements are issued to provide additional evidence relative to certain estimates or to identify matters that require additional disclosure. The results of operations for interim periods are not necessarily indicative of results to be expected for the full year or any other interim period.

#### Note 2. Summary of significant accounting policies

The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2020, and notes thereto, which are included in the Company's Annual Report on Form 10-K that was filed with the Securities and Exchange Commission on March 24, 2021. Since the date of those financial statements, there have been no material changes to significant accounting policies except as noted below.

#### Principles of consolidation

The accompanying condensed consolidated financial statements include the Company's accounts and those of its wholly owned subsidiaries. All intercompany accounts, transactions and balances have been eliminated.

#### Use of estimates

The preparation of the Company's consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, and expenses, as well as the related disclosures of contingent assets and liabilities. Estimates are used to determine the fair value of the preferred stock tranche rights liability, the fair value of common stock and stock-based awards and other issuances, accruals for research and development costs, useful lives of long-lived assets, probability of repayment for grants repayable, and uncertain tax positions. Actual results could differ materially from the Company's estimates.

The full extent to which the COVID-19 pandemic will directly or indirectly impact the Company's business, results of operations and financial condition, including expenses, research and development costs and employee-related amounts, will depend on future developments that are highly uncertain, including as a result of new information that may emerge concerning COVID-19 and the actions taken to contain or treat COVID-19, as well as the economic impact on local, regional, national and international markets. The Company has considered the impact of COVID-19 on estimates within its financial statements and there may be changes to those estimates in future periods. As of the date of issuance of these unaudited condensed consolidated financial statements, the Company has not experienced material business disruptions or incurred impairment losses in the carrying value of its assets as a result of the pandemic and is not aware of any specific related event or circumstance that would require it to update its estimates.

#### Cash, Cash Equivalents and Restricted Cash

Cash and cash equivalents consist of standard checking accounts, money market accounts, and a sweep account that consists of money market funds with highly liquid investments with maturities of three months or less. Restricted cash represents collateral provided for letters of credit issued as security deposits in connection with the Company's leases of its corporate facilities.

#### Recently adopted accounting standards updates

On January 1, 2021, the Company adopted Accounting Standard Update, or ASU No. 2016-02 (Topic 842), *Leases*, or ASC 842. Under the standard, the Company accounts for leases using a right-of-use, or ROU, model, which recognizes that, at the date of commencement, a lessee has a financial obligation to make lease payments to the lessor for the right to use the underlying asset during the lease term. On the date of adoption, the Company recognized a \$0.9 million of right-to-use assets and lease liabilities in the consolidated balance sheet.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement. Leases with a term greater than one year are recognized on the balance sheet as ROU assets and short-term and long-term lease liabilities, as applicable. ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent its obligation to make lease payments arising from the lease. The Company typically only includes an initial lease term in its assessment of a lease arrangement. It also considers termination options and factors those into the determination of lease payments. Options to renew a lease are not included in the assessment unless there is reasonable certainty that the Company will renew.

Operating lease liabilities and their corresponding ROU assets are recorded based on the present value of lease payments over the expected remaining lease term. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which it could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. Lease expense for lease payments is recognized on a straight-line basis over the lease term.

The Company is required to pay fees for operating expenses in addition to monthly base rent for certain operating leases (non-lease components). The Company has not elected the practical expedient which allows non-lease components to be combined with lease components for all asset classes. Variable non-lease components are not included within the lease right-of-use asset and lease liability on the consolidated balance sheet, and instead are reflected as expense in the period they are paid.

The Company's real estate operating leases provide for scheduled annual rent increases throughout the lease terms. The Company recognizes the effects of the scheduled rent increases on a straight-line basis over the full terms of such leases.

#### Note 3. Fair value measurements

The following tables set forth the Company's financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy as of June 30, 2021 and December 31, 2020:

June 30, 2021								
	Level 1	evel 1 Leve		Le	Level 3		Total	
\$	286,752	\$	_	\$	_	\$	286,752	
\$	286,752	\$	_	\$	_	\$	286,752	
			December	31, 2020				
	Loval 1				10		Total	
	Level 1		vel 2		vel 3		Total	
\$	Level 1 314,636				vel 3	\$	Total 314,636	
	\$ \$	\$ 286,752	\$ 286,752 \$ \$ 286,752 \$	Level 1         Level 2           \$ 286,752         \$ —           \$ 286,752         \$ —	Level 1         Level 2         Level 3           \$         286,752         \$         —         \$	Level 1         Level 2         Level 3           \$ 286,752         \$         \$           \$ 286,752         \$         \$           \$ 286,752         \$         \$	Level 1         Level 2         Level 3           \$ 286,752         \$         \$         \$           \$ 286,752         \$         \$         \$	

Cash equivalents consist of money market funds, which are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices in an active market.



The fair value of the Series B Preferred Stock tranche rights liability was estimated using a probability-weighted present value of the benefit of investment with the following significant unobservable inputs (Level 3):

	March (Tra	on Dates 23, 2020 nche 3 ement)
Implied equity value (in millions)	\$	208.2
Probability of success of reaching necessary		
milestone:		
Tranche 2 milestone		N/A
Tranche 3 milestone (by March 31, 2020)		90%
Expected industry return over period during which		
milestones are expected to be achieved		13.0%
Risk-free interest rate		1.1%

During the periods presented, the Company has not changed the manner in which it values assets and liabilities that are measured at fair value. The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers within the hierarchy during the three and six month periods ended June 30, 2021 and 2020.

The following table presents changes during the three and six months ended June 30, 2020 in Level 3 liabilities measured at fair value on a recurring basis:

(in thousands)	1	referred Stock Tranche Rights .iability
Balances at January 1, 2020	\$	5,400
Change in estimated fair value		(1,265)
Settlement of tranche right		(4,135)
Balances at June 30, 2020	\$	

The preferred stock tranche rights liability was settled on March 24, 2020 and no liability exists thereafter.

There were no Level 3 measurements used during the three and six months ended June 30, 2021.

The above fair value measurements are sensitive to changes in the underlying unobservable inputs. A change in those inputs could result in a significantly higher or lower fair value measurement.

#### Note 4. Supplemental balance sheet information

#### Property and equipment

Property and equipment, net consisted of the following:

(in thousands)	J	une 30, 2021	Dec	ember 31, 2020
Scientific equipment	\$	3,059	\$	2,617
Furniture & office equipment		749		542
Leasehold improvements		1,023		855
Total		4,831		4,014
Accumulated depreciation and amortization		(2,810)		(2,662)
Property & equipment, net	\$	2,021	\$	1,352

Depreciation and amortization expense was \$0.2 and \$0.1 million for the three months ended June 30, 2021 and 2020, respectively, and \$0.3 million for the six months ended June 30, 2021 and 2020, respectively.

#### Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of the following:

(in thousands)	June 30, 2021		De	cember 31, 2020
Accrued clinical trial costs	\$	5,116	\$	4,012
Accrued personnel costs		2,395		3,208
Accrued professional fees		25		37
Accrued other		34		229
Total accrued expenses and other current liabilities	\$	7,570	\$	7,486

#### Note 5. License and collaboration agreements

#### Adimab

In January 2017, the Company entered into a collaboration agreement (as amended, the Adimab Agreement) with Adimab, LLC (Adimab). Adimab has developed an antibody discovery and optimization technology platform. This collaboration enables the Company's research and development efforts on discovery and optimization of new antibodies against immuno-oncology targets the Company may identify.

Under the terms of the Adimab Agreement, Adimab has granted the Company a worldwide, non-exclusive research license for a oneyear research term period and evaluation period for up to 18 months per research program. The Company is required to use commercially reasonable efforts to perform its research activities under the Adimab Agreement and, if the Company exercises its right to obtain a development and commercialization license, the Company is required to use commercially reasonable efforts to pursue development and commercialization of a product directed to the applicable target. Under the terms of the Adimab Agreement, the Company granted Adimab a worldwide, non-exclusive license under all of its patents and know-how that are reasonably necessary or useful for Adimab to perform its research activities under the Adimab Agreement.

Payment terms to Adimab include a one-time upfront technology access fee in the tens of thousands and payments for research support. Adimab is entitled to additional fees of up to a maximum of \$0.4 million on a program-by-program basis for the achievement of certain technical milestones, one of which was met and the Company paid \$0.2 million in April 2017. Upon the Company's exercise of an option for an exclusive development and commercialization license, with respect to a target, the Company is required to make a low single digit million-dollar payment to Adimab for each exercised option. In August 2018, the Company paid a \$1.0 million nonrefundable fee to exercise an option to acquire certain licenses from Adimab. One of the antibodies licensed under the Adimab Agreement is now what the Company refers to as EOS-448. In February 2021, the Company entered into an amendment to the Adimab Agreement (the Amended Adimab Agreement). The Amended Adimab Agreement specifies different milestone payments for new products that are derived from research programs beginning after February 22, 2021 (the New Products). For New Products, on a per target basis, the Company may be required to pay development, regulatory and commercial milestone payments totaling up to an aggregate of \$45.8 million for the first three products and additional milestone payments up to \$14.5 million for each additional product. As of the date of these condensed consolidated financial statements, the Company has not pursued any additional targets under the Adimab agreement that could potentially result in such milestone payments. The Company will pay Adimab low to mid single-digit percentage royalties on a country-by-country and product-byproduct basis, on worldwide net product sales of licensed products. Royalties are payable on a licensed product-by-licensed product and country-by-country basis until the later of (i) expiration of the last valid claim of a licensed patent right that covers such licensed product in such country, and (ii) ten years following the first commercial sale of such licensed product in such country. To date, the Company has paid a total of \$3.4 million to Adimab under the Adimab Agreement.

Adimab controls the filing, prosecution, maintenance and enforcement of the intellectual property that it licenses to the Company under the Adimab Agreement. The Company has the right to enforce such licensed intellectual property against infringement if the infringement is competitive with the Company's licensed products and Adimab does not pursue enforcement. The Company controls the filing, prosecution, maintenance and enforcement of the intellectual property the Company licenses to Adimab under the Adimab Agreement and all program antibody patents.

The term of the Adimab Agreement will continue until the last to expire royalty term on a product-by-product and country-by-country basis if the Company exercises its option, or in the event no option is exercised, the conclusion of the

last-to-expire evaluation term, unless terminated earlier by either party. Each party has the right to terminate the Adimab Agreement due to the other party's uncured material breach or the Company's abandonment of the product.

#### GSK

On June 11, 2021, the Company and GlaxoSmithKline Intellectual Property (No. 4) Limited ("GSK") executed a Collaboration and License Agreement (the "GSK Collaboration Agreement") pursuant to which the Company agrees to grant GSK a license under certain of the Company's intellectual property rights to develop, manufacture, and commercialize products comprised of or containing the Company's antibody product, EOS-448. Under the GSK Collaboration Agreement, GSK agrees to make an upfront payment of \$625 million to the Company within 10 business days of the date on which the GSK Collaboration Agreement becomes effective, which occurred on July 26, 2021. Additionally, the Company is eligible to receive up to \$1.45 billion in milestone payments, contingent upon the EOS-448 program achieving certain development and commercial milestones. Within the collaboration, GSK and the Company agree to share responsibility and costs for the global development of EOS-448, and will jointly commercialize and equally split profits in the United States. Outside of the United States, GSK will receive an exclusive license for commercialization, and the Company is eligible to receive tiered double digit royalty payments up to 20% during a customary royalty term.

#### MSD International GmbH

On December 10, 2019, the Company entered into a Clinical Trial Collaboration and Supply Agreement (the MSD Agreement) with MSD International GmbH (MSD), a subsidiary of Merck & Co., Inc. Under the MSD Agreement, the Company will sponsor a clinical trial in which both the Company's compound and MSD's compound will be dosed in combination. The Company will conduct the research at its own cost and MSD will contribute its compound towards the study at no cost to the Company. The parties will equally own the clinical data and inventions from the study, with the exception of inventions relating solely to each party's compound class. The MSD Agreement will expire upon the delivery of a written report on the results of the study, unless earlier terminated or agreed by the parties.

The Company began receiving compounds from MSD on April 1, 2020 and the Company began the research study in the third quarter of 2020. The terms of the MSD Agreement meet the criteria under ASC Topic 808, *Collaborative Arrangements* (ASC 808), as both parties are active participants in the activity and are exposed to the risks and rewards dependent on the commercial success of the activity. ASC 808 does not provide guidance on how to account for the activities under the collaboration, and the Company determined that neither party met the definition of a customer under ASC 606, *Revenue from Contracts with Customers*. Accordingly, the Company considered other guidance to determine the accounting for the respective elements of the arrangement. The Company accounted for the collaboration activities by analogy to ASC Topic 845, *Nonmonetary Transactions*, and recognized nonmonetary income with an offsetting entry to expense for amounts received from MSD within research and development expense in the condensed consolidated statement of operations and comprehensive loss.

#### Note 6. Government grant funding and potential repayment commitments under recoverable cash advance grants (RCAs)

The Company has been awarded grants from the Walloon Region, a federal region of Belgium (the Walloon Region) and the European Union (the granting agencies) to fund research and development activities. The grants reimburse a percentage (55-100%) of actual qualifying expenditures. The Company periodically submits proof of qualifying expenditures to the granting agencies for approval and reimbursement. To date, the Company has received funding under several grants which included no obligation to repay and two grants that include potential obligations to repay (RCAs).

As the granting agencies do not meet the definition of a customer under Topic 606, qualifying grants receipts are recognized as grant income within other income in the condensed consolidated statement of operations and comprehensive loss.

#### Grants which do not include an obligation to repay

The total amount that the granting agencies have agreed to fund in the future if the Company incurs qualifying research and development expenses under these grants is \$1.3 million.



#### Grants which include a potential obligation to repay-RCAs

On July 20, 2017, the Company entered into a recoverable cash advance arrangement whereby the Walloon Region will provide the Company with up to \$22.3 million for a research and development program to perform clinical validation of an A2A receptor antagonist drug candidate for immune-oncology (RCA-1).

On December 3, 2019, the Company entered into another recoverable cash advance arrangement with the Walloon Region (RCA-2) for up to \$4.2 million to be received to fund a research and development program conducted to develop a TIGIT blocking antibody with anti-tumor properties.

Under the terms of both agreements, the Company must decide within 6 months after the end of the research period whether it will further pursue commercial development or out licensing of the drug candidate. The research period for RCA-1 ends in December 2021 per the current agreement. The Company negotiated an extension on the research period for RCA-2 with the Walloon Region. The original research period for RCA-2 ended February 2021, and was extended to March 2022. The Company must repay 30% of the amount received under the grant by annual installments from 2022 to 2041 (the fixed annual repayments) unless the Company decides not to pursue commercial development or out licensing of the drug candidate, applies for a waiver from the Walloon Region justifying its decision based upon the failure of the program, and returns the intellectual property to the Walloon Region. Because of the requirement to repay 30% of the amounts received under the grant, the Company records the present value of such amounts as grants repayable on the condensed consolidated balance sheets.

In addition, in the event that the Company receives revenue from products or services related to the results of the research, it has to pay to the Walloon Region a 0.33% royalty on revenue resulting from RCA-1 and a 0.12% royalty on revenue resulting from RCA-2. The maximum amount payable to the Walloon Region under each grant, including the fixed annual repayments, the royalty on revenue, and the interest thereon, is twice the amount of funding received. The Company assessed whether there is an obligation to make a royalty payment based on the probability of successful completion of the research and development and future sales and commercial success of the drug candidate, and no grant repayable related to royalties was recorded as of June 30, 2021 or December 31, 2020.

The Company recorded grant income in the condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2021 and 2020 for amounts of grants received from the Walloon Region in the period during which the related qualifying expenses were incurred, net of any grants repayable recorded in the condensed consolidated balance sheets.

The Company recorded receivables on the condensed consolidated balance sheets related to amounts the Walloon Region owes the Company based on qualifying expenses incurred by the Company. The Company recorded deferred income in the condensed consolidated balance sheets for amounts received from the Walloon Region in advance of incurring qualifying expenses.

The following table reflects activity for grant programs for the three and six months ended June 30, 2021 and 2020 and end of period balances as of June 30, 2021 and December 31, 2020:

	RCA -1 RCA-2 Other Grants						RCA -1 RCA-2 Oth											tal
<u>(</u> In thousands)	2021	2020	2021	2020	2021	2020	2021	2020										
Cash received during the three months ended June 30	\$ —	\$ —	\$ —	\$ 30	\$ —	\$ 168	\$ —	\$ 198										
Grant income recognized during the three months ended June 30	2,140	725	290	137	271	219	2,701	\$ 1,081										
Cash received during the six months ended June 30	_	7,693	_	1,968	_	168	_	\$ 9,829										
Grant income recognized during the six months ended June 30	2,995	1,857	725	508	3,896	305	7,616	\$ 2,670										
Grants receivable at the end of the period	2,414	_	944	_	874	133	4,232	\$ 133										
Grants repayable at the end of the period	4,942	5,102	751	781	N/A		5,693	\$ 5,883										
			12															

#### Note 7. Stockholders' equity

On July 20, 2020, the Company effected a 1-for-3.3115 reverse stock split of the Company's common stock and adjusted the ratio at which the Company's preferred stock was convertible into common stock, as well as the number of shares under the 2019 Stock Option and Grant Plan and the Amended and Restated Certificate of Incorporation of iTeos Therapeutics, Inc., as well as the share amounts of stock grants under the plan and the number of options and exercise prices of options under the plan. All shares of common stock, stock options exercisable for shares of common stock, and per share information presented in the accompanying consolidated financial statements and notes thereto have been adjusted, where applicable, to reflect the reverse stock split on a retroactive basis for all periods presented. There was no change in the par value of the Company's common stock.

On July 28, 2020, the Company completed an IPO of 10,586,316 shares of its common stock, for aggregate gross proceeds of \$201.1 million and its shares started trading on The Nasdaq Global Select Market under the ticker symbol "ITOS." The Company received approximately \$184.0 million in net proceeds after deducting underwriting discounts and commissions and other estimated offering expenses payable by the Company. Upon closing of the IPO, all of the Company's outstanding shares of convertible preferred stock automatically converted into 22,460,076 shares of common stock. On August 5, 2020, the underwriters purchased an additional 1,505,359 shares of common stock pursuant to their option to purchase additional shares for net proceeds of \$26.6 million after deducting underwriting discounts and commissions.

On July 28, 2020, in connection with the IPO, the Company filed a restated Certificate of Incorporation, which, among other things, restated the number of shares of all classes of stock that the Company has authority to issue to 160,000,000 shares, of which (i) 150,000,000 shares shall be a class designated as common stock, par value \$0.001 per share, and (ii) 10,000,000 shares shall be a class designated as undesignated preferred stock, par value \$0.001 per share. Each share of common stock entitles the holders to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are not entitled to receive dividends, unless declared by the board of directors.

#### Note 8. Stock-based compensation

#### 2019 Stock Option and Grant Plan

The Company's 2019 Stock Option and Grant Plan (the 2019 Plan) provided for the Company to grant stock options and other stockbased awards to employees and non-employees to purchase the Company's common stock. On March 24, 2020, the Board of Directors approved an increase to the total authorized options under the 2019 Stock Option and Grant Plan to 3,464,316. Upon the effectiveness of the 2020 Plan (as defined below), no further issuances will be made under the 2019 Plan.

On July 15, 2020, the Company's Board of Directors approved an amendment stock options outstanding under the 2019 Stock Option and Grant Plan to provide for immediate 100% vesting for all outstanding options under the plan upon the consummation of a Sale Event, as defined by the amendment.

#### 2020 Stock Option and Incentive Plan

The 2020 Stock Option and Incentive Plan (the 2020 Plan) was approved by the Company's board of directors on July 15, 2020, and the Company's stockholders on July 20, 2020 and became effective on July 22, 2020, the date immediately prior to the date on which the registration statement for the Company's IPO became effective. The 2020 Plan provides for the grant of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock units, restricted stock awards, unrestricted stock awards, cash-based awards and dividend equivalent rights to the Company's officers, employees, directors and consultants. The number of shares of common stock initially reserved for issuance under the 2020 Plan was 3,809,818 which was cumulatively increased on January 1, 2021 and will be increase each January 1 thereafter by 5% of the number of shares of the Company's common stock outstanding on the immediately preceding December 31 or such lesser number of shares as determined by the Company's compensation committee of the board of directors. Accordingly, on January 1, 2021, the number of shares of common stock reserved and available for issuance under the 2020 Plan increased by 1,752,237. The number of shares of common stock reserved for issuance as of June 30, 2021 under the 2020 Plan was 5,562,055. The 2020 Plan replaced the 2019 Plan, as the Company's board of directors is not expected to make additional awards under the 2019 Plan following the completion of the IPO. However, the 2019 Plan will continue to govern outstanding equity awards granted thereunder.

#### Employee Stock Purchase Plan

The 2020 Employee Stock Purchase Plan (the 2020 ESPP) was approved by the Company's board of directors on July 15, 2020, and the Company's stockholders on July 20, 2020, and became effective on July 22, 2020, the date immediately prior to the date on which the registration statement for the Company's IPO was declared effective. The ESPP initially reserved and authorized the issuance of up to a total 317,484 shares of common stock to participating employees. The ESPP provides that the number of shares reserved and available for issuance automatically increased on January 1, 2021 and will automatically increase each January 1 thereafter by the lesser of 634,969 shares of common stock, 1% of the outstanding number of shares of common stock on the immediately preceding December 31, or such lesser number of shares as determined by the Company's compensation committee. Accordingly, on January 1, 2021, the number of shares of common stock reserved and available for issuance under the 2020 ESPP increased by 350,447. The number of shares of common stock reserved for issuance as of June 30, 2021 under the 2020 ESPP was 667,931. As of June 30, 2021, no shares had been issued under the 2020 ESPP.

#### Stock-Based Compensation Expense

Stock-based compensation expense is classified in the condensed consolidated statements of operations and comprehensive loss as follows:

	1	Three Months Ended June 30,				Six Months En	ided June 30,		
(in thousands)		2021		2020		2021		2020	
Research and development	\$	496	\$	67	\$	771	\$	117	
General and administrative		2,731		283		5,040		419	
Total stock-based compensation expense	\$	3,227	\$	350	\$	5,811	\$	536	

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

	Stock Options							
	Shares	i	Veighted average exercise price	Weighted average remaining contractual life (in years)	i	ggregate intrinsic value (in ousands)		
Outstanding as of December 31, 2020	4,552,396	\$	9.13	8.2				
Granted	983,450		34.27					
Forfeited	(3,075)		4.24					
Exercised	(103,352)		5.82					
Outstanding as of June 30, 2021	5,429,419	\$	13.70	8.1	\$	74,160		
Exercisable at June 30, 2021	1,469,512	\$	5.46	6.1	\$	29,794		

The weighted-average grant-date fair value of options awarded during the six month periods ended June 30, 2021 and 2020 was approximately \$26.56 per share and \$3.21 per share, respectively. As of June 30, 2021, there was a total of \$44.0 million of unrecognized employee compensation costs related to non-vested stock option awards expected to be recognized over a weighted average period of 3.2 years.

The Company estimates the fair value of stock-based compensation utilizing the Black-Scholes option pricing model, which is dependent upon several variables, such as expected term, volatility, risk-free interest rate, and expected dividends. Each of these inputs is subjective and generally requires significant judgment to determine. Stock-based compensation is measured at the grant date based on the fair value of the award and is recognized as expense over the requisite service period, which is generally the vesting period of the respective award.

The following table summarizes the range of key assumptions used to determine the fair value of stock options granted during:

	Three Months Er	nded June 30,	Six Months End	ded June 30,
	2021	2020	2021	2020
Risk-free interest rate	0.84% - 0.90%	0.45%	0.42% - 0.90%	0.45% - 1.35%
Expected term (in years)	6	6	6	6
Expected volatility	94% - 99%	92%	94% - 100%	90% - 92%
Expected dividend yield	_	_	_	_
Estimated fair value of common stock	\$23.19 - \$34.18	\$4.24 - \$6.16	\$23.19 - \$41.58	\$2.95 - \$6.16

#### Note 9. Commitments and contingencies

#### Purchase commitments

The Company has contractual arrangements with research and development organizations and suppliers; however, these contracts are generally cancelable on 30-60 days' notice and the obligations under these contracts are largely based on services performed. The Company may also enter into contracts in the normal course of business with clinical research organizations for clinical trials, with contract manufacturing organizations for clinical supplies and with other vendors for preclinical studies, supplies and other services and products for operating purposes. These contracts generally provide for termination on notice. As of June 30, 2021 and December 31, 2020, there were no amounts accrued related to termination charges.

#### **Operating leases**

The Company's operating leases are as follows:

 An April 2016 lease for 1,577 square meters of office and laboratory space in Gosselies, Belgium, which commenced in May 2016 and terminates in December 2021. In January 2021, the Company entered into an agreement to extend the lease, effective February 2021 with a termination date of January 2030, and increase the office and laboratory space by 201 square meters.



- A December 2018 lease for 2,479 square feet of office in Cambridge, Massachusetts, which commenced in May 2019 and terminates in May 2022. The lease is subject to fixed-rate rent escalations.
- Various car leases that the Company enters into from time to time. The average life of each car lease is 48 to 60 months.

Rent expense was \$0.1 million and \$0.2 million for the three months ended June 30, 2021 and 2020, respectively, and \$0.3 million for the six months ended June 30, 2021 and 2020.

The following table summarizes lease terms and discount rate:

	June 30, 2021	2020 December 31,
Weighted-average remaining lease term (years)	7.0	_
Weighted-average discount rate	4.82%	—

The following table summarizes the cash flow and other information:

	Three Months Ended June 30,			Six Months Ended June 30			June 30,	
(in thousands)		2021		2020		2021		2020
Operating lease liabilities arising from obtaining right-of-use assets (non-								
cash)	\$	110	\$	—	\$	3,316	\$	
Operating cash flows used in operating leases	\$	189		—	\$	374		—

As of June 30, 2021, the Company had the following future minimum lease payments under non-cancelable operating leases for the remainder of 2021 and the future years thereafter (in thousands):

Year ending December 31:	
2021	\$ 370
2022	592
2023	480
2024	464
2025	421
Thereafter	1,339
Total Lease Payments	3,666
Less: Interest	(610)
Total Lease Liability	\$ 3,056
Lease liability	 555
Lease liability, net of current portion	\$ 2,501

In March 2019, the Company provided a letter of credit for approximately \$57,000 to secure its obligation under its lease in Cambridge. The Company maintains that amount of cash on hand to fund any necessary draws on the letter of credit. In addition, as of June 30, 2021 and December 31, 2020, the Company had approximately \$82,000 and \$71,000 on hand serving as a guarantee for its lease obligation in Belgium. These amounts have been classified as restricted cash in the condensed consolidated balance sheets as of June 30, 2021 and December 31, 2020.

#### Note 10. Related party transactions

On June 11, 2018, the Company entered into a Royalty Transfer Agreement with the charitable foundations of two of its investors (MPM Oncology Charitable Foundation, Inc. and UBS Optimus Foundation), which requires it to pay a royalty equal to a total of 1% percent of its net product sales each year within 120 days following each year end. Such agreement was entered into as a result of the capital contributions received from the investors. As the Company has no product sales to date, no royalties were owed to these charitable foundations as of June 30, 2021.

#### Note 11. Net loss per share attributable to common stock

The following common stock equivalents were excluded from the calculation of net loss per share due to their anti-dilutive effect:

	June 3	0,
	2021	2020
Series B and B-2 Preferred Stock, as converted		20,597,566
Series A Preferred Stock, as converted	—	1,862,510
Stock options outstanding	5,429,419	3,323,378
Total	5,429,419	25,783,454

#### Note 12. Subsequent events

On June 11, 2021, the Company and GSK executed the GSK Collaboration Agreement, pursuant to which the Company agrees to grant GSK a license under certain of the Company's intellectual property rights to develop, manufacture, and commercialize products comprised of or containing the Company's antibody product, EOS-448. Under the GSK Collaboration Agreement, GSK agrees to make an upfront payment of \$625 million to the Company within 10 business days of the date on which the GSK Collaboration Agreement becomes effective, which occurred on July 26, 2021. Additionally, the Company is eligible to receive up to \$1.45 billion in milestone payments, contingent upon the EOS-448 program achieving certain development and commercial milestones. Within the collaboration, GSK and the Company agree to share responsibility and costs for the global development of EOS-448 and will jointly commercialize and equally split profits in the United States. Outside of the United States, GSK will receive an exclusive license for commercialization, and the Company is eligible to receive tiered double digit royalty payments up to 20% during a customary royalty term.

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

#### Management's discussion and analysis of financial condition and results of operation

The following discussion and analysis of our financial condition and results of operations should be read together with our unaudited condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q and our audited consolidated financial statements and related notes for the year ended December 31, 2020 included in our Annual Report on Form 10-K filed with the SEC. Some of the information contained in this discussion includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk factors" section of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

#### Overview

We are a clinical-stage biopharmaceutical company pioneering the discovery and development of a new generation of highly differentiated immuno-oncology therapeutics for patients. We leverage our deep understanding of the tumor microenvironment and immunosuppressive pathways to design novel product candidates with the potential to fully restore the immune response against cancer. Our innovative pipeline includes two clinical-stage programs targeting novel, validated immuno-oncology pathways designed with optimized pharmacologic properties for improved clinical outcomes. Our lead antibody product candidate, EOS-448, is an antagonist of TIGIT, or T-cell immunoreceptor with Ig and ITIM domains, an immune checkpoint with multiple mechanisms of action leading to immunosuppression. EOS-448 was also selected to engage the Fc gamma receptor, or FcyR, to activate dendritic cells and macrophages and to promote antibodydependent cellular cytotoxicity, or ADCC, activity. In 2020 we enrolled an open-label Phase 1/2a clinical trial of EOS-448 in adult cancer patients with advanced solid tumors. In April 2021, we reported preliminary safety, pharmacokinetic, efficacy and pharmacodynamic, or PD, data at the American Association of Cancer Research (AACR) annual meeting, indicating target engagement and early evidence of clinical activity of a single agent. On June 11, 2021, our affiliate, iTeos Belgium S.A. and GlaxoSmithKline Intellectual Property (No. 4) Limited, or GSK, executed a Collaboration and License Agreement, or the Collaboration Agreement, pursuant to which we agree to grant GSK a license under certain of our intellectual property rights to develop, manufacture, and commercialize products comprised of or containing EOS-448, which license is exclusive in all countries outside of the United States and co-exclusive, with ITEOS, in the United States. Under the Collaboration Agreement, GSK will make an upfront payment of \$625 million to us, or the Upfront Payment, within 10 business days of the date on which the GSK Collaboration becomes effective, which occurred on July 26, 2021. Additionally, we are eligible to receive up to \$1.45 billion in milestone payments, contingent upon the EOS-448 program achieving certain development and commercial milestones. Within the collaboration, GSK and we agree to share responsibility and costs for the global development of EOS-448 and will jointly commercialize and equally split profits in the United States. Outside of the United States, GSK will receive an exclusive license for commercialization, and we are eligible to receive tiered double digit royalty payments up to 20% during a customary royalty term. GSK and ITEOS intend to develop EOS-448 in combination with certain other oncology assets of GSK, and ITEOS and GSK will jointly own the intellectual property created under the Collaboration Agreement that covers such combinations. Subject to certain limited exceptions, other than under the Collaboration Agreement, GSK and ITEOS each agree not to, alone or with or for any Third Party, (i) develop a monospecific, monoclonal antibody that inhibits or is an antagonist of TIGIT through direct physical interaction for a period of time following the first regulatory approval of a Licensed Product in the United States, Germany, France, United Kingdom, Spain, or Italy or (ii) commercialize any such a product during the term of the Collaboration Agreement.

The Collaboration Agreement became effective on July 26, 2021, and GSK paid the Upfront Payment on August 5, 2021. We are also advancing inupadenant, a next-generation adenosine A2A receptor, or A2AR, antagonist tailored to overcome cancer immunosuppression. Inupadenant formerly referred to as EOS-850, is designed as a highly selective small molecule antagonist of the A2AR, in the adenosine pathway, a key driver of immunosuppression in the tumor microenvironment across a broad range of tumors. We are investigating inupadenant in an open-label multi-arm Phase 1/2a clinical trial in adult cancer patients with advanced solid tumors and in the dose escalation portion of the trial, it has shown encouraging preliminary single-agent activity. In addition to the single-agent cohort, we commenced dosing in a cohort evaluating inupadenant in combination with pembrolizumab in the third quarter or 2020 and a cohort evaluating inupadenant with chemotherapy in the fourth quarter of 2020. In June 2021, we reported additional data from monotherapy expansion cohorts at the American Society of Clinical Oncology (ASCO) annual meeting. These data from the single-agent dose-escalation and expansion portions of our Phase 1/2a clinical trial of inupadenant provided evidence of durable antitumor activity in patients with advanced solid tumors and indicated safety consistent with previously reported results.

We are using our expertise in tumor immunology to select additional targets for other novel, differentiated programs. We continue to progress research programs focused on additional targets that complement our TIGIT and A2AR programs or address additional pathways immunosupression. We expect to nominate an additional product candidate for commencement of Investigational New Drug, or IND, enabling studies before the end of 2021.

Since our inception in August 2011, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, conducting discovery and research activities, filing patent applications, identifying potential product candidates, undertaking preclinical studies and clinical trials and establishing arrangements with third parties for the manufacture of initial quantities of our product candidates and component materials. To date, we have not generated any revenue from product sales and have financed our operations primarily through our IPO. Through June 30, 2021, we had raised an aggregate of \$210.6 million of net proceeds from the IPO and \$177.1 million from the sale of preferred stock. As of June 30, 2021, our principal source of liquidity was cash and cash equivalents, which totaled \$302.9 million.

We have incurred recurring losses since inception. Our net losses were \$26.5 million and \$7.2 million for the three months ended June 30, 2021 and 2020, respectively, and \$40.0 million and \$12.4 million for the six months ended June 30, 2021 and 2020, respectively. As of June 30, 2021, we had an accumulated deficit of \$113.9 million. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product candidates.

We expect to continue to incur significant expenses and increasing operating losses in connection with ongoing development activities, particularly if and as we:

- continue preclinical studies and clinical trials and initiate new clinical trials for our product candidates;
- pursue regulatory approvals for our product candidates;
- advance the development of our product candidate pipeline;
- continue research activities as we seek to discover and develop additional product candidates;
- obtain, maintain, expand and protect our intellectual property portfolio;
- hire additional research and development, clinical and commercial personnel;
- scale up our clinical and regulatory capabilities; and
- add operational, financial and management information systems and personnel, including personnel to support our research and development programs, any future commercialization efforts and our transition to operating as a public company.

As a result of these anticipated expenditures, we will need substantial additional financing 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, grants, collaborations, strategic alliances and licensing arrangements. We may be unable to raise additional funds or enter into such other agreements when needed on favorable terms or at all. Our inability to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenue to achieve profitability, and we may never do so.

As of June 30, 2021, we had cash and cash equivalents of \$302.9 million. As a result of the upfront payment we received August 5, 2021 from GSK pursuant to our Collaboration and License Agreement, we believe our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into 2026. Our future viability beyond that point is dependent on our ability to raise additional capital to finance our operations. 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. See "Liquidity and capital resources." Because of the numerous risks and uncertainties associated with our programs, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates.

We are party to collaboration and license agreements pursuant to which we may be required to make future royalty and milestone payments. In January 2017, we entered into a collaboration agreement with Adimab, LLC, or Adimab, pursuant to which we paid \$1.0 million to exercise an option to acquire certain licenses from Adimab. One of the antibodies licensed under this agreement is what we now refer to as EOS-448. In February 2021, we entered into an amendment to this agreement (the Amended Adimab Agreement). The Amended Adimab Agreement specifies different milestone payments for new products that are derived from research programs beginning after February 22, 2021 (the New Products). For New Products, on a per target basis, we may be required to pay development, regulatory and



commercial milestone payments totaling up to an aggregate of \$45.8 million for the first three products and additional milestone payments up to \$14.5 million for each additional product. As of the date of this Quarterly Report on Form 10-Q, we have not pursued any additional targets under the Amended Adimab Agreement that could potentially result in such milestone payments. We will also pay Adimab low to mid single-digit percentage royalties on a country-by-country and product-by-product basis on worldwide net sales of licensed products. To date, we have paid a total of \$3.4 million to Adimab pursuant the Adimab Agreement. We are also party to a biologics master services agreement with WuXi Biologics Hong Kong Limited, or WuXi, pursuant to which we will pay WuXi, at our election, either a low single-digit percentage royalty on global net sales of manufactured products or a one-time milestone payment in the low tens of millions.

On December 10, 2019, we entered into a Clinical Trial Collaboration and Supply Agreement (the MSD Agreement) with MSD International GmbH (MSD), a subsidiary of Merck & Co., Inc. Under the MSD Agreement, we sponsor a clinical trial in which both our compound and MSD's compound are dosed in combination. We conduct the research at our own cost and MSD contributes its compound towards the study at no cost to us. We will equally own the clinical data and inventions from the study, with the exception of inventions relating solely to each party's compound class. The MSD Agreement will expire upon the delivery of a written report on the results of the study, unless earlier terminated or agreed by the parties. We began receiving compounds from MSD on April 1, 2020 and we began the research study in the third quarter of 2020.

#### Impact of COVID-19

With the ongoing concern related to the COVID-19 pandemic during 2020 and in the first six months of 2021, the Company has maintained and expanded its business continuity plans to address and mitigate the impact of the COVID-19 pandemic on its business. In March 2020, to protect the health of its employees, and their families and communities, the Company restricted access to its offices to personnel who performed critical activities that must be completed on-site, limited the number of such personnel that could be present at its facilities at any one time, and requested that most of its employees work remotely. In May 2020, as certain states eased restrictions, the Company established new protocols to better allow its full laboratory staff access to the Company's facilities. These protocols included several shifts working over a seven-day-week protocol. The Company expects to continue incurring additional costs to ensure it adheres to the guidelines instituted by the Centers for Disease Control and Prevention, or CDC, and to provide a safe working environment to its onsite employees.

The extent to which the COVID-19 pandemic impacts the Company's business, its corporate development objectives, results of operations and financial condition, and the value of and market for its common stock, will depend on future developments that are highly uncertain and cannot be predicted with confidence at this time, such as the ultimate duration of the pandemic, the severity of the COVID-19 or the effectiveness of actions taken globally to contain and treat CoVID-19, such as travel restrictions, quarantines, social distancing and business closure requirements but particularly I the geographies where we, our third party manufacturers, contract research organizations (CROs) or current and planned clinical trial sites operate. Disruptions to the global economy, disruption of global healthcare systems, and other significant impacts of the COVID-19 pandemic could have a material adverse effect on the Company's business, financial condition, results of operations and growth prospects.

While the COVID-19 pandemic did not significantly impact the Company's business or results of operations during the six months ended June 30, 2021, the length and extent of the pandemic, its consequences, and containment efforts will determine the future impact on the Company's operations and financial condition.

The future impact of the COVID-19 pandemic on our industry, the healthcare system and our current and future operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the scope, severity and duration of the pandemic, the actions taken to contain the pandemic or mitigate its impact, and the direct and indirect economic effects of the pandemic and containment measures, and the impact of the available vaccines, among others. See "Risk factors" for a discussion of the potential adverse impact of COVID-19 on our business, results of operations and financial condition.

#### Components of our results of operations

#### Revenue

To date, we have not generated any revenue from product sales and do not expect to do so in the near future, if at all. All of our revenue to date has been derived from licensing fees in connection with a research collaboration and license agreement with Pfizer, which terminated in 2017. We had no revenue for the three and six months ended June 30, 2021 and 2020.

We expect that our revenue, if any, will be less than our expenses for the foreseeable future and that we will experience increasing losses as we continue our development of, and seek regulatory approvals for, our product candidates and begin to commercialize any approved products. Our ability to generate revenue for each product



candidate for which we receive regulatory approval will depend on numerous factors, including competition, commercial manufacturing capability and market acceptance of our products.

#### Research and development expenses

Research and development expenses consist primarily of costs incurred for the development of our product candidates, which include:

- costs to obtain licenses to intellectual property and related future payments should certain success, development and regulatory milestones be achieved;
- employee-related expenses, including salaries, benefits and stock-based compensation expense;
- expenses incurred under agreements with contract research organizations, or CROs, contract manufacturing organizations, or CMOs, and independent contractors that conduct research and development, preclinical and clinical activities on our behalf;
- costs of purchasing lab supplies and non-capital equipment used in our preclinical activities and in manufacturing clinical study materials through CMOs;
- · consulting and professional fees related to research and development activities; and
- facility costs, depreciation, and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance, and other supplies.

We expense research and development costs as incurred. We recognize costs for certain development activities, such as preclinical studies and clinical trials, based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors, such as patient enrollment or clinical site activations for services received and efforts expended.

Research and development activities are central to our business model. We expect research and development costs to increase significantly for the foreseeable future as our current development programs progress and new programs are added.

Because of the numerous risks and uncertainties associated with product development, we cannot determine with certainty the duration and completion costs of the current or future preclinical studies and clinical trials or if, when, or to what extent we will generate revenues from the commercialization and sale of any product candidates that receive regulatory approval. We may never succeed in achieving regulatory approval for our product candidates. The duration, costs and timing of preclinical studies and clinical trials and development of our product candidates will depend on a variety of factors, which could all be impacted by the COVID pandemic, including, but not limited to:

- successful enrollment in, and completion of, clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- successful completion of preclinical studies and IND-enabling studies;
- · establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and non-patent exclusivity;
- launching commercial sales of the product, if and when approved, whether alone or in collaboration with others;
- acceptance of a product, if and when approved, by patients, the medical community and third-party payors;
- effectively competing with other therapies and treatment options;
- a continued acceptable safety profile following approval;
- · enforcing and defending intellectual property and proprietary rights and claims; and
- achieving desirable medicinal properties for the intended indications.

A change in the outcome of any of these factors could mean a significant change in the costs and timing associated with the development of our current and future preclinical and clinical product candidates. For example, if the FDA or comparable foreign regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development, or if we experience significant delays in execution of or enrollment in any of our preclinical studies or clinical trials, we could be required to expend significant additional financial resources and time on the completion of preclinical and clinical development.



The following table summarizes our principal product development programs, including direct research and development expenses allocated to each clinical product candidate:

	Three Months Ended June 30,			Six Mont Jun	led		
(in thousands)		2021		2020	 2021		2020
Direct research and development expenses by							
program:							
EOS-448	\$	3,763	\$	1,552	\$ 6,191	\$	2,465
Inupadenant		4,848		2,379	9,171		4,781
Other non-clinical programs		1,259		1,093	2,810		1,758
Indirect research and development expenses(1)		4,368		1,113	7,709		2,958
Total research and development expense	\$	14,238	\$	6,137	\$ 25,881	\$	11,962

(1) The substantial majority of these costs relate to the EOS-448 and inupadenant programs. Approximately half of these costs are payroll and related costs for our employees performing in-house research and development activities and the remainder represents other research and development costs.

#### General and administrative expenses

General and administrative expenses consist primarily of employee-related expenses, including salaries, benefits and stock-based compensation, for personnel in executive, finance, business development, facility operations and administrative functions. Other significant costs include facility costs not otherwise included in research and development expenses, legal fees relating to patent and corporate matters and fees for accounting, tax and consulting services.

#### Grant income

We have agreements with granting agencies whereby we receive funding under grants that partially or fully reimburse us for eligible research and development expenditures. Certain grant agreements require us to repay the funding depending on whether we decide to pursue commercial development or out-licensing of any drug candidate that is produced from the research program. The repayment provision includes portion that is fixed (corresponding to 30% of the grant), payable in annual installments, which is effective unless we decide not to pursue commercial development or out licensing of the drug candidate. The repayment provision also includes a potential obligation to pay a royalty that is contingent upon achieving sales of a product developed through the program. The maximum amount payable to the granting agency under each grant, including the fixed repayments, the royalty on revenue and the interest thereon, is twice the amount of funding received.

#### Research and development tax credits

Our subsidiary iTeos Belgium SA, as a Belgian biotechnology company, qualifies for a cash-based tax credit on research and development expenses. The credit is calculated based on a percentage of eligible research and development expenses defined by the Belgian government for each fiscal year (13.5% for 2021 and 2020) and then applying the effective tax rate to that result. The research and development tax credits are refundable to us if we are unable to use the credits to offset income taxes for the five subsequent tax years. We record a receivable and other income as the qualified expenses are incurred, as we are reasonably assured that the credit will be received, based upon our history of filing for the tax credits. Research and development tax credits receivable where we expect to receive refunds more than one year after the balance sheet date are classified as noncurrent in the consolidated balance sheet.

#### Fair value adjustment for tranche rights

Prior to March 2020, we had an obligation to issue and our investors' had an obligation to purchase additional shares of Series B preferred stock. This obligation represented a freestanding financial instrument. The resulting preferred stock tranche right liabilities were initially recorded at fair value, with gains and losses arising from changes in fair value recognized in the statement of operations and comprehensive loss during each period while such instruments were outstanding and the tranche rights were settled in the first quarter of 2020. Accordingly, we are no longer required to record liabilities for these obligations or changes in the fair value of those liabilities.



#### Other income (expense), net

Other income (expense), net includes income and expenses that do not fall within other categories of the statement of operations and comprehensive loss. Items included are interest income, bank fees and gain or loss on foreign currency transactions.

#### **Results of operations**

#### Comparison of the six months ended June 30, 2021 and 2020

The following table summarizes our results of operations for the six months ended June 30, 2021 and 2020, together with the dollar change in those items:

	Six Months Ended June 30,					Period to period	
(in thousands)		2021	2020			change	
Operating expenses:							
Research and development expenses	\$	25,881	\$	11,962	\$	13,919	
General and administrative expenses		22,147		4,812		17,335	
Total operating expenses		48,028		16,774	_	31,254	
Loss from operations		(48,028)		(16,774)		(31,254)	
Other income and expenses:							
Grant income		7,616		2,670		4,946	
Fair value adjustment for preferred stock tranche							
rights liability		_		1,265		(1,265)	
Research and development tax credits		119		370		(251)	
Other income (expense), net		300		(30)		330	
Loss before income taxes		(39,993)		(12,499)		(27,494)	
Income tax benefit		—		50		(50)	
Net loss	\$	(39,993)	\$	(12,449)	\$	(27,544)	

#### Research and development expenses

Research and development expenses increased by \$13.9 million to \$25.9 million for the six months ended June 30, 2021, from \$12.0 million for the six months ended June 30, 2020. This increase was primarily related to an increase of \$4.1 million of payroll and related costs, a \$9.8 million increase CRO and CMO fees and internal laboratory expenses, a \$0.7 million increase in stock-based compensation and an increase of \$0.3 million related to facilities. The increases were offset by a \$1.0 million decrease in various other research and development expenses. The overall increase was due to an increase in activities related to clinical trials, with the commencement of a Phase 1/2a clinical trial for EOS-448 in February 2020, as well as increased clinical activities for inupadenant. In addition, there was an increase in spending related to our preclinical programs during the six months ended June 30, 2021.

#### General and administrative expenses

General and administrative expenses increased by \$17.3 million to \$22.1 million for the six months ended June 30, 2021 from \$4.8 million for the six months ended June 30, 2020.

The increase was primarily attributable to an increase of \$1.6 million of payroll and related costs resulting from additional executives and finance and administrative employees added to enable us to operate as a public company, a \$4.6 million increase in stock-based compensation, an increase of \$8.4 million in professional fees and an increase of \$1.4 million for directors and officers insurance as a result of becoming a public company in July 2020. In addition, there was also a \$1.3 million net increase related to various other general and administrative expenses. The overall increase in professional fees can be primarily attributed to the advisor fees incurred by us for the GSK Collaboration Agreement. The advisory fee equaled \$6.3 million for the six months ended June 30, 2021. In addition, we incurred additional professional fees related to SEC reporting, SOX compliance and consulting related to our corporate structure in Belgium.

#### Grant income

Grant income increased by \$4.9 million to \$7.6 million for the six months ended June 30, 2021 from \$2.7 million for the six months ended June 30, 2020. The overall increase in grant income, driven by spending on qualified research and development activities, was primarily attributable to the ENT1, which was approved in March 2021, and inupadenant program. For the six months ended June 30, 2021, we recognized \$3.7 million in grant income related to the ENT1



program. The grant income relating to the inupadenant program increased by \$1.1 million. The remaining \$0.1 million net increase in grant income related to other grants.

#### Research and development tax credits

Research and development tax credits decreased by \$0.3 million. The decrease was caused by a decrease in qualifying research and development expenses in Belgium.

#### Fair value adjustment for preferred stock tranche rights liability

As a result of changes in the fair value of the preferred stock tranche rights liability, we recognized other income of \$1.3 million for the six months ended June 30, 2020. As of June 30, 2020, the tranche rights have been settled and the remaining liability has been reclassified to additional paid-in capital.

#### Other income (expense), net

The other income (expense), net for the six months ended June 30, 2021 primarily relates to foreign exchange gains recorded as a result of the change in euro to U.S. dollar exchange rate that occurred in the second half of 2021.

#### **Results of operations**

#### Comparison of the three months ended June 30, 2021 and 2020

The following table summarizes our results of operations for the three months ended June 30, 2021 and 2020, together with the dollar change in those items:

	_	Period to period				
(in thousands)		2021	2020			change
Operating expenses:						
Research and development expenses	\$	14,238	\$	6,137	\$	8,101
General and administrative expenses		15,101		2,394		12,707
Total operating expenses		29,339		8,531		20,808
Loss from operations		(29,339)		(8,531)		(20,808)
Other income and expenses:						
Grant income		2,701		1,081		1,620
Research and development tax credits		119		186		(67)
Other income, net		60		12		48
Loss before income taxes		(26,459)		(7,252)		(19,207)
Income tax benefit				50		(50)
Net loss	\$	(26,459)	\$	(7,202)	\$	(19,257)

#### Research and development expenses

Research and development expenses increased by \$8.1 million to \$14.2 million for the three months ended June 30, 2021, from \$6.1 million for the three months ended June 30, 2020. This increase was primarily related to an increase of \$2.5 million of payroll and related costs, a \$5.7 million increase CRO and CMO fees and internal laboratory expenses, a \$0.4 million increase in stock-based compensation and an increase of \$0.1 million related to facilities. The increases were offset by a \$0.6 million decrease in various other research and development expenses. The overall increase was due to an increase in activities related to EOS-448 and inupadenant clinical trials. In addition, there was an increase in spending related to our preclinical programs during the three months ended June 30, 2021.

#### General and administrative expenses

General and administrative expenses increased by \$12.7 million to \$15.1 million for the three months ended June 30, 2021 from \$2.4 million for the three months ended June 30, 2020.

The increase was primarily attributable to an increase of \$0.8 million of payroll and related costs resulting from additional executives and finance and administrative employees added to enable us to operate as a public company, a \$2.4 million increase in stock-based compensation, an increase of \$7.9 million in professional fees and an increase of \$0.7 million for directors and officers insurance as a result of becoming a public company in July 2020. In addition, there was also a \$0.9 million increase related to in various other general and administrative expenses. The overall increase in professional fees can be primarily attributed to the advisor fees incurred by us for the GSK Collaboration Agreement. The

advisory fee equaled \$6.3 million for the three months ended June 30, 2021. In addition, we incurred additional professional fees related to SEC reporting, SOX compliance and consulting related to our corporate structure in Belgium.

#### Grant income

Grant income increased by \$1.6 million to \$2.7 million for the three months ended June 30, 2021 from \$1.1 million for the three months ended June 30, 2020. The overall increase in grant income was driven by spending on qualified research and development activities. The grant income relating to the inupadenant program increased by \$1.4 million. The remaining \$0.2 million net increase in grant income related primarily to EOS-448.

#### Research and development tax credits

Research and development tax credits decreased by \$0.1 million. The decrease was caused by a decrease in qualifying research and development expenses in Belgium.

#### Other income (expense), net

The other income (expense), net for the three months ended June 30, 2021 primarily relates to foreign exchange gains recorded as a result of the change in euro to U.S. dollar exchange rate that occurred in the second quarter of 2021.

#### Liquidity and capital resources

In July 2020, we completed our IPO in which we issued and sold 10,586,316 shares of our common stock at a public offering price of \$19.00 per share. We received net proceeds from our IPO of \$184.0 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. In early August 2020, we sold an additional 1,505,359 shares of common stock pursuant to the underwriters' exercise of their option to purchase additional shares for net proceeds of \$26.6 million.

Since our inception, we have incurred significant operating losses. We expect to incur significant expenses and operating losses for the foreseeable future as we advance the clinical development of our programs. To date, we have funded our operations primarily with proceeds from the IPO, the sales of preferred stock, and grants and licenses. As of June 30, 2021, we had \$302.9 million in cash and cash equivalents.

To date, we have not generated any revenue from product sales and do not expect to generate revenue from the sale of products for the foreseeable future. We anticipate the need for additional capital in order to continue to fund our research and development, including our plans for clinical and preclinical trials and new product development, as well as to fund general operations. As and if necessary, we will seek to raise these additional funds through various potential sources, such as equity and debt financings or through corporate collaboration and license agreements. Especially in light of the COVID-19 pandemic, we can give no assurances that we will be able to secure such additional sources of funds to support our operations on acceptable terms, if at all, or, if such funds are available to us, that such additional financing will be sufficient to meet our needs. For a more detailed discussion of risks related to COVID-19, please see Part II., Item 1A., Risk factors—Risks related to our relationships with third parties, in this Quarterly Report on Form 10-Q.

#### Cash flows

The following table provides information regarding our cash flows for the six months ended June 30, 2021 and 2020:

	_	Six Months Ended June 30,							
(in thousands)		2021		2020					
Net cash (used in) provided by:									
Operating activities	\$	(33,045)	\$	(9,481)					
Investing activities		(549)		(138)					
Financing activities		862		126,633					
Effects of exchange rate changes on cash, cash equivalents and restricted cash		(650)		(11)					
Net increase in cash, cash equivalents and restricted cash	\$	(33,382)	\$	117,003					

#### Net cash used in operating activities

During the six months ended June 30, 2021, we used cash in operating activities of \$33.0 million, primarily resulting from operating expenses and partially offset by no cash received from grants. Net cash used in operating activities was \$9.5 million during the six months ended June 30, 2020, was primarily due to our net loss of \$12.4 million, offset primarily by the decrease of \$5.0 million in grants receivable.

#### Net cash used in investing activities

Net cash used in investing activities increased \$0.4 million for the six months ended June 30, 2021 compared to the six months ended June 30, 2020. The increase in cash used in investing activities was primarily due to higher investments in laboratory and other equipment and software during the six months ended June 30, 2021.

#### Net cash provided by financing activities

Net cash provided by financing activities was \$0.9 million during the six months ended June 30, 2021. This was due to the proceeds received from the exercise of stock options during the period. Net cash provided by financing activities was \$126.6 million during the six months ended June 30, 2020. We raised cash through the issuance of Series B-2 preferred stock, with net proceeds of \$125.0 million. In addition, we received \$2.7 million under grant programs with a potential obligation for repayment.

#### Effects of exchange rate changes on cash, cash equivalents and restricted cash

The \$0.7 million reduction of cash, cash equivalents and restricted cash for the six months ended June 30, 2021 was primarily caused by the reduction of the euro to dollar exchange rate between December 31, 2020 and June 30, 2021.

#### Funding requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue our Phase 1/2a clinical trial of EOS-448, continue our multi-arm Phase 1/2a clinical trial of inupadenant, advance the development of pipeline programs, initiate new research and preclinical development efforts and seek marketing approval for any product candidates that we successfully develop. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to establishing sales, marketing, distribution and other commercial infrastructure to commercialize such products. In July 2020, we completed our IPO in which we issued and sold 10,586,316 shares of our common stock at a public offering price of \$19.00 per share. We received net proceeds from our IPO of \$184.0 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. In early August 2020, we issued and sold an additional 1,505,359 shares of common stock pursuant to the underwriters' exercise of their option to purchase additional shares for net proceeds of \$26.6 million. Going forward, we expect to continue to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We believe that our cash and cash equivalents as of June 30, 2021, will enable us to fund our operating expenses and capital expenditure requirements through the second half of 2023. As a result of the upfront payment we received August 5, 2021 from GSK pursuant to our Collaboration and License Agreement, we believe our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into 2026.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with the development and commercialization of EOS-448 and inupadenant, and the research, development and commercialization of other potential product candidates, we are unable to estimate the exact amount of our operating capital requirements. Our future capital requirements will depend on many factors, including:

- the scope, progress, timing, costs and results of clinical trials of product candidates;
- · research and preclinical development efforts for any future product candidates that we may develop;
- our ability to enter into and the terms and timing of any collaborations, licensing agreements or other arrangements;



- the number of future product candidates that we pursue and their development requirements;
- the outcome, timing and costs of seeking regulatory approvals;
- the costs of commercialization activities for any of our product candidates that receive marketing approval to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- subject to receipt of marketing approval, revenue, if any, received from commercial sales of our current and future product candidates;
- our headcount growth and associated costs as we expand our research and development and establish a commercial infrastructure;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims;
- the costs of operating as a public company; and
- the emergence of competing therapies and other adverse market developments.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes many years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, grants, collaborations, strategic alliances and licensing arrangements. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to 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 grants when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

#### Contractual obligations and commitments

We enter into contracts in the normal course of business with CROs and clinical sites for the conduct of clinical trials, professional consultants for expert advice and other vendors for clinical supply manufacturing or other services. These contracts provide for termination on notice, and therefore are cancelable contracts and do not include any minimum purchase commitments.

During the six months ended June 30, 2021, we entered into an agreement to extend the Belgium lease, effective February 2021 with a termination date of January 2030, and increase the office and laboratory space by 201 square meters. There were no other significant changes to our contractual obligations and commitments as of June 30, 2021, as described in the section entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in our final Annual Report on Form 10-K for the year ended December 31, 2020.

#### Critical accounting policies and significant judgments and estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles. We believe that several accounting policies are important to understanding our historical and future performance. We refer to these policies as critical because these specific areas generally require us to make judgments and estimates about matters that are uncertain at the time we make the estimate, and different estimates— which also would have been reasonable—could have been used. On an ongoing basis, we evaluate our estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and other market-specific or other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for

making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no significant changes to our existing critical accounting policies discussed in our Annual Report on Form 10-K for the year ended December 31, 2020. We believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements:

#### **Research and development expenses**

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed for us 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 the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time, which we periodically confirm with the service providers and make adjustments if necessary. Examples of accrued research and development expenses include fees paid to:

- CROs in connection with clinical trials;
- CMOs with respect to clinical materials, intermediates, drug substance and drug product;
- vendors in connection with research and preclinical development activities; and
- vendors related to manufacturing, development and distribution of clinical supplies.

We base our expenses related to clinical trials on our estimates of the services received and efforts expended pursuant to contracts with multiple CROs that conduct and manage clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors for goods or services will exceed the level of services provided and result in a prepayment of the clinical expense. Payments under some of these contracts depend on factors such as the successful enrollment of subjects and the completion of clinical trial milestones. In accruing service fees, we determine the time period over which services will be performed, enrollment of subjects and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid expense accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, differences may cause us to report amounts that are too high or too low in any particular period. To date, there have been no material differences from our estimates to the amounts actually incurred.

#### Stock-based compensation expense

Prior to our IPO in July 2020, there had been no public market for our common stock. The estimated fair value of our common stock was determined by our board of directors as of the date of each option grant, with input from management, considering our most recently available third-party valuations of common stock, and our board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation. Our common stock valuations were prepared using an option pricing method, or OPM, which used market approaches to estimate our enterprise value. The OPM treats common stock and preferred stock as call options on the total equity value of a company, with exercise prices based on the value thresholds at which the allocation among the various holders of a company's securities changes. Under this method, the common stock has value only if the funds available for distribution to stockholders exceeded the value of the preferred stock liquidation preferences at the time of the liquidity event, such as a strategic sale or a merger. A discount for lack of marketability of the common stock is then applied to arrive at an indication of value for the common stock. In addition to considering the results of these third-party valuations, our board of directors considered both objective and subjective factors, including:

- the prices at which we sold preferred stock and the superior rights and preferences of the preferred stock relative to our common stock at the time of each grant;
- the progress of our research and development programs, including the status of preclinical studies and planned clinical trials for our product candidates;



- our stage of development and our business strategy;
- external market conditions affecting the biotechnology industry, and trends within the biotechnology industry;
- our financial position, including cash and cash equivalents on hand, and our historical and forecasted performance and operating results;
- the lack of an active public market for our common stock and our preferred stock; and
- the likelihood of achieving a liquidity event, such as an initial public offering or a sale of our company in light of prevailing market conditions.

The assumptions underlying these valuations represented management's best estimate, which involved inherent uncertainties and the application of management judgement. As a result, if factors or expected outcomes changed and we used significantly different assumptions or estimates, our stock-based compensation could be materially different.

Following our IPO, the fair value of our common stock is determined based on the quoted market price of our common stock.

There were no significant changes to assumptions used to value options using the Black Scholes option pricing model in 2021, with the exception of the stock and exercise prices.

#### Government grant funding and potential repayment commitments under recoverable cash advance grants (RCAs)

We have agreements with granting agencies whereby we receive funding under grants, which partially or fully reimburse us for eligible research and development expenditures. Certain grant agreements require us to repay the funding wherein the repayment provision of the grants are predicated on whether we decide to pursue commercial development or out licensing of the drug candidate that is produced from the results of the research program. The repayment provision includes a portion that is fixed (corresponding to 30% of the grant) which is effective after we decide to pursue commercial development or out licensing of the drug candidate. The repayment provision also includes a potential obligation to pay a royalty that is contingent upon achieving sales of a product developed through the program. The maximum amount payable to the granting agency under each grant, including the fixed repayments, the royalty on revenue, and the interest thereon, is twice the amount of funding received.

Grant funding for research and development received under grant agreements where there is a repayment provision is recognized as other income to the extent there is no potential obligation to repay this funding. We record the present value of the liability as a grant repayable in the accompanying consolidated balance sheets. The grant repayable is subsequently recorded at amortized cost. There were no significant changes to assumptions in 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 under the applicable regulations of the SEC.

#### Recent accounting pronouncements

Refer to Note 2, "Summary of Significant Accounting Policies," in the accompanying notes to the consolidated financial statements for a discussion of recent accounting pronouncements.

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

We are exposed to market risk related to changes in interest rates. As of June 30, 2021 and December 31, 2020, we had cash and cash equivalents of \$302.9 million and \$336.3 million, respectively. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of interest rates in the United States and Belgium. As of June 30, 2021, our cash and cash equivalents is held primarily in savings, money market accounts and money market funds. Because of the short-term nature of the instruments in our portfolio, an immediate 10% change in the interest rate would not have a material impact on the fair market value of our investment portfolio or on our financial position or results of operations.

We are subject to the risk of fluctuations in foreign currency exchange rates, specifically with respect to the euro. Our functional currency is the U.S. dollar and the functional currency of our wholly owned subsidiary, iTeos Belgium SA, is



the euro. An immediate 5% change in the Euro exchange rate would not have any material effect on our results of operations.

Assets and liabilities of iTeos Belgium SA are translated into U.S. dollars at the exchange rate in effect on the balance sheet date. Income items and expenses are translated at the average exchange rate in effect during the period. Unrealized translation gains and losses are recorded as a cumulative translation adjustment, which is included in the consolidated statements of stockholders' deficit as a component of accumulated other comprehensive loss. Adjustments that arise from exchange rate changes on transactions denominated in a currency other than the local currency are included in other income and expenses, net in the consolidated statements of operations and comprehensive loss as incurred.

#### Item 4. Controls and Procedures.

#### Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our chief executive officer and our chief financial officer, has evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls, and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on such evaluation, our principal executive officer and principal financial officer have concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

#### Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the period covered by this Quarterly Report on Form 10-Q that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

#### PART II—OTHER INFORMATION

#### Item 1. Legal Proceedings.

From time to time, we may be a party to litigation or subject to claims incident to the ordinary course of business. Although the results of litigation and claims cannot be predicted with certainty, we currently believe that the final outcome of these ordinary course matters will not have a material adverse effect on our business. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors. We are not currently a party to any material legal proceedings.

#### Item 1A. Risk Factors.

#### **Risk factors**

The following risk factors and other information included in this Quarterly Report on Form 10-Q should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Please see the Section titled "Forward-Looking Statements" in this Quarterly Report on Form 10-Q for a discussion of some of the forward-looking statements that are qualified by these risk factors. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected.

#### Risks related to the development of our product candidates

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

We are currently focusing on the development of inupadenant and EOS-448. A key part of our strategy, however, is to continue to pursue clinical development of additional product candidates designed to address the main causes of PD-1 or other standard-of-care resistance. 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 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 our current product candidates and any future product candidates may not be predictive of the results of later-stage clinical trials. 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 approvals from the FDA or comparable foreign regulatory authorities. While we are currently conducting first-in-human Phase 1/2a trials of EOS-448 and inupadenant, we have not yet completed any clinical trials. Our current product candidates and any future product candidates may not perform as we expect, may ultimately have a different or no impact on tumors, may have a different mechanism of action than we expect, and may not ultimately prove to be safe and effective.

Preliminary and final results from preclinical studies and early stage trials, and trials in compounds that we believe are similar to ours, may not be representative of results that are found in larger, controlled, blinded, and longer-term studies. Product candidates may fail at any stage of preclinical or clinical development. Product candidates may fail to show the desired safety and efficacy traits even if they have progressed through preclinical studies or initial clinical trials. Preclinical studies and clinical trials may also reveal unfavorable product candidate characteristics, including safety concerns. A number of companies in the biopharmaceutical industry have suffered significant setbacks in clinical trials, notwithstanding promising results in earlier preclinical studies or clinical trials or promising mechanisms of action. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. Moreover, should there be an issue with the design of a clinical trial, our results may be impacted. We may not discover such a flaw until the clinical trial is at an advanced stage.

Additionally, our clinical trials, to date, have been open-label trials, where both the patient and investigator know whether the patient is receiving the investigational product candidate or either 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 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. 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. Therefore, it is possible that positive results observed in open-label trials will not be replicated in later placebo-controlled trials. 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 our current product candidates and any future product candidates, including:

- regulators or institutional review boards, or IRBs, may not authorize us or our investigators to commence a clinical trial, conduct a clinical trial at a prospective trial site, or amend trial protocols, or may require that we modify or amend our clinical trial protocols;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and/or clinical research organizations, or CROs;
- we may be unable to initiate or complete preclinical studies or clinical trials on time or at all due to the impacts of COVID-19;
- clinical trials of our current product candidates and any 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 or abandon product development programs;
- the number of patients required for clinical trials of our current product candidates and any 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, or may elect to participate in alternative clinical trials sponsored by our competitors
  with product candidates that treat the same indications as our current product candidates and any 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, or we may be required to engage in additional clinical trial site monitoring;
- we, regulators, or IRBs may require that we or our investigators suspend or terminate clinical research 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, including where combination dosing of or with our
  product candidates results in serious adverse events or undesirable side effects, or due to findings of undesirable effects caused by a
  chemically or mechanistically similar therapeutic or therapeutic candidate;
- changes could be adopted in marketing approval policies during the development period, rendering our data insufficient to obtain marketing approval;
- statutes or regulations or site policies could be amended or new ones could be adopted;
- changes could be adopted in the regulatory review process for submitted product applications;
- the cost of clinical trials of our current product candidates and any future product candidates may be greater than we anticipate or we
  may have insufficient funds for a clinical trial or to pay the substantial user fees required by the FDA or comparable foreign regulatory
  authorities upon the filing of a Biologics License;
- Application, or BLA, or a New Drug Application, or NDA, or equivalent authorizations from comparable foreign regulatory authorities;
- the supply or quality of our current product candidates and any future product candidates or other materials necessary to conduct clinical trials of our current product candidates and any future product candidates may be insufficient or inadequate or may be interrupted or impacted by the COVID-19 pandemic;
- we may decide, or regulators may require us, to conduct or gather, as applicable, additional clinical trials, analyses, reports, data, or preclinical trials, or we may abandon product development programs;
- we may fail to reach an agreement with regulators or IRBs regarding the scope, design, or implementation of our clinical trials, and the FDA or comparable foreign regulatory authorities may require changes to our study designs that make further study impractical or not financially prudent;
- regulators may ultimately disagree with the design or our conduct of our preclinical studies or clinical trials, finding that they do not support product candidate approval;

- we may have delays in adding new investigators or clinical trial sites, or we may experience a withdrawal of clinical trial sites;
- 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;
- there may be regulatory questions or disagreements regarding interpretations of data and results, or new information may emerge regarding our current product candidates and any future product candidates;
- the FDA or comparable foreign regulatory authorities may disagree with our study design, including endpoints, or our interpretation of data from preclinical studies and clinical trials or find that a product candidate's benefits do not outweigh its safety risks;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a drug or biologic candidate is safe and effective for its proposed indication or a related companion diagnostic is suitable to identify appropriate patient populations;
- 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 intended indications;
- the FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or our manufacturing facilities for clinical and future commercial supplies;
- the data collected from clinical trials of our current product candidates and any future product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of an BLA or NDA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may take longer than we anticipate to make a decision on our current product candidates and any future product candidates; and
- 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.

Our development costs will also increase if we experience delays in testing or approvals, and we may not have sufficient funding to complete the testing and approval process for our current product candidates and any future product candidates. We may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of our current product candidates and any future product candidates. We do not know whether any preclinical tests or clinical trials beyond what we currently have planned will be required, will begin as planned, will need to be restructured, or will be completed on schedule, or at all. Significant delays relating to any preclinical or clinical trials also could shorten any periods during which we may have the exclusive right to commercialize our current product candidates and any future product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our current product candidates and any 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 any of our current product candidates and any future product candidates. If any of these occur, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

### We may find it difficult to enroll patients in our current and/or future clinical trials, which could delay or prevent clinical trials of our product candidates.

Identifying and qualifying patients to participate in clinical studies of our current product candidates and any future product candidates is critical to our success. The timing of completion of our clinical trials depends in part on the speed at which we can recruit patients to participate in testing our current product candidates and any future product candidates, and we may experience delays in our clinical trials if we encounter difficulties in enrollment or patient retention due to other unforeseen factors. We may not be able to initiate or continue clinical trials for our current product candidates and any future product candidates if we are unable to locate and enroll and retain a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities outside the United States. For example, the COVID-19 pandemic may impact our ability to initiate clinical sites and recruit, enroll and retain patients or may divert healthcare resources away from clinical trials.

In addition to the competitive trial environment, 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 either severe enough or not too advanced to include them in a study. Additionally, the process of finding patients 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 and benefits of the product candidates under study, the availability and efficacy of competing therapies and clinical trials, the proximity and availability of clinical trial sites for prospective patients, and the patient referral practices of physicians. 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.

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

- the size of the patient population and process for identifying patients;
- the eligibility criteria for the clinical trial in question;
- the availability of an appropriate screening test, as necessary;
- · the perceived risks and benefits of the product candidate under study;
- the efforts to facilitate timely enrollment in clinical trials;
- the proximity and availability of clinical trial sites for prospective patients;
- the design of the clinical trial;
- · our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents;
- reporting of the preliminary results of any of our clinical trials; and
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before clinical trial completion.

In addition, our clinical trials will compete with other clinical trials for product candidates that treat the same indications or are in the same therapeutic areas as our current product candidates and any future product candidates, and this competition will reduce the number and types of eligible patients available to us because some patients who might have opted to enroll in our clinical trials may instead opt to enroll in a clinical trial being conducted by one of our competitors. 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 will reduce the number of patients who are available for our clinical trials at such clinical trial sites. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining enrollment of such patients in our clinical trials.

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

# We anticipate that our current product candidates and any future product candidates will be used in combination with third-party drugs or biologics, some of which are still in development, and we have limited or no control over the supply, regulatory status, or regulatory approval of such drugs or biologics.

Our current product candidates and any future product candidates have the potential to be administered in combination with checkpoint inhibitor immunotherapies or other standards of care like chemotherapies, targeted therapies or radiotherapy. For example, we are currently conducting a multi-arm Phase 1/2a clinical trial of inupadenant as a single agent and in combination with pembrolizumab. Our ability to develop and ultimately commercialize our current product candidates and any future product candidates used in combination with pembrolizumab or any other checkpoint inhibitor immunotherapies will depend on our ability to access such drugs or biologics 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, including our relationship with Merck with respect to our multi-arm Phase 1/2a clinical trial of inupadenant, will provide us with a steady supply of such drugs or biologics on commercially reasonable terms or at all.

Any failure to maintain or enter into new successful commercial relationships, or the expense of purchasing checkpoint inhibitor immunotherapies or other comparator therapies in the market, may delay our development timelines, increase our costs and jeopardize our ability to develop our current product candidates and any future product candidates as commercially viable therapies. If any of these occur, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

Moreover, the development of product candidates for use in combination with another product or product candidate may present challenges that are not faced for single agent product candidates. We are currently developing inupadenant and EOS-448 and may develop other future product candidates for use in combination with checkpoint inhibitor immunotherapies and may develop inupadenant, EOS-448, or any future product candidates for use with other therapies. The FDA or comparable foreign regulatory authorities 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. It is possible that the results of such trials could show that any positive previous trial results are attributable to the combination therapy and not our current product candidates and any future product candidates. Moreover, following product approval, the FDA or comparable foreign regulatory authorities 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 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, quality, manufacturing and supply issues, and changes to the standard of care.

In the event that Merck 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 checkpoint inhibitor immunotherapies. Additionally, should the supply of products from Merck or any future collaborator or supplier be interrupted, delayed or otherwise be unavailable to us, our clinical trials 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.

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

Because we have limited financial and managerial resources, we 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.

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

From time to time, we may publish interim top-line or preliminary results from our clinical trials. Interim results from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or top-line results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Differences between preliminary or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly.

### We may not be able to file Investigational New Drug, or IND, applications or IND amendments to commence additional clinical trials on the timelines we expect, and even if we are able to, the FDA or a comparable foreign regulatory may not permit us to proceed.

The FDA or comparable foreign regulatory authorities may require us to file separate INDs for additional clinical trials we plan to conduct with our current lead product candidates, inupadenant and EOS-448. We may not be able to file any additional INDs required for our current product candidates and any future product candidates on the timelines we expect. For example, we may experience manufacturing delays or other delays with IND-enabling studies, including due to the impact of the COVID-19 pandemic on suppliers, study sites or third-party contractors and vendors on whom we depend. Moreover, we cannot be sure that submission of an IND will result in the FDA or comparable foreign regulatory authorities allowing further clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND. Any failure to file INDs on the timelines we expect or to obtain regulatory approvals for our trials may prevent us from

completing our clinical trials or commercializing our products on a timely basis, if at all. There are similar risks related to the review and authorization of our protocols and amendments by comparable foreign regulatory authorities.

### We are conducting clinical trials for product candidates outside the United States, and the FDA and comparable foreign regulatory authorities may not accept data from such trials.

We are conducting and in the future may conduct one or more clinical trials outside the United States, including in Europe, and we may conduct trials in the future in Asia. The acceptance of data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and medical practice; and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to good clinical practice, or GCP, regulations. In general, the patient population for any clinical trials conducted outside the United States must be representative of the population for whom we intend to label the product candidate in the United States. Additionally, the FDA's clinical trial approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in product candidates that we may develop not receiving approval for commercialization in the applicable jurisdiction.

### As an organization, we have never conducted pivotal clinical trials, and we may be unable to do so for any product candidates we may develop.

We will need to successfully complete pivotal clinical trials in order to obtain the approval of the FDA or comparable foreign regulatory authorities to market inupadenant, EOS-448, or any future product candidate. Carrying out pivotal clinical trials is a complicated process. As an organization, we have not previously conducted any later stage or pivotal clinical trials. In order to do so, we will need to expand our clinical development and regulatory capabilities, and we may be unable to recruit and train qualified personnel. We also expect to continue to rely on third parties to conduct our pivotal clinical trials. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to BLA or NDA submission and approval of inupadenant, EOS-448, or future product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in commercializing our product candidates.

# 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 our current product candidates, 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. 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 our product candidates are intended to be used in combination with other drugs or biologics with different mechanisms of action, if and when marketed they will still compete with a number of drugs and biologics that are currently marketed or in development that also target cancer. To compete effectively with these products, our current product candidates 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 or biologics.



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 FDA 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.

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

The potential market opportunities for our current product candidates or any future product candidates are difficult to estimate and will depend in large part on the drugs with which our current product candidates or any future product candidates are co-administered and the success of competing therapies and therapeutic approaches. Our estimates of the potential market opportunities 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. Further, new studies may change the estimated incidence or prevalence of these diseases, and any regulatory approvals that we may receive for a product candidate may include limitations for use or contraindications that decrease the addressable patient population. If any of the assumptions proves to be inaccurate, the actual markets for our current product candidates and any 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 our current or future product candidates and negatively affect our business.

The commercial success of our current product candidates or any future product candidates will depend in part on public acceptance of the use of cancer immunotherapies. Adverse events in clinical trials of inupadenant, EOS-448, or any future product candidates, or in clinical trials of others developing similar products and the resulting publicity, as well as any other negative developments in the field of immunooncology that may occur in the future, including in connection with competitor therapies, could result in a decrease in demand for inupadenant, EOS-448, 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, our current product candidates and any 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 or may discontinue their participation 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 our current product candidates or any future product candidates. Any increased scrutiny could delay or increase the costs of obtaining marketing approval for inupadenant, EOS-448, or any future product candidates.

### If we are unable to successfully commercialize 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 our current or future product candidates, our ability to generate revenues from our current product candidates or any future product candidates will depend on our success in:

- launching commercial sales of our current product candidates and any 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 our current product candidates 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 our current product candidates or any future product candidates in the United States;
- manufacturing 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 our current product candidates or any future product candidates;
- achieving market acceptance of our current product candidates or any future product candidates by patients, the medical community, and third-party payors;
- achieving appropriate reimbursement for our current product candidates or any future product candidates;
- effectively competing with other therapies; and
- maintaining a continued acceptable safety profile of our current product candidates 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.

#### **Risks related to government regulation**

Even if our development efforts are successful, we may not obtain regulatory approval for any of our current product candidates or any future product candidates in the United States or other jurisdictions, which would prevent us from commercializing our current product candidates and any future product candidates. Even if we obtain regulatory approval for our current product candidates and any 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 our current product candidates or any future product candidates.

We are not permitted to market or promote or sell our current product candidates 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 our current product candidates and any future product candidates, we will not be able to commercialize such product candidates and any future product candidates in obtaining approval for and commercializing our current product candidates and any future product candidates occur in any jurisdictions, our business, financial condition, results of operations, stock price and prospects will be materially harmed. Even if our current product candidates and any 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 risk evaluation and mitigation strategy, or REMS, to monitor the safety or efficacy of the products.

We have not previously submitted a BLA or NDA to the FDA, or a similar marketing application to comparable foreign regulatory authorities, for any product candidate, and we can provide no assurance that will ultimately be successful in obtaining regulatory approval for claims that are necessary or desirable for successful marketing, or 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 our current product candidates and any 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 the 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 our current product candidates and any future product candidates will never obtain the appropriate regulatory approvals necessary for us to commence product sales.

Even if we eventually complete clinical testing and receive approval of a BLA, NDA or foreign marketing application for inupadenant, EOS-448, or any future product candidates, the FDA or a comparable foreign regulatory authority may grant approval or other marketing authorization contingent on the performance of costly additional clinical trials, including post-marketing clinical trials. The FDA or a comparable foreign regulatory authority also may approve or authorize for marketing a product candidate for a more limited indication or patient population than we originally request, and the FDA or a comparable foreign regulatory authority may not approve or authorize the labeling that we believe is necessary or desirable for the successful commercialization of a product candidate.

In addition, the FDA and comparable foreign regulatory authorities may change their policies, issue additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval of our future products under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain approvals, increase the costs of compliance or restrict our ability to maintain any marketing authorizations we may have obtained.

If we experience delays in obtaining approval, if we fail to obtain approval of a 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.

# The FDA or a comparable foreign regulatory authority may determine that our current product candidates and any future product candidates have serious adverse events or undesirable side effects that could delay or prevent their regulatory approval or commercialization.

Serious adverse events or undesirable side effects caused by our current product candidates and any 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 enrollment challenges, discontinuation of trial subjects, a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. For example, we have identified in the past and may in the future identify unexpected serious adverse events of suspected potential relatedness to our product candidates. If concerns are raised regarding the safety of a new therapeutic as a result of undesirable side effects or serious adverse events identified during clinical or preclinical testing, including any dose-limiting toxicities that may be identified with our product candidates, the FDA or comparable foreign regulatory authority may request additional data or information or order us to pause or cease further development, e.g., by issuing a clinical hold on ongoing or planned clinical trials, declining to approve the product candidate or issuing 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, reconsent of enrolled patients, or the monitoring of safety data by a data monitoring committee, among other strategies. The FDA or a comparable foreign regulatory authority requests for additional data or information could also result in substantial delays in the approval of our current product candidates and any future product candidates. Additionally, we may evaluate our product candidates in combination with one another, and safety concerns arising during a combination trial could negatively affect the individual development program of each candidate, as the FDA or comparable foreign regulatory authorities may require us to discontinue single-candidate trials until the contribution of each product candidate to any safety issues is better understood.

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 drug or biologic candidate may only be uncovered when a significantly larger number of patients are exposed to the drug or biologic candidate or when patients are exposed for a longer period of time.

Undesirable side effects caused by our current product candidates 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 our current product candidates and any future product candidates. Later discovered undesirable side effects may further result in the imposition of a REMS, label revisions, post-approval study requirements, or other testing and surveillance.



If our current product candidates and any 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 or comparable foreign regulatory authorities, Department of Justice, Department of Health and Human Services', or HHS, 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 or comparable foreign regulatory authority approval for desired uses or indications for our current product candidates and any 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 our products, including claims comparing our products to other companies' products, and must abide by the FDA or a comparable foreign regulatory authority's strict requirements regarding the content of promotion and advertising.

While 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, we and any third parties engaged on our behalf are prohibited from marketing and promoting the products for indications and uses that are not specifically approved by the FDA or comparable foreign 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 our current product candidates and any 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, the promotion of biopharmaceutical products are subject to additional FDA requirements and restrictions on promotional statements. If after one or more of our current product candidates and 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.

Furthermore, the use of our products for indications other than those approved by the FDA or comparable foreign regulatory authorities may not effectively treat such conditions. Any such off-label use of our product candidates could harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use our products for these uses for which they are not approved, which could lead to product liability suits that that might require significant financial and management resources and that could harm our reputation.

# Even if our current product candidates and 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 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, applicable tracking and tracing requirements, 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 cGMP requirements relating to manufacturing, quality control, quality assurance, and corresponding maintenance of records and documents, and good clinical practices, or 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 our current product candidates and any 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 manufacturing organizations, or CMOs, 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.

In addition, later discovery of previously unknown adverse events or that the product is less effective than previously thought or other problems with our 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 candidate is administered;
- 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 candidate;
- 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 or comparable foreign regulatory authority 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 the particular product candidate, if approved, 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.

The FDA's policies or those of comparable foreign regulatory authorities may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our current product candidates and any future product candidates, limit the marketability of our current product candidates and any future product candidates, or impose additional regulatory obligations on us. Changes in medical practice and standard of care may also impact the marketability of our current product candidates and any future product candidates.

If we are slow or unable to adapt to changes in existing requirements, standards of care, 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.

Should any of the above actions take place, we could be prevented from or significantly delayed in achieving profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operations and business and could adversely impact our business, financial condition, results of operations, stock price and prospects.

# We may in the future seek orphan drug status for our current or 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.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting an NDA or BLA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process.

If a product that has orphan drug designation subsequently receives the first FDA approval for a particular active ingredient for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same product for the same indication for seven years, except in limited circumstances such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. As a result, even if our current product candidates and any future product candidates receive orphan exclusivity, the FDA can still approve other drugs that have a different active ingredient for use in treating the same indication or disease. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product.

We may seek orphan drug designation for some or all of our current or future product candidates in orphan indications in which there is a medically plausible basis for the use of these products. Even if we obtain orphan drug designation, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. In addition, the FDA has expressed concerns regarding the regulatory considerations for orphan drug designation as applied to tissue agnostic therapies, and the FDA may interpret the federal Food, Drug and Cosmetic Act, as amended, or the FD&C Act, and regulations promulgated thereunder in a way that limits or blocks our ability to obtain orphan drug designation or orphan drug exclusivity, if our current product candidates and any future product candidates are approved, for our targeted indications.



The FDA may reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

# We may pursue Fast Track or Breakthrough Therapy designation by FDA. These designations may not actually lead to a faster development or regulatory review or approval process, and they do not assure FDA approval of any product candidates we may develop.

FDA's Fast Track and Breakthrough Therapy designations programs are intended to expedite the development of certain qualifying products intended for the treatment of serious diseases and conditions. If a product candidate is intended for the treatment of a serious or life threatening condition and preclinical or clinical data demonstrate the product's potential to address an unmet medical need for this condition, the sponsor may apply for FDA Fast Track designation. A product candidate may be designated as a Breakthrough Therapy if it is intended to treat a serious or life-threatening condition and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. While we may seek Fast Track or Breakthrough Therapy designation, there is no guarantee that we will be successful in obtaining any such designation. Even if we do obtain such designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. A Fast Track or Breakthrough Therapy designation does not ensure that the product candidate will receive marketing approval or that approval will be granted within any particular timeframe. In addition, the FDA may withdraw Fast Track or Breakthrough Therapy designation if it believes that the designation is no longer supported by data from our clinical development program. Fast Track or Breakthrough Designation for the FDA's priority review procedures.

# If we are unable to successfully validate, develop and obtain regulatory approval for companion diagnostic tests for our product candidates that require or would commercially benefit from such tests, or experience significant delays in doing so, we may not realize the full commercial potential of these product candidates.

In connection with the clinical development of our product candidates for certain indications, we may engage third parties to develop or obtain access to *in vitro* companion diagnostic tests to identify patient subsets within a disease category who may derive selective and meaningful benefit from our product candidates. Such companion diagnostics would be used during our clinical trials as well as in connection with the commercialization of our product candidates. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. The FDA and comparable foreign regulatory authorities regulate *in vitro* companion diagnostics as medical devices and, under that regulatory framework, will likely require the conduct of clinical trials to demonstrate the safety and effectiveness of any diagnostics we may develop, which we expect will require separate regulatory clearance or approval prior to commercialization.

We intend to rely on third parties for the design, development and manufacture of companion diagnostic tests for our therapeutic product candidates that may require such tests. If we enter into such collaborative agreements, we will be dependent on the sustained cooperation and effort of our future collaborators in developing and obtaining approval for these companion diagnostics. It may be necessary to resolve issues such as selectivity/specificity, analytical validation, reproducibility, or clinical validation of companion diagnostics during the development and regulatory approval processes. Moreover, even if data from preclinical studies and early clinical trials appear to support development of a companion diagnostic for a product candidate, data generated in later clinical trials may fail to support the analytical and clinical validation of the companion diagnostic. We and our future collaborators may encounter difficulties in developing, obtaining regulatory approval for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our therapeutic candidates themselves, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we are unable to successfully develop companion diagnostics for these therapeutic product candidates, or experience delays in doing so, the development of these therapeutic product candidates may be adversely affected, these therapeutic product candidates may not obtain marketing approval, and we may not realize the full commercial potential of any of these therapeutics that obtain marketing approval. As a result, our business, results of operations and financial condition could be materially harmed. In addition, a diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic test that we anticipate using in connection with development and commercialization of our product candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our therapeutic candidates.

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

The ability of the FDA or comparable foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

For example, over the last several years, including beginning on December 22, 2018, the United States government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Since March 2020 when foreign and domestic inspections of facilities 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 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, 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 United States 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 March 26, 2021, the FDA noted it is continuing to ensure timely reviews of applications for medical products during the ongoing COVID-19 pandemic in line with its user fee performance goals. However, FDA may not be able to continue its current pace and review timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the ongoing COVID-19 pandemic and travel restrictions FDA is unable to complete such required inspections during the review period.

# Even if we are able to commercialize any current product candidates or any future product candidates, such drugs and biologics 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 and biologics vary widely from country to country. Some countries require approval of the sale price of a drug or biologic 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 one or more of our current product candidates and any future product candidates, even if our current product candidates and any future product candidates obtain marketing approval.



Our ability to commercialize our current product candidates and any future product candidates successfully also will depend in part on the extent to which coverage and reimbursement for our current product candidates and any future product candidates and related treatments will be available from government 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 HHS. 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. Other 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 United States healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular drugs and biologics. 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 and biologics. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs and biologics. 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 candidates. We, or our collaborators, will be required to obtain coverage and reimbursement for these tests separate and apart from the coverage and reimbursement we seek for our product candidates, once approved. There is significant uncertainty regarding our ability, or a collaborator's ability, to obtain coverage and adequate reimbursement for the same reasons applicable to our product candidates.

There may be significant delays in obtaining reimbursement for newly approved drugs and biologics, and coverage may be more limited than the purposes for which the drug is approved or for which a biologic is licensed 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, manufacture, 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 or biologic and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost products and may be incorporated into existing payments for other services. Net prices for drugs and biologics 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 or biologics 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 or biologics that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize drugs and biologics and our overall financial condition. Further, due to the COVID-19 pandemic, millions of individuals have lost/will be losing employer-based insurance coverage, which may adversely affect our ability to commercialize our products.

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

The delivery of healthcare in the European Union, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than European Union, law and policy. National governments and health service providers have different priorities and approaches to the delivery of

healthcare and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most European Union member states, or Member States, have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. For example, some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed to by the government. Some Member States approve a specific price for the medicinal product, whilst others adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market, including volume-based arrangements, caps and reference pricing mechanisms. It is increasingly common in many Member States for marketing authorization holders to be required to demonstrate the pharmaco-economic superiority of their products as compared to products already subject to pricing and reimbursement in specific countries. Coupled with ever-increasing European Union and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize any products for which we obtain marketing approval.

#### 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 our current product candidates and any 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 Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the United States pharmaceutical industry. The ACA, among other things, subjected biological products to potential competition by lower-cost biosimilars, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs and biologics that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs and biologics, and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (increased from 50% pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs and biologics to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs or biologics to be covered under Medicare Part D.

Some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to reform through legislation and Executive Orders by the previous United States presidential administration and to judicial challenges. In 2012, the United States Supreme Court heard challenges to the constitutionality of the individual mandate and the viability of certain provisions of the ACA. The Supreme Court's decision upheld most of the ACA and determined that requiring individuals to maintain "minimum essential" health insurance coverage or pay a penalty to the Internal Revenue Service was within Congress's constitutional taxing authority. However, as a result of tax reform legislation enacted into law in late December 2017, the individual mandate has been eliminated, effective January 1, 2019. On December 14, 2018, a United States District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the 2017 Tax Reform Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the Fifth Circuit United States Court of Appeals held that the individual mandate is unconstitutional. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and held oral arguments on November 10, 2020. On June 17, 2021, the United States 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 the purpose of obtaining health insurance coverage through the ACA marketplace. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. It is unclear how other healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal or replace the ACA will impact our business.

On October 13, 2017, President Trump signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. On August 14, 2020, the United States Court of Appeals for the Federal Circuit ruled in two separate cases that the federal government is liable for the full amount of unpaid CSRs for the years preceding and including 2017. For CSR claims made by health insurance companies for years 2018 and later, further litigation will be required to determine the amounts due, if any. In December 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans, or QHPs, and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. Since then, the ACA risk adjustment program payment parameters have been updated annually. However, on April 27, 2020, the United States Supreme Court reversed a Federal Circuit decision that previously upheld Congress' denial of \$12 billion in "risk corridor" funding. The United States federal government has since started sending third-party payors owed payments. It is not clear what effect this result will have on our business, but we will continue to monitor any developments.

In addition, the 2020 federal spending package permanently eliminated, effective January 1, 2020, the ACA-mandated "Cadillac" tax on highcost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminated the health insurer tax. The Bipartisan Budget Act of 2018 also amended the ACA, effective January 1, 2019, by increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and closing the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole." In addition, CMS published a final rule that would give states greater flexibility, effective January 1, 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2% per fiscal year, and, due to subsequent legislative amendments, will remain in effect through 2030 unless additional Congressional action is taken. The Coronavirus Aid, Relief and Economic Security Act, or CARES Act, and subsequent legislation, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020. The Consolidated Appropriations Act of 2021, extended the suspension period to March 31, 2021. An Act to Prevent Across-the-Board Direct Spending Cuts, and for Other Purposes, signed into law on April 14, 2021, has extended the suspension period to December 31, 2021. Proposed legislation, if passed, would extend this suspension until the end of the pandemic. The American Taxpayer Relief Act of 2012, or ATRA, 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.

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 United States 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, President Biden signed an Executive Order on July 9, 2021 affirming the administration's policy to (i) support legislative reforms that would lower the prices of prescription drug and biologics, including by allowing Medicare to negotiate drug prices, by imposing inflation caps, and, by supporting the development and market entry of lower-cost generic drugs and biosimilars; and (ii) support the enactment of a public health insurance option. Among other things, the Executive Order also directs HHS to provide a report on actions to combat excessive pricing of prescription drugs, enhance the domestic drug supply chain, reduce the price that the Federal government pays for drugs, and address price gouging in the industry; and directs the FDA to work with states and Indian Tribes that propose to develop section 804 Importation Programs in accordance with the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, and the FDA's 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. The MFN is currently subject to ongoing litigation. 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 certain fixed fee arrangements between pharmacy benefit managers and 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.

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 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 our current product candidates and any future product candidates or additional pricing pressures. It is possible that additional governmental action is taken to address the COVID-19 pandemic.

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/or impose price controls may adversely affect:

- · the demand for our current product candidates and any 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 healthcare providers, customers 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 significant administrative, civil, and criminal penalties, damages, fines, disgorgement, imprisonment, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

Although we do not currently have any products on the market, our current and future arrangements with healthcare providers, third-party payors, customers, and others may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations which 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 research, market, sell and distribute our current product candidates and any 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. Further, courts have found that if "one purpose" of remuneration is to induce referrals, the federal Anti-Kickback Statute is violated. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution; but the exceptions and safe harbors are drawn narrowly and require strict compliance in order to offer protection. On November 30, 2020, United States Department of Health and Human Services Office of Inspector General, or OIG, published a final rule effective January 1, 2022 amending the existing safe harbor protecting certain discounts to eliminate safe harbor protection for certain rebates provided by a manufacturer of prescription pharmaceutical products to a plan sponsors under Part D or pharmacy benefit managers (PBMs) under contract with them. The final rule also creates new safe harbors effective January 29, 2021 for point-of-sale reductions in price on prescription pharmaceutical products and certain PBM service fees. Pursuant to an order entered by the United States District Court for the District of Columbia, the portion of the rule eliminating safe harbor protection for certain rebates related to the sale or purchase of a pharmaceutical product from a manufacturer to a plan sponsor under Medicare Part D has been delayed to January 1, 2023. 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;
- the federal civil and federal false claims laws and civil monetary penalty laws, including the False Claims Act which can be enforced through civil whistleblower or qui tam actions, impose criminal and civil penalties 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, or 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 certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report CMS information related to payments and other transfers of value to physicians, as defined by such law, and teaching hospitals 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 to certain non-physician providers such as physician assistants and nurse practitioners;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, 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. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions; and

analogous state laws and regulations, such as state anti-kickback and false claims laws that may be broader in scope and apply to sales
or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors,
including private insurers; and 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;
state and local laws that require the registration of pharmaceutical sales representatives; 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.

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 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, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations 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 significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

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

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

Although we 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.

### Our business activities will be subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery and anti-corruption laws.

As we expand our business activities outside of the United States, including our clinical trial efforts, we will be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-United States government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls.



Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-United States governments. Additionally, in many other countries, the healthcare providers who prescribe pharmaceuticals are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers will be subject to regulation under the FCPA. Recently the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

#### **Risks related to reliance on third parties**

# We rely on third parties to conduct our clinical trials and perform some of our research and preclinical studies. If these third parties do not satisfactorily carry out their contractual duties or fail to meet expected deadlines, our development programs may be delayed or subject to increased costs, each of which may have an adverse effect on our business and prospects.

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

There is no guarantee that any such CROs, clinical trial investigators or other third parties on which we rely will devote adequate time and resources to our development activities or perform as contractually required. Further, the performance of our CROs may also be interrupted by the ongoing COVID-19 pandemic, including due to travel or quarantine policies, heightened exposure of CRO staff who are healthcare providers to COVID-19 or prioritization of resources toward the pandemic. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, otherwise performs in a substandard manner, or terminates its engagement with us, the timelines for our development programs may be extended or delayed or our development activities may be suspended or terminated. If any of our clinical trial sites terminates for any reason, we may experience the loss of follow-up information on subjects enrolled in such clinical trials unless we are able to transfer those subjects to another qualified clinical trial site, which may be difficult or impossible. In addition, clinical trial investigators for our clinical trials may serve as scientific advisors or consultants to us from time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA or comparable foreign regulatory authorities concludes that the financial relationship may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection of any marketing application we submit by the FDA or any comparable foreign regulatory authority. Any such delay or rejection could prevent us from commercializing our current product candidates and any future product candidates.

Furthermore, these third parties may also have relationships with other entities, some of which may be our competitors. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed

in obtaining, marketing approvals for our current product candidates or any future product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our products.

If any of our relationships with these third-party CROs or others terminate, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms.

Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which can materially impact our ability to meet our desired development timelines. Though we endeavor to carefully manage our relationships with our CROs and other third parties, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

### We may form or seek collaborations or strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such collaborations, alliances or licensing arrangements.

We may form or seek strategic alliances, create joint ventures or collaborations, or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our product candidates and any future product candidates that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business.

In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety, potency, purity and efficacy and obtain marketing approval.

Further, collaborations involving our product candidates are subject to numerous risks, which may include the following:

- · collaborators have significant discretion in determining the efforts and resources that they will apply to a collaboration;
- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization of our product candidates based on clinical trial results, changes in their strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial, stop a clinical trial, abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to their marketing and distribution;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development or commercialization
  of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; and
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to commercialize such intellectual property.

For example, under the Collaboration Agreement with GSK, we share with GSK responsibility and costs for the global development of EOS-448 and the parties will jointly commercialize and equally split profits in the United States. Outside of the United States, GSK will receive an exclusive license for commercialization, and we are eligible to receive tiered double digit royalty payments up to 20% during a customary royalty term. As a result of these terms, our control over the

development and commercialization activities of EOS-448 may be limited. GSK's commercialization activities outside the United States may adversely impact our own efforts in the United States. Failure by GSK to meet its obligations under the Collaboration Agreement, to apply sufficient efforts at developing and commercializing EOS-448, or to comply with applicable legal or regulatory requirements, may materially adversely affect our business and our results of operations. In addition, to the extent we rely on GSK to commercialize any products containing or comprising EOS-448 that obtain regulatory approval, we may receive less revenues than if we commercialized these products ourselves, which could materially harm our prospects.

If we enter into additional collaboration agreements and strategic partnerships or license our product candidates, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture, which could delay our timelines or otherwise adversely affect our business. We also cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new collaborations or strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates in certain geographies for certain indications, which would harm our business prospects, financial condition and results of operations.

We rely on third parties to manufacture our product candidates, and we expect to continue to rely on third parties for the clinical as well as any future commercial supply of our product candidates and other future product candidates. The development of our current and future product candidates, and the commercialization of any approved products, could be stopped, delayed or made less profitable if any such third party fails to provide us with sufficient clinical or commercial quantities of such product candidates or products, fails to do so at acceptable quality levels or prices or fails to achieve or maintain satisfactory regulatory compliance.

We do not currently have, and we do not plan to build, the infrastructure or capability internally to manufacture current product candidates or any future product candidates for use in the conduct of our clinical trials or, if approved, for commercial supply. We rely on, and expect to continue to rely on, contract manufacturing organizations, or CMOs. Reliance on third-party providers may expose us to more risk than if we were to manufacture our product candidates ourselves. We do not control the manufacturing processes of the CMOs we contract with and are dependent on those third parties for the production of our product candidates in accordance with relevant applicable regulations such as cGMP, which includes, among other things, quality control, quality assurance and the maintenance of records and documentation.

In complying with the manufacturing regulations of the FDA and comparable foreign regulatory authorities, we and our third-party suppliers must spend significant time, money and effort in the areas of design and development, testing, production, record-keeping and quality control to assure that the products meet applicable specifications and other regulatory requirements. The failure to comply with these requirements could result in an enforcement action against us, including the seizure of products and shutting down of production. We and any of these third-party suppliers may also be subject to audits by the FDA or comparable foreign regulatory authorities. If any of our third-party suppliers fails to comply with cGMP or other applicable manufacturing regulations, our ability to develop and commercialize our product candidates could suffer significant interruptions.

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, license revocation, seizures or recalls of product candidates or drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

Any disruption, such as a fire, natural hazards or vandalism at our CMOs, or any impacts on our CMOs due to the COVID-19 pandemic, could significantly interrupt our manufacturing capability. We currently do not have alternative production plans in place or disaster-recovery facilities available. In case of a disruption, we will have to establish alternative manufacturing sources. This would require substantial capital on our part, which we may not be able to obtain on commercially acceptable terms or at all. Additionally, we would likely experience months of manufacturing delays as we build facilities or locate alternative suppliers and seek and obtain necessary regulatory approvals. If this occurs, we will be unable to satisfy manufacturing needs on a timely basis, if at all. If changes to CMOs occur, then there also may be changes to manufacturing processes inherent in the setup of new operations for our product candidates and any products that may obtain approval in the future. Any such changes could require the conduct of bridging studies before we can use any materials produced at new facilities or under new processes in clinical trials or, for any products reaching approval, in our commercial supply. Further, business interruption insurance may not adequately compensate us for any losses that may occur and we would have to bear the additional cost of any disruption. For these reasons, a significant disruptive event of any CMOs could have drastic consequences, including placing our financial stability at risk.

Our product candidates and any drugs that we may develop may compete with other product candidates and drugs for access to manufacturing facilities. There are no assurances we would be able to enter into similar commercial arrangements with other manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval.

If we were to experience an unexpected loss of supply of or if any supplier were unable to meet our clinical or commercial demand for any of our product candidates, we could experience delays in our planned clinical studies or commercialization. For example, the COVID-19 pandemic may impact our ability to procure sufficient supplies for the development of our current and future product candidates, and the extent of such impacts will depend on the severity and duration of the spread of the virus and the actions undertaken to contain COVID-19 or treat its effects. We could be unable to find alternative suppliers of acceptable quality and experience that can produce and supply appropriate volumes at an acceptable cost or on favorable terms. Moreover, our suppliers are often subject to strict manufacturing requirements, which could limit or delay production. The long transition periods necessary to switch manufacturers and suppliers, if necessary, would significantly delay our clinical trials and, for any product candidates that reach approval, the commercialization of our products, which would materially adversely affect our business, financial condition and results of operation.

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

Manufacturing biologics, especially in large quantities, is often complex and may require the use of innovative technologies to handle living cells. Each lot of an approved biologic must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing biologics requires facilities specifically designed for and validated for this purpose, and sophisticated quality assurance and quality control procedures are necessary. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our manufacturers, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. The use of biologically derived ingredients can also lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination.

In addition, there are risks associated with large scale manufacturing for clinical trials or commercial scale including, among others, cost overruns, potential problems with process scale-up, process reproducibility, stability issues, compliance with good manufacturing practices, lot consistency and timely availability of raw materials. Even if we obtain marketing approval for any of our current product candidates or any future product candidates, there is no assurance that our manufacturers will be able to manufacture the approved product to specifications acceptable to the FDA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential commercial launch of the product or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

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

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

discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with will likely expect to be granted rights to publish data arising out of such collaboration and any joint research and development programs may require us to share trade secrets under the terms of our research and development or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business. Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets.

#### Risks related to our limited operating history, financial position and capital requirements

### Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We are a clinical-stage immuno-oncology company with a limited operating history. We commenced operations in 2012, and our operations to date have been limited to organizing and staffing our company, business planning, raising capital, conducting discovery and research activities, filing patent applications, identifying potential product candidates, undertaking preclinical studies and clinical trials and establishing arrangements with third parties for the manufacture of initial quantities of our product candidates and component materials. Our two lead product candidates, inupadenant and EOS-448, are currently in clinical trials and we have additional programs in preclinical development. We have financed our operations primarily through private placements of our preferred stock, grants from the Walloon Region, a federal region of Belgium, or the Walloon Region, and the European Union to fund research and development activities, our initial public offering, or IPO, in July 2020, and our Collaboration Agreement with GSK.

We have not yet demonstrated our ability to successfully conduct or complete any clinical trials, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales, marketing and distribution activities necessary for successful product commercialization. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history.

In addition, as an early-stage business, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors. We will need to transition at some point from a company with a research and development focus to a company capable of supporting commercial activities. We may not be successful in such a transition.

We expect our financial condition and operating results to continue to fluctuate significantly from quarter to quarter and year to year due to a variety of factors, many of which are beyond our control. Accordingly, you should not rely upon the results of any quarterly or annual periods as indications of future operating performance.

We have incurred significant losses since inception, and we expect to incur losses over the next several years and may not be able to achieve or sustain revenues or profitability in the future.

Investment in biopharmaceutical product development is a highly speculative undertaking and entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We are still in the early stages of development of our product candidates. Our most advanced product candidate, inupadenant, and our lead antibody product candidate, EOS-448, are each in ongoing Phase 1/2a clinical trials. We have no products licensed 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.

We have incurred significant net losses in each period since inception. For the three months ended June 30, 2021 and 2020, our net losses were \$26.5 million and \$7.2 million, respectively, and six months ended June 30, 2021 and 2020, our net losses were \$40.0 million and \$12.4 million, respectively. As of June 30, 2021, we had an accumulated deficit of \$113.9 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase substantially if and as we:

- conduct preclinical studies and clinical trials for our current and future product candidates;
- continue our research and development efforts and submit INDs for future product candidates;
- seek marketing approvals for any product candidates that successfully complete clinical trials;
- build commercial infrastructure to support sales and marketing for any approved product candidates;
- scale up external manufacturing and distribution capabilities for clinical and, if approved, commercial supply of our product candidates;
- expand, maintain and protect our intellectual property portfolio;
- hire additional clinical, regulatory and scientific personnel and scale up such capabilities; and
- operate as a public company.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses we will incur or when, if ever, we will be able to achieve profitability. Even if we succeed in eventually commercializing one or more of our product candidates, we will continue to incur substantial research and development and other expenditures to develop, seek approval for, and market additional product candidates. We may never succeed in these activities and, even if we succeed in commercializing one or more of our current product candidates and any future product candidates, we may never generate revenues that are significant or large enough to achieve profitability. In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown challenges 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 stockholders' equity (deficit).

#### We have never generated any revenue from product sales and may never be profitable.

Our ability to become profitable depends upon our ability to generate revenue. To date, we have not generated any revenue from any product sales. We have no products approved for commercial sale, 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 research regarding, and preclinical and clinical development of, inupadenant, EOS-448, and any future product candidates;
- obtaining marketing approvals for inupadenant, EOS-448, and any future product candidates for which we complete clinical trials;
- developing a sustainable and scalable manufacturing process for inupadenant, EOS-448, and any future product candidates, including establishing and maintaining commercially viable supply and manufacturing relationships with third parties;
- launching and commercializing inupademant, EOS-448, and any future product candidates for which we obtain marketing approvals, either directly or with a collaborator or distributor;
- obtaining market acceptance of inupadenant, EOS-448, and any future product candidates as viable treatment options;
- 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 our current product candidates 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 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 inupadenant, EOS-448, 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 our current product candidates and any 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.

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, obtain product approvals, diversify our offerings or continue our operations.

# 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 development of our product candidates, including our ongoing Phase 1/2a clinical trials of inupadenant and EOS-448 and our ongoing and planned IND-enabling studies for our other product candidates. If approved, we will require significant additional amounts in order to launch and commercialize our product candidates.

As of June 30, 2021, we had \$302.9 million of cash and cash equivalents. Our net proceeds from our IPO, were \$210.6 million, after deducting underwriting discounts and commissions and IPO expenses payable by us. Our existing cash and cash equivalents will not be sufficient to fund all of our efforts that we plan to undertake.

We believe the net proceeds from the IPO and from the Collaboration Agreement with GSK, together with our existing cash and cash equivalents as of the filing date of this Quarterly Report on a Form 10-Q, will enable us to fund our operations into the 2026 However, we have based this estimate on assumptions that may prove to be wrong.

Additionally, changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. Accordingly, we will need to raise substantial additional capital in connection with our continuing operations.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing inupadenant, EOS-448, and any future product candidates, and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining marketing approvals for inupadenant, EOS-448, and any future product candidates if clinical trials are successful;
- the extent to which we develop, in-license or acquire other product candidates and technologies;
- the number and development requirements of other product candidates we may pursue;
- the success of any collaborations;
- · the cost of commercialization activities for any approved product, including marketing, sales and distribution costs;
- the cost of manufacturing inupademant, EOS-448, and any future product candidates for clinical trials in preparation for marketing approval and commercialization;
- our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;



- 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, future approved products, if any; and
- the emergence of competing cancer therapies and other adverse market developments.

We have limited 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 and grant arrangements and other marketing or distribution arrangements. We cannot be certain that additional funding will be available on acceptable terms, or at all. Further, our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue our research and development initiatives. We could be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves.

Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

#### **Risks related to intellectual property**

# If we are unable to obtain and maintain sufficient intellectual property protection for our current product candidates or any future product candidates, or if the scope of the intellectual property protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our products may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our current product candidates or any future product candidates and research programs. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our novel discoveries and technologies that are important to our business, however, we cannot predict:

- if and when patents may issue based on our patent applications;
- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will protect our current product candidates or any future
  product candidates and their intended uses or prevent others from commercializing competitive technologies or products;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; and/or
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file and prosecute all necessary or desirable patent applications, or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, contract research organizations, or CROs, CMOs, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

We also cannot be certain that the claims in our pending patent applications directed to our product candidates and/or technologies will be considered patentable by the United States Patent and Trademark Office, or the USPTO, or by patent offices in foreign countries. One aspect of the determination of patentability of our inventions depends on the scope and



content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Even if the patents do issue based on our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our current product candidates or any future product candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our current product candidates or any future product candidates. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries.

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

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our current product candidates or any future product candidates in any jurisdiction.

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

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

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

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

Patents are of national or regional effect, and filing, prosecuting and defending patents on all of our current product candidates or any future product candidates throughout the world would be prohibitively expensive. As such, 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. Further, the legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals or biologics, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. In addition, certain developing countries, including China and India, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we and our licensors may have limited remedies if patents are infringed or if we or our licensors are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. However, the patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation, resulting in court decisions, including Supreme Court decisions, that have increased uncertainties as to the ability to obtain and enforce patent rights in the future. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries could increase the uncertainties and costs. For example, in September 2011 the Leahy-Smith America Invents Act, or the America Invents Act, was signed into law and included a number of significant changes to United States patent law as then existed. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including post-grant review, *inter partes* review, and derivation proceedings. After March 2013, under the America Invents 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 America Invents 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 and prospects

The United States 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 United States Congress, the United States courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

### We may rely on trade secret and proprietary know-how which can be difficult to trace and enforce and, if we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

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

Trade secrets and know-how can be difficult to protect. We require our employees to enter into written employment agreements containing provisions of confidentiality and obligations to assign to us any inventions generated in the course of their employment. We enter into written agreements that include confidentiality and intellectual property obligations to protect each party's property, potential trade secrets, proprietary know-how, and information. We further seek to protect our potential trade secrets, proprietary know-how, and information. We further seek to protect our potential trade secrets, proprietary know-how, and information. We further seek to protect our potential trade secrets, proprietary know-how, and information in part, by entering into non-disclosure and confidentiality agreements with parties who are given access to them, such as our corporate collaborators, outside scientific collaborators, CROs, CMOs, consultants, advisors and other third parties. With our consultants, contractors, and outside scientific collaborators, these agreements typically include invention assignment obligations. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be harmed.

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

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

#### We may become involved in lawsuits alleging that we have infringed the intellectual property rights of third parties or to protect or enforce our patents or other intellectual property, which litigation could be expensive, time consuming and adversely affect our ability to develop or commercialize our current product candidates or any future product candidates.

The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our products candidates. Third parties may assert infringement claims against us based on existing or future intellectual property rights. If we were sued for patent infringement, we would need to demonstrate that our current product candidates or any future product candidates, products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity may be difficult. For example, in the United States, proving invalidity in court requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our current product candidates or any future product candidates or force us to cease some of our

In addition, we may find that competitors are infringing our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitive parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against who we have asserted trademarks. Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy.



Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Moreover, we cannot assure you that we will have sufficient financial or other resources to defend or pursue such litigation, which typically last for years before they are concluded. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could have a material adverse effect on our business and operations. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

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

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

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

We could in the future be subject to claims that we or our employees have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors. 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 become subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement, or that we or these individuals have, inadvertently or otherwise, used or disclosed the alleged trade secrets or other proprietary information of a former employer or competitor.

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

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

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



#### Risks related to our employee matters, business operations and managing growth

### If the current public health pandemic related to coronavirus (COVID-19) continues to worsen, our operations, business and financial results may be adversely impacted.

Widespread outbreak of illness or other communicable diseases, health epidemics, or any other public health crisis could adversely affect our ongoing or planned research and development activities. For example, the COVID-19 pandemic has presented a substantial public health and economic challenge around the world. The rapid spread of COVID-19 has led to the implementation of various responses, including government-imposed quarantines, shelter-in-place mandates, sweeping restrictions on travel, mandatory shutdowns for non-essential businesses, requirements regarding social distancing, and other public health safety measures, as well as reported adverse impacts on healthcare resources, facilities and providers across the United States and in other countries. In response to the pandemic, healthcare providers have, and may need to further, reallocate resources, such as physicians, staff, hospital beds, and intensive care unit facilities, as they prioritize limited resources and personnel capacity to focus on the treatment of patients with COVID-19. To date, the COVID-19 pandemic has caused widespread disruptions to the United States and global economy and has contributed to significant volatility and negative pressure in financial markets.

The continued spread of COVID-19 and identification of new strains of the virus could adversely impact our manufacturing and other operations, including our ability to recruit and retain patients, principal investigators, clinical trial sites and their staff, caregivers and healthcare providers as necessary. The COVID-19 pandemic may negatively affect the operations of third-party suppliers and service providers that we rely upon to carry out our clinical trials or the operations of our third-party manufacturers, which could result in delays or disruptions in the supply of our product candidates for our clinical trials. Furthermore, COVID-19 may delay startup of new clinical trial sites and enrollment in our clinical trials due to prioritization of hospital resources toward the outbreak, restrictions in travel and site enrollment restrictions. For example, we have previously reported enrollment delays for the third cohort of our Phase 1/2a trial of inupadenant in adult patients with advanced solid tumors, in which we plan to evaluate inupadenant in combination with chemotherapy. Some patients may be unwilling to enroll in future clinical trials or be unable to comply with clinical trial protocols if quarantines or travel restrictions impede patient movement or interrupt healthcare services. Increased demand at clinical trial sites and guarantined doctors and staff may reduce personnel and other available resources at clinical trial sites needed to conduct our clinical trials and may cause the screening of new patients or clinical trial operations to be paused, and the procedures or assessments of patients on trial to be delayed or missed. Trial sites may also limit or prohibit on site monitoring to decrease potential exposure of doctors, staff and patients to COVID-19, which would require us to use remote monitoring via video conferences. While we do not anticipate any negative effects from remote monitoring, it could potentially affect quality, training and source data verification at clinical trial sites. Additionally, if a clinical trial site does not have remote monitoring capabilities, we may be required to find other distance monitoring solutions. Further, restricted physical access to health care systems due to COVID-19 has the potential to impact source data verification in our clinical trials, which could lead to delays in having final verified data. Missing data could undermine data integrity and probability of success. Additionally, we are currently experiencing challenges with respect to climate-controlled shipping of our product candidates, which may delay our ability to dose patients in our ongoing trials. Any negative impact COVID-19 has to patient enrollment, retention or treatment could delay our clinical trial timelines and adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, particularly on our current projected timelines, increase our operating expenses and have a material adverse effect on our business and financial results. We remain in active dialog with our CROs and clinical sites to minimize the impact of this pandemic to our clinical trials of inupadenant and EOS-448 without adversely impacting the safety of patients. Despite our best efforts, it may prove difficult to continue to treat patients in a timely manner and activation of new sites could be delayed, particularly for our clinical trial sites in areas with high rates of community spread.

Furthermore, 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. In addition, the roll-out of the vaccines could slow patient enrollment in our studies as some patients may be unwilling to enroll in clinical trials before or soon after receiving the vaccination.

In addition, COVID-19 has resulted in significant governmental measures being implemented to control the spread of the virus, including quarantines, travel restrictions and business shutdowns. As of the date hereof, we have taken temporary precautionary measures intended to help minimize the risk of the virus to our employees and their families, including temporarily requiring all non-laboratory employees and all non-essential employees for laboratory work to work remotely. We have suspended non-essential travel worldwide for our employees and are discouraging employee attendance at other gatherings. Further measures may be taken as the pandemic continues. These measures could negatively affect our business. For instance, temporarily requiring most employees to work remotely has required us to decrease preclinical laboratory work, which may delay and otherwise adversely impact our pre-clinical program development. Further,



remote work may disrupt our operations or increase the risk of a cybersecurity incident. In addition, although our employees are accustomed to working remotely, changes in internal controls due to remote work arrangements could potentially result in control deficiencies in the preparation of our financial reports, which could be significant. COVID-19 has also caused volatility in the global financial markets and threatened a slowdown in the global economy, which may negatively affect our ability to raise additional capital on attractive terms or at all.

The extent to which COVID-19 may impact our business will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the duration of the outbreak, the severity of COVID-19 or the effectiveness of actions to contain and treat COVID-19, particularly in the geographies where we, our third party manufacturers, CROs or current and planned clinical trial sites operate. We cannot presently predict the scope and severity of any potential business shutdowns or disruptions. If we or any of the third parties with whom we engage, however, were to experience 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 operation and financial condition.

In addition, to the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described in this "Risk factors" section.

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

As of June 30, 2021, we had 78 full-time employees. As we advance our research and development programs and as we begin operating as a public company, we expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of management and operations, clinical development, quality, regulatory affairs and, if any of our current product candidates or any future product candidates receive marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must:

- · identify, recruit, integrate, maintain and motivate additional qualified personnel;
- manage our development efforts effectively, including the initiation and conduct of clinical trials for our current product candidates or any future product candidates, both as monotherapy and in combination with other intra-portfolio product candidates; and
- improve our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to develop, manufacture and commercialize our current product candidates or any future product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert financial and other resources, and a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time, to managing these growth activities. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including substantially all aspects of regulatory approval, clinical trial management and manufacturing. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all.

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

### We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may not be able to successfully implement our business strategy.

We are highly dependent on the services of our founder, Michel Detheux, Ph.D., who serves as our Chief Executive Officer and President. Although we have entered into an employment agreement with him, it is not for a specific term and

he may terminate his employment with us at any time, though we are not aware of any present intention of him to leave us. We do not maintain "key person" insurance for Dr. Detheux or any of our other executives or employees.

Dr. Detheux has significant experience identifying and developing drugs and biopharmaceuticals. We believe that his drug discovery and development experience, and overall biopharmaceutical company management experience, would be difficult to replace. However, the historical results, past performance and/or acquisitions of companies with which they were affiliated do not necessarily predict or guarantee similar results for our company.

Our industry has experienced a high rate of turnover in recent years. Our ability to compete in the highly competitive biopharmaceuticals industry depends upon our ability to attract, retain and motivate highly skilled and experienced personnel with scientific, medical, regulatory, manufacturing and management skills and experience. Although we conduct our research and development in Belgium, our headquarters with management is located, and we plan on expanding our clinical development activities, in the Boston area, a region that is home to many other biopharmaceutical companies as well as many academic and research institutions, resulting in fierce competition for qualified personnel. We may not be able to attract or retain qualified personnel in the future due to the intense competition for a limited number of qualified personnel among biopharmaceutical companies. Many of the other biopharmaceutical companies against which we compete have greater financial and other resources, different risk profiles and a longer history in the industry than we do. Our competitors may provide higher compensation, more diverse opportunities and/or better opportunities for career advancement. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our 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. Any or all of these competing factors may limit our ability to continue to attract and retain high quality personnel, which could negatively affect our ability to successfully develop and commercialize our current product candidates or any future product candidates and to grow our business and operations as currently contemplated.

## Our employees, clinical trial investigators, CROs, consultants, vendors and any potential commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, clinical trial investigators, CROs, consultants, vendors and any potential commercial partners. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (i) FDA laws and regulations or those of comparable foreign regulatory authorities, including those laws that require the reporting of true, complete and accurate information, (ii) manufacturing standards, (iii) federal and state health and data privacy, security, fraud and abuse, government price reporting, transparency reporting requirements, and other healthcare laws and regulations in the United States and abroad, or (iv) laws that require the true, complete and accurate reporting of financial information or data. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct applicable to all of our employees, as well as a disclosure program and other applicable policies and procedures, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

# 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 HITECH), and international law (*e.g.*, the General Data Protection Regulation, or 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 partners, 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, or 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. In March 2020, the California State Attorney General has proposed varying versions of companion draft regulations which are not yet finalized. Despite the delay in adopting regulations, the California State Attorney General has commenced enforcement actions against violators beginning July 1, 2020. Further, a new California privacy law, the California Privacy Rights Act, or CPRA, was passed by California voters on November 3, 2020. The CPRA will create additional obligations with respect to processing and storing personal information that are scheduled to take effect on January 1, 2023 (with certain provisions having retroactive effect to January 1, 2022). We will continue to monitor developments related to the CPRA and anticipate additional costs and expenses associated with CPRA compliance. Other U.S. states also are considering omnibus privacy legislation and industry organizations regularly adopt and advocate for new standards in these areas. While the CCPA and CPRA contain an exception for certain activities involving PHI under HIPAA, we cannot vet determine the impact the CCPA, CPRA or other such future laws, regulations and standards may have on our business. By way of example regarding foreign laws and regulations with respect to data privacy and security, the GDPR went into effect in the EU 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.

If we or third-party CMOs, CROs or other contractors or consultants fail to comply with United States and international data protection laws and regulations, it could result in government enforcement actions (which could include civil or criminal penalties), private litigation, and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

### Unfavorable global economic and trade conditions could adversely affect our business, financial condition or results of operations.

Our current operations are located in Belgium, while our headquarters with management is located in Massachusetts. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, including any potential effects from the current global spread of COVID-19, power shortage, telecommunication failure or other natural or man-made accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party CMOs, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Natural disasters or pandemics such as the COVID-19 outbreak could further

disrupt our operations, and have a material and adverse effect on our business, financial condition, results of operations and prospects. For example, we have instituted a temporary work from home policy for non-essential office personnel and it is possible that this could have a negative impact on the execution of our business plans and operations. 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 our research facilities or the manufacturing facilities of our third-party CMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place 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. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure our investors that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities or the manufacturing facilities of our third-party CMOs are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects. Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets and global trade. We conduct, and we expect to continue to conduct, portions of our clinical trials outside the United States, and unfavorable economic conditions resulting in the weakening of the United States dollar would make those clinical trials more costly to operate. Furthermore, the most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including a reduced ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption. In addition, proposed tariffs by the Trump administration have included a 25% tariff on raw ingredients for pharmaceuticals, such as the active pharmaceutical ingredients for our proposed product candidates. Furthermore, EOS-448 and precursors of inupadenant are produced in China, and may be subject to governmental controls, trade restrictions and tariffs. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

## A portion of our manufacturing of our lead product candidates takes place in China through third-party manufacturers. A significant disruption in the operation of those manufacturers, a trade war or political unrest in China could materially adversely affect our business, financial condition and results of operations.

We currently contract manufacturing operations to third parties, and clinical quantities of our lead product candidates inupadenant and EOS-448 are manufactured by these third parties outside the United States, including in China, and we expect to continue to use such third-party manufacturers for such product candidates. Any disruption in production or inability of our manufacturers in China to produce adequate quantities to meet our needs, whether as a result of a natural disaster, the COVID-19 pandemic or other causes, could impair our ability to operate our business on a day-to-day basis and to continue our development of our product candidates. Furthermore, since these manufacturers are located in China, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the United States or Chinese governments, political unrest or unstable economic conditions in China. For example, a trade war could lead to tariffs on the chemical intermediates we use that are manufactured in China. Any of these matters could materially and adversely affect our business and results of operations. Any recall of the manufacturing lots or similar action regarding our product candidates used in clinical trials could delay the trials or detract from the integrity of the trial data and its potential use in future regulatory filings. In addition, manufacturing interruptions or failure to comply with regulatory requirements by any of these manufacturers could significantly delay clinical development of potential products and reduce third-party or clinical researcher interest and support of proposed trials. These interruptions or failures could also impede commercialization of our product candidates and impair our competitive position. Further, we may be exposed to fluctuations in the value of the local currency in China. Future appreciation of the local currency could increase our costs. In addition, our labor costs could continue to rise as wage rates increase due to increased demand for skilled laborers and the availability of skilled labor declines in China.

### Our future growth may depend, in part, on our ability to operate in 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 our current product candidates or any future product candidates in foreign markets for which we may rely on collaboration with third parties. We are not permitted to market or promote any of our current product candidates or any future product candidates before we receive marketing approval from the applicable regulatory authority in that foreign market, and we may never receive such marketing approval for any of our current product candidates or any future product candidates. To obtain marketing approval in

many foreign 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 our current product candidates or any future product candidates, and we cannot predict success in these jurisdictions. If we obtain approval of our current product candidates or any future product candidates and ultimately commercialize our current product candidates or any future product candidates in foreign markets, we would be subject to additional risks and uncertainties, including:

- · differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- our customers' ability to obtain reimbursement for our current product candidates or any 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;
- 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 our current product candidates or any future product candidates could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

### The United Kingdom's withdrawal from the European Union may have a negative effect on global economic conditions, financial markets and our business.

Following the result of a referendum in 2016, the United Kingdom left the European Union on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed to by the United Kingdom and the European Union, the United Kingdom was subject to a transition period until December 31, 2020, or the Transition Period, during which European Union rules and legislation continued to apply in the United Kingdom. The United Kingdom and the European Union have signed a EU-UK Trade and Cooperation Agreement, or TCA, which became provisionally applicable on January 1, 2021 and has been formally applicable since May 1, 2021. This agreement provides details on how some aspects of the United Kingdom and the European Union's relationship will operate going forwards, however there are still many uncertainties.

Since a significant proportion of the regulatory framework in the United Kingdom applicable to our business and our product candidates is derived from European Union Directives and Regulations, Brexit, following the Transition Period, could materially impact the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the United Kingdom or the European Union. For example, now that the Transition Period is over, Great Britain is no longer covered by the centralized procedures for obtaining European Union-wide marketing and manufacturing authorizations from the EMA (centralized marketing authorizations will continue to be valid in Northern Ireland under the Northern Ireland Protocol) and a separate process for authorization of drug products will be required in Great Britain. For a period of two years from January 1, 2021, the MHRA may rely on a decision taken by the European Commission on the approval of a new marketing authorization in the centralized procedure, in order to more quickly grant a UK marketing authorization. A separate application will, however, still be required. The MHRA has published a series of guidance notes on how the process for authorization of medicines will now work, however whether the United Kingdom regulatory system will diverge significantly from the European Union system in future remains unknown. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from commercializing our product candidates in the United Kingdom or the European Union and achieve and sustain profitability. In addition, we may be required to pay taxes or duties or be subjected to other hurdles in connection with the importation of our product candidates into the European Union, or we may incur expenses in establishing a manufacturing facility in the European Union in order to circumvent such hurdles. If



any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom or the European Union for our product candidates, or incur significant additional expenses to operate our business, which could significantly and materially harm or delay our ability to generate revenues or achieve profitability of our business. Any further changes in international trade, tariff and import/export regulations as a result of Brexit or otherwise may impose unexpected duty costs or other non-tariff barriers on us. These developments, or the perception that any of them could occur, may significantly reduce global trade and, in particular, trade between the impacted nations and the United Kingdom. It is also possible that Brexit may negatively affect our ability to attract and retain employees, particularly those from the European Union.

### We may be exposed to significant foreign exchange risk.

We incur portions of our expenses, and may in the future derive revenues, in a variety of currencies. As a result, we are exposed to foreign currency exchange risk as our results of operations and cash flows are subject to fluctuations in foreign currency exchange rates. Fluctuations in currency exchange rates have had, and will continue to have, an impact on our results as expressed in United States dollars. We currently do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the euro. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our financial condition, results of operations and cash flows.

#### United States federal income tax reform could adversely affect our business and financial condition.

The rules dealing with United States 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 United States 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. For example, on March 27, 2020, President Trump signed into law the CARES Act, which included certain changes in tax law intended to stimulate the United States economy in light of the COVID-19 coronavirus outbreak, including temporary beneficial changes to the treatment of net operating losses, interest deductibility limitations and payroll tax matters. Additionally, on December 22, 2017, President Trump signed into law the Tax Cuts and Jobs Act, or the TCJA, which significantly reformed the Internal Revenue Code of 1986, as amended. The TCJA, among other things, contains significant changes to corporate and individual taxation, some of which could adversely impact an investment in our common stock. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

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

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. United States federal net operating losses generated after December 31, 2017, the TCJA, as modified by the CARES Act, will not expire and may be carried forward indefinitely, and generally may not be carried back to prior taxable years, except that, under the CARES Act, net operating losses generated in 2018, 2019 and 2020 may be carried back five taxable years. Additionally, for taxable years beginning after December 31, 2020, the deductibility of such United States federal net operating losses is limited to 80% of our taxable income in any future taxable year. In addition, both our current and our future unused losses may be subject to limitation under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (IRC), if we undergo an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which are outside the Company's control. As of December 31, 2020, we had United States federal net operating loss carryforwards of \$29.2 million, and our ability to utilize those net operating loss carryforwards could be limited by an "ownership change" as described above, which could result in increased tax liability to the Company.

## We are exposed to unanticipated changes in Belgian tax laws and regulations, as well as to adjustments to our Belgian tax provisions, exposure to additional tax liabilities in Belgium, or forfeiture of our Belgian tax assets.

The determination in Belgium of our provision for income taxes and other tax liabilities requires significant judgment, including the adoption of certain accounting policies and our determination of whether our deferred tax assets are, and will remain, tax effective. We cannot guarantee that our interpretation or application of accounting policies will not be

questioned by the relevant tax authorities, or that the relevant tax laws and regulations, or the interpretation thereof, including through tax rulings, by the relevant tax authorities, will not be subject to change. Any adverse outcome of such a review or change may lead to adjustments in the amounts recorded in our financial statements, and could have a materially adverse effect on our operating results and financial condition.

We are subject to laws and regulations on tax levies and other charges or contributions in different countries, including transfer pricing and tax regulations for the compensation of personnel and third parties. Dealings between current and former group companies as well as additional companies that may form part of our group in the future are subject to transfer pricing regulations, which may be subject to change and could affect us.

Our effective tax rates in Belgium could be adversely affected by changes in tax laws, treaties and regulations, both internationally and domestically, or the interpretation thereof by the relevant tax authorities, including changes to the innovation income deduction, possible changes to the corporate income tax base, wage withholding tax incentive for qualified research and development personnel in Belgium and other tax incentives and the implementation of new tax incentives. An increase of the effective Belgian tax rates could have an adverse effect on our business, financial position, results of operations and cash flows.

## If we are unable to use Belgian tax loss carryforwards to reduce future taxable income or benefit from the favorable Belgian tax legislation, our business, results of operations and financial condition may be adversely affected.

At December 31, 2020, we had cumulative carry forward tax losses of €56.7 million in Belgium. Under the current legislation these are available to carry forward and offset against future taxable income for an indefinite period in Belgium. If we are unable to use tax loss carryforwards to reduce future taxable income, our business, results of operations and financial condition may be adversely affected. As a company active in research and development in Belgium we have benefited from certain research and development incentives including, for example, the Belgian research and development tax credit. This tax credit can be offset against the Belgian corporate income tax due. The excess portion may be refunded as from the end of a five-year fiscal period. The research and development incentive is calculated based on the amount of eligible research and development expenditure. The Belgian tax authorities may audit each research and development program in respect of which a tax credit has been claimed and assess whether it qualifies for the tax credit regime. The tax authorities may challenge our eligibility for, or our calculation of, certain tax reductions and/or deductions in respect of our research and development activities be successful, we may be liable for additional corporate income tax, and penalties and interest related thereto, which could have a significant impact on our results of operations and future cash flows. Furthermore, if the Belgian government decides to eliminate, or reduce the scope or the rate of, the research and development incentive benefit, either of which it could decide to do at any time, our results of operations could be adversely affected.

As a company active in research and development in Belgium, we also expect to benefit from the innovation income deduction, or IID, in Belgium. The IID regime allows net profits attributable to revenue from patented products (or products for which the patent application is pending), among other things, be taxed at a lower rate than other revenues, 3.75% as of January 1, 2020.

Our inability to qualify for the abovementioned advantageous tax regimes, as well as the application of the minimum taxable base, may adversely affect our business, results of operations and financial condition.

### We are subject to certain covenants as a result of certain non-dilutive financial support we have received to date.

We have been awarded grants from the Walloon Region, a federal region of Belgium, or the Walloon Region, and the European Union to fund research and development activities. Several of the grants include no obligation to repay the amount received under the grants. We own the intellectual property rights that result from the research programs or with regard to a patent covered by these grants. Subject to certain exceptions, however, we cannot grant to third parties, by way of license, transfer or otherwise, any right to use the patents or research results without the prior consent of the Walloon Region. In addition, certain grants require that we exploit the patent in the countries where the protection was granted and to make an industrial use of the underlying invention. In case of bankruptcy, liquidation or dissolution, the rights to the patents covered by the patent grants will be assumed by the Walloon Region by operation of law unless the grants are reimbursed. Furthermore, we would lose our qualification as a small or medium-sized enterprise, the grants subsidies would terminate and no additional expenses would be covered by such patent grants.

Two of the grants, which are referred to as recoverable cash advance grants, or RCAs, include a potential obligation to repay the amount received under the grants. Under the RCAs, the Walloon Region will provide us with up to €22.4 million for our research and development programs for EOS-448 and inupadenant. During the three months ended June 30, 2021, we received no cash under the EOS-448 grant and inupadenant grant.



We must repay 30% of the amount received under the grants unless we decide not to pursue commercial development or out licensing of the drug candidate, apply for a waiver from the Walloon Region justifying our decision based upon the failure of the program, and return the intellectual property to the Walloon Region. This is referred to as the fixed repayment. In addition, in the event that we receive revenue from products or services related to the results of the program, we will have to pay to the Walloon Region a 0.33% royalty on revenue resulting from the first RCA grant and a 0.12% royalty on revenue resulting from the second RCA grant. The maximum amount payable to the Walloon Region under each grant, including the fixed repayment, the royalty on revenue, and the interest thereon, is twice the amount of funding received.

Subject to certain exceptions, we cannot grant to third parties, by way of license or otherwise, any right to use the results without the prior consent of the Walloon Region. We also need the consent of the Walloon Region to transfer an intellectual property right resulting from the research programs or a transfer or license of a prototype or installation. Obtaining such consent from the Walloon Region could give rise to their review of the applicable financial terms. The RCAs also contain provisions prohibiting us from conducting research within the scope of the RCAs for any third parties. This prohibition is applicable beyond the research phase and decision phase and could restrict our ability to enter into research-related collaboration or partnership agreements with respect to those programs.

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

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

- · delay or termination of clinical trials;
- · decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial subjects;
- initiation of investigations by regulators;
- significant costs to defend the related litigation and diversion of management's time and our resources;
- substantial monetary awards to study subjects or patients;
- · product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue; and
- the inability to commercialize any products 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 as our current product candidates or any future product candidates advance through clinical trials and if we successfully commercialize any products. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

#### We may be at an increased risk of securities class action litigation.

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

### Risks related to ownership of our common stock

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

Our IPO closed on July 28, 2020. Prior to our IPO, there was no public market for our common stock. Although shares of our common stock are listed and trading on The Nasdaq Global Market, an active trading market for our shares may never develop or be sustained. Our stockholders may not be able to sell shares quickly or at the market price if trading in shares of our common stock is not active. Further, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic partnerships or acquire companies or products by using our shares of common stock as consideration.

### The trading price of our common stock may be volatile.

The trading price of our common stock is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk factors" section, these factors include:

- the results of our ongoing, planned or any future preclinical studies, clinical trials or clinical development programs;
- the commencement, enrollment, or results of clinical trials of our product candidates or any future clinical trials we may conduct, or changes in the development status of our product candidates;
- adverse results or delays in preclinical studies and clinical trials;
- our decision to initiate a clinical trial, not to initiate a clinical trial, or to terminate an existing clinical trial;
- any delay in our regulatory filings or any adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals;
- adverse developments concerning our manufacturers or our manufacturing plans;
- our inability to obtain adequate product supply for any licensed product or inability to do so at acceptable prices;
- our inability to establish collaborations if needed;
- our failure to commercialize our product candidates;
- additions or departures of key scientific or management personnel;
- unanticipated serious safety concerns related to the use of our product candidates;
- introduction of new products or services offered by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- changes in the structure of healthcare payment systems;
- our ability to effectively manage our growth;
- the size and growth of our initial cancer target markets;
- our ability to successfully treat additional types of cancers or at different stages;
- actual or anticipated variations in quarterly operating results;
- our cash position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public;
- publication of research reports about us or our industry, or immunotherapy in particular, or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- changes in the market valuations of similar companies;



- · overall performance of the equity markets;
- sales of our common stock by us or our stockholders in the future;
- trading volume of our common stock;
- · changes in accounting practices;
- ineffectiveness of our internal controls;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- · significant lawsuits, including intellectual property or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and the market for biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies, including very recently in connection with the ongoing COVID-19 pandemic, which has resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Broad market and industry factors, including potentially worsening economic conditions and other adverse effects or developments relating to the ongoing COVID-19 pandemic, may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results, or financial condition.

# Raising additional capital and future issuances of our common stock or rights to purchase common stock could result in additional dilution of the percentage ownership of our stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidate, and could cause our stock price to fall.

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, expanded research and development activities, and costs associated with operating as a public company. To raise capital, we may sell common stock, convertible securities, or other equity securities in one or more transactions, including through a combination of public and private equity offerings, debt financings, strategic partnerships and alliances and licensing arrangements, at prices and in a manner we determine from time to time. If we sell common stock, convertible securities, or other equity securities, or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences, and privileges senior to the holders of our common stock.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholder's ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect our stockholder's rights as a stockholder. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

### We do not intend to pay dividends on our common stock, so any returns will be limited to the value of our stock.

We currently anticipate that we will retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, we may enter into agreements that prohibit us from paying cash dividends without prior written consent from our contracting parties, or which other terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock. Any return to stockholders will therefore be limited to the appreciation of their stock, which may never occur.

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

Our executive officers, directors, and 5% stockholders beneficially owned approximately 60.5% of our outstanding voting stock as of June 30, 2021. These stockholders will have the ability to influence us through this ownership position. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents, or approval of any merger, sale of assets, or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that our stockholders may feel are in their best interest.

# We are an emerging growth company and a smaller reporting company, and the reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, or JOBS Act, enacted in April 2012. 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 of 2002, as amended, or 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 could be an emerging growth company for up to five years following 2020, the year in which we completed our IPO, although circumstances could cause us to lose that status earlier. We will remain an emerging growth company until the earlier of (1) the last day of the fiscal year (a) following the fifth anniversary of 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 (2) 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 avail ourselves of this exemption from complying with new or revised accounting standards and, therefore, will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

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 take advantage of many of the same exemptions from disclosure requirements, including 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.

# We incur significant increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives.

As a public company, we 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 Securities Exchange Act of 1934, as amended, which requires, among other things, that we file with the Securities and Exchange Commission, or SEC, annual, quarterly, and current reports with respect to our business and financial condition. In addition, the Sarbanes-Oxley Act, as well as rules subsequently adopted by the SEC and The Nasdaq Global Market 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, or the Dodd-Frank Act, was enacted. There are significant corporate governance and executive compensation related provisions in the Dodd-Frank Act that require the SEC to adopt additional rules and regulations in these areas, such as "say on pay" and proxy access. Recent legislation permits emerging growth companies to implement many of these requirements over a longer period and up to five years from our IPO. We intend to take advantage of this new legislation 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 environment, and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, and results of operations. The increased costs will decrease our net income or increase our net loss and may require us to reduce costs in other areas of our business or increase the prices of our products or services. 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.

### We have broad discretion over the use of our cash and cash equivalents and may not use them effectively.

Our management has broad discretion to use our cash and cash equivalents to fund our operations and could spend these funds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by our management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending our use to fund operations, we may invest our cash and cash equivalents in a manner that does not produce income or that losse value.

# 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, defer 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 a majority of the members of our board of 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 and not less than two-thirds of the outstanding shares of each class entitled to vote thereon as a class to amend specific provisions of our certificate of incorporation;
- 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; 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 antitakeover 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 stockholders to elect directors of their choosing or cause us to take other corporate actions they 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 certain courts 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.

Our amended and restated bylaws provide that, unless we consent in writing to an alternative forum, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for any state law claim 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, and employees 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 or our amended and restated bylaws or (iv) 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, or 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. Our bylaws further provide that, unless we consent in writing to the selection of an alternative forum, the United States 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, or the Federal Forum Provision, as our principle 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 shares of our common stock is deemed to have notice of and consented to the foregoing provisions; 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.

We recognize that the Delaware Forum Provision and the Federal Forum Provision in our bylaws may impose additional litigation costs on stockholders in pursuing any such claims, particularly if the stockholders do not reside in or near the State of Delaware or the Commonwealth of Massachusetts. Additionally, the forum selection clauses in our amended and restated bylaws may limit our stockholders' ability to bring a claim in a 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. In addition, 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 Court of Chancery of the State of Delaware and the United States District Court for the District of Massachusetts 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.

# If we fail to establish and maintain proper and effective internal control over financial reporting, our operating results and our ability to operate our business could be harmed.

Ensuring that we have adequate internal control over financial reporting in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with generally accepted accounting principles. In connection with our IPO, we began the process of documenting, reviewing, and improving our internal controls and procedures for compliance with Section 404 of the Sarbanes-Oxley Act, which will require annual management assessment of the effectiveness of our internal control over financial reporting. We have begun recruiting additional finance and accounting personnel with certain skill sets that we will need as a public company. If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities.

Implementing any appropriate changes to our internal controls may distract our officers and employees, entail substantial costs to modify our existing processes, and take significant time to complete. These changes may not, however, be effective in maintaining the adequacy of our internal controls, and any failure to maintain that adequacy, or consequent inability to produce accurate financial statements on a timely basis, could increase our operating costs and harm our business. In addition, investors' perceptions that our internal controls are inadequate or that we are unable to produce accurate financial statements on a timely basis may harm our stock price and make it more difficult for us to effectively market and sell our service to new and existing customers.

# If securities or industry analysts do not publish research or publish inaccurate research or unfavorable research about our business, the price of our common stock and trading volume could decline.

The trading market of our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. We do not have control over these analysts. There can be no assurance that analysts will continue to cover us, or provide favorable coverage. If no or few securities or industry analysts cover our company, the trading price of our common stock would be negatively impacted. If one or more of the analysts who covers us downgrades our common stock or publishes incorrect or unfavorable research about our business, the price of our common stock would likely decline. If one or more of these analysts coverage of our company or fails to publish reports on us regularly, or downgrades our common stock, demand for our common stock could decrease, which could cause the price of our common stock or trading volume to decline.

### Special note regarding forward-looking statements

This Quarterly Report on Form 10-Q contains express or implied forward-looking statements that are based on our management's belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future operational or financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- the timing, progress and the success of our clinical trials of inupadenant and EOS-448 and any other product candidates, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs;
- whether the results of our trials will be sufficient to support domestic or foreign regulatory approvals for inupadenant and EOS-448 or any other product candidates we may develop;
- regulatory actions with respect to our product candidates or our competitors' products and product candidates;
- our ability to obtain, including on an expedited basis, and maintain regulatory approval of inupadenant and EOS-448 or any other product candidates we may develop;
- the outcomes of our preclinical studies;
- our ability to enroll patients in our clinical trials at the pace that we project;
- our ability to establish clinical programs moving forward in multiple indications by 2021, with a rapidly advancing portfolio and sustainable platform, including our expectation to nominate an additional product candidate for commencement of IND enabling studies before the end of 2021;
- · our ability to establish and conduct our clinical programs on our expected timelines;
- the costs of development of any of our product candidates or clinical development programs;
- our expectation about the period of time over which our existing capital resources will be sufficient to fund our operating expenses and capital expenditures, and the degree to which such resources will enable us to fund our planned development of inupadenant and EOS-448 and any other product candidates we may identify and pursue;
- the potential attributes and clinical benefits of the use of inupadenant and EOS-448 or any other product candidate, if approved;
- our ability to successfully commercialize inupadenant and EOS-448 or any other product candidates we may identify and pursue, if approved;
- our ability to successfully establish or maintain collaborations or strategic relationships for our product candidates and the expected benefits of such collaborations, including potential milestones and royalty payments from GSK pursuant to the Collaboration Agreement;
- the rate and degree of market acceptance of inupadenant and EOS-448 or any other product candidates we may identify and pursue;
- our ability to obtain orphan drug or Breakthrough Therapy designation or other accelerated approval for any of our product candidates we may identify;



- our ability to manufacture inupadenant and EOS-448 or any other product candidate in conformity with the Food and Drug Administration's requirements and to scale up manufacturing of our product candidates to commercial scale, if approved;
- our ability to compete with companies currently producing or engaged in the clinical development of treatments for the disease indications that we pursue and treatment modalities that we develop;
- our ability to retain and recruit key personnel;
- our ability to obtain and maintain intellectual property protection for inupadenant and EOS-448 or any other product candidates we may identify and pursue;
- our estimates of our expenses, ongoing losses, future revenue, and capital requirements, including our belief that our existing cash and cash equivalents as of the filing date of this Quarterly Report on a Form 10-Q will enable us to fund our operating expenses and capital expenditure requirements into 2026, and our needs for or ability to obtain additional financing;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;
- our financial performance;
- the effect of the COVID-19 pandemic, including mitigation efforts and economic effects, on any of the foregoing or other aspects of our business operations, including but not limited to our preclinical studies including but not limited to our current and future preclinical and clinical studies;
- the impact of laws and regulations; and
- · developments and projections relating to our competitors or our industry.

In some cases, you can identify forward-looking statements by terminology such as "may," "should," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," "continue" or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks, uncertainties, and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the section titled "Risk factors" and elsewhere in this Quarterly Report on Form 10-Q. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forwardlooking statements. No forward-looking statement is a guarantee of future performance. You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q and have filed with the Securities and Exchange Commission as exhibits to the registration statement, of which this Quarterly Report on Form 10-Q forms a part, completely and with the understanding that our actual future results may be materially different from any future results expressed or implied by these forward-looking statements.

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.

This Quarterly Report on Form 10-Q also contains estimates, projections and other information concerning our industry, our business and the markets for our 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. While we are not aware of any misstatements regarding any third-party information presented in this Quarterly Report on Form 10-Q, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties and are subject to change based on various factors, including those discussed under the section titled "Risk factors" and elsewhere in this Quarterly Report on Form 10-Q.

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

In July 2020, we issued to the CEO and directors options to purchase an aggregate of 1,151,680 shares of our common stock at an exercise price of \$19.00. In August 2020, we issued and sold to fifteen employees and consultants an aggregate of 104,592 shares of common stock upon the exercise of stock options under our 2019 Stock Option and Grant Plan at an exercise price of \$4.30. We deemed the issuance of stock options and the common stock issuable upon exercise of such options to be exempt from registration under the Securities Act of 1933 (the "Securities Act") either in reliance on Rule 701 of the Securities Act as sales and offers under compensatory benefit plans and contracts relating to compensation in compliance with Rule 701, or in reliance on Section 4(a)(2), as transactions by an issuer not involving a public offering. All recipients either received adequate information about our company or had access, through employment or other relationships, to such information. No underwriters were involved in the foregoing issuances of securities.

#### Use of Proceeds from Initial Public Offering of Common Stock

On July 28, 2020, we closed our initial public offering of 10,586,316 shares of our common stock at a public offering price of \$19.00 per share for an aggregate offering of \$201.1 million. In addition, on August 5, 2020, we issued and sold an additional 1,505,359 shares of common stock pursuant to the underwriters' option to purchase additional shares for aggregate gross proceeds of \$28.6 million.

All shares issued and sold in the initial public offering were registered under the Securities Act pursuant to a Registration Statement on Form S-1 (File No. 333-239415), which was declared effective by the SEC on July 23, 2020. J.P. Morgan Securities LLC, SVB Leerink LLC and Piper Sandler & Co. acted as joint book-running managers and Wedbush Securities Inc. acted as lead manager for the initial public offering.

We received aggregate gross proceeds from our initial public offering of approximately \$229.7 million, or aggregate net proceeds of approximately \$210.6 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. None of the underwriting discounts and commissions or offering expenses were incurred or paid to directors or officers of ours or their associates or to persons owning 10% or more of our common stock or to any affiliates of ours. As of June 30, 2020, we have not used any of the net proceeds from the initial public offering.

We have not used any of the net proceeds from the offering to make payments, directly or indirectly, to any director or officer of ours, or any of their associates, to any person owning 10 percent or more of our common stock or to any affiliate of ours. There has been no material change in our planned use of the net proceeds from the offering as described in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on July 27, 2020.

### Item 3. Defaults Upon Senior Securities.

Not applicable.

#### Item 4. Mine Safety Disclosures.

Not applicable.

#### Item 5. Other Information.

Not applicable.

### Item 6. Exhibits.

Exhibit Number	Description
3.1	Second Amended and Restated Certificate of Incorporation of the Registrant (Incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-39401) filed with the Securities and Exchange Commission on July 28, 2020)
3.2	Amended and Restated Bylaws of the Registrant (Incorporated by reference to Exhibit 3.3 to the Registrant's Current Report on Form 8-K (File No. 001-39401) filed with the Securities and Exchange Commission on July 28, 2020)
4.1	Specimen Common Stock Certificate (Incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1/A (File No. 333-239415) filed with the Securities and Exchange Commission on July 20, 2020)
10.1**	Collaboration and License Agreement between iTeos Belgium S.A and GlaxoSmithKline Intellectual Property (No. 4) Limited dated June 11, 2021
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*+	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	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 Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)
* Filed I	nerewith.

<sup>\*\*</sup> Identified information has been excluded from this exhibit because it is both (i) not material and (ii) would be competitively harmful if publicly disclosed.

<sup>+</sup> This certification will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.

### SIGNATURES

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

Company Name

Date: August 11, 2021

By: /s/ Michel Detheux

Michel Detheux President and Chief Executive Officer (Principal executive officer)

Date: August 11, 2021

By: /s/ Matthew Gall

Matthew Gall Chief Financial Officer (Principal financial and accounting officer)

Certain information (indicated by "[\*\*\*]") and schedules have been excluded from this agreement because such information (i) is not material and (ii) would be competitively harmful if publicly disclosed.

### COLLABORATION AND LICENSE AGREEMENT

Between

### GLAXOSMITHKLINE INTELLECTUAL PROPERTY (NO. 4) LIMITED

And

**ITEOS BELGIUM S.A.** 

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### **SCHEDULES**

SCHEDULE 1.84 – EOS-448 Antibody SCHEDULE 1.250 – Third Party Component Contracts SCHEDULE 3.2 – Initial Global Development Plan SCHEDULE 3.12 – Form of Material Transfer Record SCHEDULE 8.3.1 – Pre-Tax Profit or Loss Schedule SCHEDULE 8.11 – Form of Invoice SCHEDULE 10.6 – Press Release SCHEDULE 14.2.1 – ITEOS Background Patents

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### **COLLABORATION AND LICENSE AGREEMENT**

This Collaboration and License Agreement (the "**Agreement**") is made and entered into as of June 11, 2021 ("**Execution Date**") and is effective as of the Effective Date (as defined below), between GLAXOSMITHKLINE INTELLECTUAL PROPERTY (No. 4) LIMITED, a company registered in England and Wales (registered number 11721880) and having business offices at 980 Great West Road, Brentford, Middlesex TW8 9GS United Kingdom ("**GSK**"), and iTeos Belgium S.A., a public limited company having an office at Rue des Frères Wright, 29, B-6041 Gosselies Belgium ("**ITEOS**"). GSK and ITEOS are sometimes referred to individually as a "**Party**" and collectively as the "**Parties**."

### BACKGROUND

**WHEREAS**, GSK, among other things, conducts programs to discover, develop, manufacture and commercialize innovative pharmaceutical medicines;

**WHEREAS**, ITEOS, among other things, conducts programs to discover and develop therapeutic products for the treatment and prevention of diseases; and

**WHEREAS**, GSK and ITEOS desire to enter into this Agreement to collaborate with respect to the Development Program and the Commercialization of Licensed Products that may result therefrom, consistent with the terms and conditions set forth herein.

**NOW, THEREFORE**, for good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties agree as follows:

### ARTICLE 1 DEFINITIONS

Capitalized terms used in this Agreement, whether used in the singular or plural, shall have the meanings set forth below, unless otherwise specifically indicated herein.

- **1.1 "AAA Rules**" has the meaning set forth in Section 16.2 (Arbitration).
- **1.2** "ACCME Standards" has the meaning set forth in Section 6.9.3 (Applicable Laws and Guidelines).
- **1.3** "Accounting Standards" means, with respect to GSK, IFRS, and with respect to ITEOS, GAAP, in each case, as consistently applied by the applicable Party and its Affiliates, as the same may be changed from time to time by the Parties.
- **1.4** "Acquiree" has the meaning set forth in Section 9.12.3(b) (New Affiliate Exception).
- **1.5** "Acquiror" has the meaning set forth in Section 9.12.3(a) (New Affiliate Exception).
- **1.6** "Additional Development Activities" has the meaning set forth in Section 3.4.1 (Additional Development Proposals).

### **1.7** "Additional Development Proposal" has the meaning set forth in Section 3.4.1 (Additional Development Proposals).

- **1.8** "Affiliate" means, with respect to a given Party, any corporation, firm, limited liability company, partnership or other entity that directly or indirectly controls, or is controlled by, or is under common control with such Party. For the purposes of this Section 1.8 (Affiliate), "control" means ownership, directly or indirectly through one or more Affiliates, of more than fifty percent (50%) of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or more than fifty percent (50%) of the equity interests in the case of any other type of legal entity, or status as a general partner in the case of any partnership, or any other arrangement whereby a corporation or other entity controls or has the right to control the board of directors or equivalent governing body or management of another corporation or other entity.
- **1.9** "**Agreement**" has the meaning set forth in the preamble.
- **1.10** "Alliance Manager" has the meaning set forth in Section 7.8 (Alliance Managers).
- **1.11 "Allowable Expenses**" has the meaning set forth in the Pre-Tax Profit or Loss Schedule.
- **1.12** "**AMA**" has the meaning set forth in Section 6.9.3 (Applicable Laws and Guidelines).
- **1.13** "**Applicable Law**" means, individually and collectively, any and all laws, statutes, ordinances, rules, directives and regulations of any governmental or regulatory authority within the applicable jurisdiction that may be in effect from time to time that apply to a Party's activities or obligations under or in connection with this Agreement, including, if applicable, GMP, GLP, GCP, the FD&C Act, the Prescription Drug Marketing Act of 1987, the Generic Drug Enforcement Act of 1992 (21 U.S.C. § 335a et seq.), the Anti-Kickback Statute (42 U.S.C. § 1320a-7b et seq.), the False Claims Act (31 U.S.C. § 3729 et seq.), Civil Monetary Penalties Law (42 U.S.C. § 1320a-7a), the Patient Protection and Affordable Care Act (42 U.S.C. § 18001 et seq.), the Social Security Act (42 U.S.C. Chapter 7), the Antifraud and Abuse Amendment to the Social Security Act, Federal Program Fraud Civil Remedies Act (31 U.S.C. § 3801 et seq.), FCPA, Data Protection Laws, and all applicable implementing regulations for the foregoing, and all applicable state laws and the laws of the District of Columbia corresponding to any of the foregoing, all as amended from time to time.
- **1.14** "**Approved Labeling**" means, with respect to a Licensed Product: (a) the Regulatory Authority-approved full prescribing information for such Licensed Product; and (b) the Regulatory Authority-approved labels and other written, printed, or graphic materials on any container, wrapper, or any package insert that is used with or for such Licensed Product.
- **1.15** "Arising Technology" means all Patents and Know-How invented, discovered, created or developed by or on behalf of a Party solely or the Parties jointly in connection with the exercise of its or their rights or performance of its or their obligations under this Agreement.

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- **1.16 "Background Technology**" of a Party means, in the case of GSK, the GSK Background Technology, and in the case of ITEOS, the ITEOS Background Technology.
- **1.17 "Balancing Payment**" has the meaning set forth in Section 8.3.5(b) (Quarterly Reconciliation Payment).
- **1.18 "Bankruptcy Code**" means Title 11 of the United States Code.
- **1.19 "Benchmark Countries**" has the meaning set forth in Section 1.181 (Net Sales).
- **1.20 "Biosimilar Product**" means with respect to a given Licensed Product in a particular country in the Territory, any product sold by a Third Party not authorized by GSK or its Affiliates or its or their Sublicensees that is approved by the applicable Regulatory Authority for such country through any application or submission filed with a Regulatory Authority for Regulatory Approval of a biological product determined to be biosimilar or interchangeable to such Licensed Product, including an application filed under 42 U.S.C. § 262(k) or any similar provisions in a country outside the United States, based in reliance, at least in part, on data generated for a Regulatory Approval of such Licensed Product.
- **1.21** "**BLA**" means a Biologics License Application (as more fully defined in 21 C.F.R. 601.2 et seq. or its successor regulation) and all amendments and supplements thereto filed with the FDA.
- **1.22 "BPCIA"** has the meaning set forth in Section 11.3.1 (Notification of Infringement).
- **1.23 "Breaching Party**" has the meaning set forth in Section 12.3.1 (Termination for Material Breach).
- **1.24 "Business Day**" means a day that is not (a) a Saturday, Sunday or a day on which banking institutions in New York, New York or London, United Kingdom are required by Applicable Law to remain closed, or (b) the nine (9) consecutive calendar days beginning on December 24 through and including January 1 of each Calendar Year to the extent those days are not included in (a) in this Section 1.24.
- **1.25** "Calendar Quarter" means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.
- **1.26** "Calendar Year" means each successive period of twelve (12) months commencing on January 1 and ending on December 31.
- **1.27 "CDA**" means that certain Mutual Confidential Disclosure Agreement between GlaxoSmithKline LLC and iTeos Belgium SA [\*\*\*].
- **1.28** "**Cessation**" has the meaning set forth in Section 12.5 (Termination for Cessation of Development or Commercialization).
- **1.29 "Change of Control**" means, with respect to a Party, an event or transaction or series of events or transactions by which: (a) any Third Party (or group of Third Parties acting in

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concert) becomes the beneficial owner, directly or indirectly, of more than fifty percent (50%) of the outstanding securities of such Party or the total voting power of such securities normally entitled to vote in elections of directors; (b) (i) such Party reorganizes, consolidates or comes under common control with, or merges into another entity, or (ii) any entity reorganizes, consolidates or comes under common control with, or merges into, such Party, in either event of the foregoing ((i) or (ii)) where more than fifty percent (50%) of the total voting power of the securities outstanding of the surviving entity normally entitled to vote in elections of directors is not held by the parties holding at least fifty percent (50%) of the outstanding shares of such Party immediately preceding such consolidation or merger; or (c) such Party conveys, transfers or leases to a Third Party all or substantially all of its assets or business relating to this Agreement.

- **1.30** "Clinical Manufacturing" or "Clinical Manufacture" means Manufacture of a Licensed Product (including the cost of Manufacturing Licensed Antibody contained in Licensed Product) or acquisition of such Licensed Antibody and Licensed Product from a CMO, in each case, for use in Clinical Trials.
- **1.31** "Clinical Manufacture Costs" means Manufacturing Costs of the Manufacture of a given Licensed Product (including the cost of Manufacturing Licensed Antibody contained in Licensed Product) or other compound, antibody, or product Controlled by GSK, in each case, for clinical use of such Licensed Product or other compound, antibody, or product Controlled by GSK, as applicable, anywhere in the Territory.
- **1.32 "Clinical Trial**" means any study in humans to obtain information regarding a pharmaceutical product, including information relating to the safety, tolerability, pharmacological activity, pharmacokinetics, dose ranging, or efficacy of such product, including a Registration Study.
- **1.33 "CMC Development**" means the following Development activities: test method development and stability testing, process development, control strategy and process validation, process scale-up, formulation development, delivery system development, quality assurance and quality control development, and other related activities, in each case, pertaining to Development of a process to Manufacture Licensed Antibody and Licensed Products.
- **1.34** "CMOs" has the meaning set forth in Section 1.167.2 (Manufacturing Cost).
- **1.35 "CMS"** has the meaning set forth in Section 6.9.5 (Reporting).
- **1.36 "Co-Administration Studies**" means clinical studies for co-administration (not co-formulation) of pharmaceutical products (that are not Licensed Products) together with the EOS-448 Sole Active Product.
- **1.37 "Co-Administration Therapy**" means the use or method of using the EOS-448 Sole Active Product and at least one other pharmaceutical product together in either concomitant or sequential administration. For the avoidance of doubt, a Co-Administration Therapy (a) will not be considered a Co-Formulated Product hereunder and (b) will not be considered

a Combination Product hereunder unless such Co-Administration Therapy is sold and invoiced under a single invoiced price.

- **1.38 "Co-Chair**" has the meaning set forth in Section 7.6.1 (Membership).
- **1.39 "Co-Formulated Product**" has the meaning set forth in Section 1.181 (Net Sales).
- **1.40 "Collaboration In-License**" has the meaning set forth in Section 9.11.3 (New Collaboration In-Licenses).
- **1.41 "Combination Product**" means a Licensed Product that includes a Licensed Antibody in combination with one or more pharmaceutically active ingredients that is not any other Licensed Antibody (the "**Other Component(s)**"), whether in a single formulation finished form, co-packaged, or as separate products otherwise sold and invoiced under a single invoiced price.
- **1.42 "Commercial Manufacturing"** or **"Commercial Manufacture**" means Manufacture of a Licensed Product (including the cost of Manufacturing Licensed Antibody contained in Licensed Product) or acquisition of such Licensed Antibody and Licensed Product from a CMO, in each case, for Commercialization of such Licensed Product in the Territory.
- **1.43** "Commercialization" means any and all activities directed to the preparation for sale of, offering for sale of, or sale of a given Licensed Product, including activities related to marketing, promoting, selling, distributing, seeking, obtaining, and maintaining Reimbursement Approvals, and importing and exporting such Licensed Product, launch preparation activities and interacting with Regulatory Authorities regarding any of the foregoing, but excluding, in each case (a) for clarity, interactions with Regulatory Authorities regarding Clinical Trials, obtaining Regulatory Approvals, and other Development activities (including for clarity Manufacturing activities related to Development) and (b) activities directed to Development, Manufacturing, or Medical Affairs. "Commercialize" and "Commercializing" shall have their correlative meanings.
- **1.44 "Commercialization Excess Costs**" has the meaning set forth in the Pre-Tax Profit or Loss Schedule.
- **1.45 "Commercialization Permitted Overage**" has the meaning set forth in the Section 8.3.5(c) (Overruns).
- **1.46 "Commercialization Plan**" means the Global Strategic Launch Plan and the Joint Commercialization Plan.
- **1.47 "Commercialization Report**" has the meaning set forth in Section 6.8 (Commercialization Reporting).
- **1.48** "Commercially Reasonable Efforts" means such efforts that are consistent with the efforts and resources normally used by GSK (in the case of GSK) or ITEOS (in the case of ITEOS) in the exercise of its reasonable business discretion relating to Development and Commercialization of a compound, antibody, or product owned by it or to which it has

exclusive rights, with similar characteristics as the applicable relevant Licensed Antibody and Licensed Product hereunder, that is of similar market potential at a similar stage in its development or product life as such Licensed Antibody or Licensed Product, taking into account issues of patent coverage, safety and efficacy, product profile, the competitiveness of the marketplace, the proprietary position, the regulatory structure involved, profitability, and other relevant factors, including technical, legal, scientific or medical factors. For purposes of clarity, it is anticipated that the level of effort may be different for different markets and may change over time, reflecting changes in the status of the product and the market(s) involved.

- **1.49** "Committed Development Spend" has the meaning set forth in Section 3.2.3 (Shared Development Costs).
- **1.50 "Committed Studies**" has the meaning set forth in Section 3.2.1 (Global Development Plan).
- **1.51 "Committee**" means, individually, the JSC, the JDC, the JCC and the Financial Working Group or any other Subcommittee established as set forth in Section 7.5 (Other Subcommittees).
- **1.52 "Committee Deadlock**" has the meaning set forth in Section 7.7.1 (Committee Decision Making).
- **1.53** "**Companion Diagnostic**" means a product designed for use in a diagnostic biomarker assay tailored or optimized for use with a Licensed Product, for predicting or monitoring the suitability of such Licensed Product for prophylactic or therapeutic use in human patients or defined subpopulations thereof. A Companion Diagnostic shall be intended for use (a) as a means to select or monitor the patient population for the conduct of clinical studies of such Licensed Product, (b) to predict predisposition to treatment in clinical use with such Licensed Product, or (c) to predict or monitor potential safety considerations in clinical use with such Licensed Product. Use of a Companion Diagnostic to guide use of the Licensed Product will be contingent on appropriate Regulatory Approvals for such uses as deemed necessary by the FDA or other similar Regulatory Authority with appropriate jurisdiction.
- **1.54 "Competing Product**" has the meaning set forth in Section 11.3.1 (Notification of Infringement).
- **1.55 "Compliance Officers**" has the meaning set forth in Section 6.9.1 (Establishment of Compliance Program).
- **1.56** "Confidential Information" means any technical, business or other information provided by or on behalf of one Party (the "Disclosing Party") to the other Party (the "Receiving Party") in connection with this Agreement, whether prior to, on, or after the Effective Date, including under the CDA.

- 1.57 "Control" (including variations such as "Controlled," "Controlling" and the like) means, (a) with respect to any Know-How, Patent, material, information or other intellectual property, the possession (whether by sole or joint ownership or license or otherwise, other than the licenses granted hereunder) of the ability to grant access, right to use, license or sublicense or other right to Exploit such Know-How, Patent, material, information or other intellectual property as set forth in this Agreement, or (b) with respect to any compound, antibody or product, the possession by a Party of the ability (whether by sole or joint ownership, license or otherwise, other than the licenses granted hereunder) to grant a license or sublicense under Patents that claim such compound, antibody or product or under Know-How that is used in connection with the Exploitation of such compound, antibody, or product, in each case ((a) and (b)), without violating the terms of any agreement or other arrangement with any Third Party, or any Applicable Law. Notwithstanding any provision to the contrary set forth in this Agreement, a Party and its Affiliates will not be deemed to "Control" any Know-How, Patent, material, information, other intellectual property, compound, antibody or product, that, prior to the consummation of a Change of Control of such Party, is owned or in-licensed by a Third Party (or an Affiliate of such Third Party) that becomes an Affiliate of such acquired Party after the Effective Date as a result of such Change of Control unless (i) prior to the consummation of such Change of Control, such acquired Party or any of its Affiliates also Controlled such Know-How, Patents, material, information, other intellectual property, compound, antibody or product, (ii) any such Know-How, Patents, material, information, other intellectual property, compound, antibody or product arise from participation by employees or consultants of such Third Party in any activities conducted under this Agreement after such Change of Control, or (iii) the Know-How, Patents, material, information, other intellectual property, compound, antibody or product, owned or in-licensed by such Third Party were not used in the performance of activities under this Agreement prior to the consummation of such Change of Control, but after the consummation of such Change of Control, such acquired Party or any of its Affiliates actually uses any such Know-How, Patents, material, information, other intellectual property, compound, antibody or product, in the performance of its obligations or exercise of its rights under this Agreement, in each of which cases ((i) through (iii)), such Know-How, Patents, material, information, other intellectual property, compound, antibody or product, will be deemed "Controlled" by such Party for purposes of this Agreement.
- **1.58** "Controlling Party" has the meaning set forth in Section 11.2.1 (Subject Patents).
- **1.59 "Cost Share End Date**" has the meaning set forth in Section 6.7.3 (Effects of Opt-Out).
- **1.60 "Cost Share Start Date**" has the meaning set forth in Section 8.3.1 (Pre-Tax Profit or Loss).
- **1.61** "Cover" or "Covered" or "Covering" means, with respect to a particular subject matter at issue and a relevant Patent, that the manufacture, use, sale, offer for sale, or importation of such subject matter would fall within the scope of one or more claims in such Patent.

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- **1.62 "Currency Gains and Losses**" means the gain or loss resulting from changes in exchange rates between the functional currency and the foreign currency in which the transaction is denominated, to the extent specifically identifiable to a Licensed Product for which costs are shared by the Parties hereunder and shall only include the currency gains and losses realized between the end of a Calendar Quarter and the date of invoice payment for that Calendar Quarter.
- **1.63 "Data"** means pre-clinical data (including computational validation, genetic data (including genotype, phenotype and genetic sequencing data), *in vitro* and *in vivo* data), clinical data (including enrollment data, broad data sets, study and investigator reports, both preliminary and final, statistical analyses, expert opinions and reports, safety and other electronic databases), and regulatory, Manufacturing, biological, chemical, pharmacological, toxicological, pharmaceutical, physical, analytical, safety and quality control data, information and documentation, whether in written or electronic form.
- **1.64 "Data Protection Law"** means all applicable laws, rules and regulations, including, to the extent applicable, the United States Health Insurance Portability and Accountability Act of 1996 and its implementing regulations ("**HIPAA**"), the California Consumer Privacy Act of 2018 ("**CCPA**"), and any applicable supranational or national legislation relating to privacy and data protection, direct marketing or the interception or communication of electronic messages, in each case as amended, consolidated, re-enacted or replaced from time to time, including, to the extent applicable, European Data Protection Laws.
- **1.65 "Data Security Breach**" has the meaning set forth in Section 10.5 (Data Breach).
- **1.66 "Data Sharing Initiative"** means GSK's policy initiative (as may be amended from time to time), known at the Effective Date as the "SHARE Initiative", to provide researchers with access to Clinical Trial and study information, including anonymized patient level data, as such initiative is described on https://www.clinicalstudydatarequest.com/.
- 1.67 [\*\*\*].
- **1.68** "**Detail**" or "**Detailing**" means, with respect to a Licensed Product, the communication made by a Sales Representative during a Sales Call (a) involving face-to-face contact or virtual meetings (such as through videoconference) with healthcare professionals, (b) describing in a fair and balanced manner the FDA-approved uses and other relevant characteristics of the Licensed Product being detailed, (c) using approved Promotional Materials in an effort to inform healthcare professionals on the Licensed Product for its FDA-approved uses in a manner consistent with Applicable Law, and (d) made at a healthcare professional's office or other appropriate venues (including audio or video teleconference) conducive to pharmaceutical product informational communication where the principal objective is to place an emphasis on the Licensed Product with such healthcare professional.
- **1.69 "Development**" means any and all research and development activities conducted that are necessary for developing, seeking, obtaining, or maintaining Regulatory Approvals for Licensed Products, which include pre-clinical studies and non-clinical studies, Clinical

Trials, quality of life assessments, translational research, Companion Diagnostic development, pharmacoeconomics, regulatory affairs, Manufacturing process development, formulation development and activities performed in support of the CMC (chemistry, manufacturing and controls, or equivalent) section of an IND or BLA and other Regulatory Filings, including all CMC Development. For clarity, Development excludes Commercialization, Manufacturing, and Medical Affairs activities. "**Develop**" and "**Developing**" shall have their correlative meanings.

- **1.70 "Development and Filing Milestone**" has the meaning set forth in Section 8.4 (Development and Filing Milestones).
- **1.71 "Development and Filing Milestone Payments**" has the meaning set forth in Section 8.4 (Development and Filing Milestones).
- **1.72** "Development Costs" means the [\*\*\*] incurred by a Party or its Affiliates, Sublicensees or subcontractors after the Effective Date in the performance of the respective Shared Global Development Activities of such Party [\*\*\*] to the Development of a Licensed Product, to the extent incurred in accordance with the Global Development Plan and Global Development Budget. Development Costs include, to the extent set forth in the Global Development Plan and corresponding Global Development Budget (a) costs for other materials (*e.g.*, non-Licensed Product comparator drugs and placebo obtained for use in Development of the Licensed Products), (b) all filing fees required for and other costs associated with, any Regulatory Filings for Licensed Products [\*\*\*] (c) [\*\*\*] (i) [\*\*\*] (ii) CMC Development, [\*\*\*] (d) Clinical Manufacture Costs, (e) Manufacturing Costs [\*\*\*], (h) Patent Costs [\*\*\*]. Development Costs excludes all costs incurred in connection with Commercialization of or performance of Medical Affairs activities [\*\*\*] for Licensed Products. Development Costs do not include any costs or expenses incurred by GSK in connection with the performance of the GSK Sole Development Activities.
- **1.73 "Development Excess Costs"** has the meaning set forth in Section 8.2.2(b) (Overruns).
- **1.74 "Development FTE Costs"** means, as applicable with respect to any period, the FTE Rate for the performance of Development activities, *multiplied by* the actual total number of FTEs (or portion thereof) directly devoted to performing such Development activities in accordance with the Global Development Plan under this Agreement, during such period. The calculation of the number of FTEs for purposes of determining Development FTE Costs will be documented by the Parties in a manner designed to ensure proper reporting and auditing of such information in accordance with this Agreement.
- **1.75 "Development Program**" has the meaning set forth in Section 7.2.1 (Establishment of the JDC).
- **1.76 "Development Reports**" has the meaning set forth in Section 3.6 (Development Reporting).
- **1.77 "Disclosing Party**" has the meaning set forth in Section 1.56 (Confidential Information).
- **1.78 "Dispute**" has the meaning set forth in Section 16.1 (Dispute Resolution).

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- **1.79 "Dollars**" or **"\$**" means the official currency of the United States of America.
- **1.80 "DOJ**" has the meaning set forth in Section 2.2 (HSR Filing).
- **1.81 "Effective Date**" has the meaning set forth in Section 2.1 (Effectiveness of the Agreement).
- **1.82 "EMA"** means the European Medicines Agency, or any successor entity thereto performing similar functions for the European Union.
- **1.83 "Entity**" has the meaning set forth in Section 8.10.4 (No Partnership).
- **1.84 "EOS-448 Antibody**" means the antibody targeting TIGIT known internally by ITEOS as EOS-448, the structure of which is set forth on <u>Schedule 1.84</u>.
- **1.85 "EOS-448 Sole Active Product**" means the pharmaceutical product that contains a Licensed Antibody as the sole active ingredient, in all forms, presentations, strengths, doses and formulations.
- **1.86** "European Data Protection Laws" means the General Data Protection Regulation 2016/679, the e-Privacy Directive 2002/58/EC, the e-Privacy Regulation 2017/003 once it takes effect, and any relevant law, statute, declaration, decree, directive, legislative enactment, order, ordinance, regulation, rule or other binding instrument that implements, replaces, adds to, amends, extends, reconstitutes or consolidates such laws from time to time, including the Data Protection Act 2018 of the United Kingdom, in each case as amended, consolidated, re-enacted or replaced from time to time.
- **1.87 "European Union**" means the economic, scientific and political organization of member states in Europe, as it may be constituted from time to time, and notwithstanding any provision to the contrary set forth in this Agreement, will include the United Kingdom for purposes of this Agreement.
- **1.88 "Excluded Commercialization Activities**" has the meaning set forth in Section 1.236 (Shared Commercialization Activities).
- **1.89 "Exclusive Sublicense**" has the meaning set forth in Section 9.3 (Sublicenses).
- **1.90 "Execution Date**" has the meaning set forth in the preamble.
- **1.91** "Existing CMO" means [\*\*\*].
- **1.92 "Existing CMO Agreement**" has the meaning set forth in Section 5.1.2 (Clinical Supply).
- **1.93 "Expansion**" has the meaning set forth in Section 1.203 (Phase 2 Adaptive Study).

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- **1.94** "Exploit" means Develop, have Developed, make, have made, use, have used, perform Medical Affairs, have performed Medical Affairs, offer for sale, have offered for sale, sell, have sold, export, have exported, import, have imported, Manufacture, have Manufactured, Commercialize, have Commercialized or otherwise exploit. "Exploitation" and "Exploiting" will be construed accordingly.
- **1.95 "FDA"** means the U.S. Food and Drug Administration, or any successor entity thereto performing similar functions in the United States.
- **1.96 "Field**" means any use or purpose, including the treatment, palliation, diagnosis or prevention of any human or animal disease.
- **1.97 "Financial Report**" has the meaning set forth in Section 8.3.2 (Reporting Generally).
- **1.98 "Financial Working Group**" has the meaning set forth in Section 7.4 (Financial Working Group).
- **1.99 "First Commercial Sale"** means, with respect to a given Licensed Product in a country, the first commercial sale in an arms-length transaction of such Licensed Product by or on behalf of GSK, its Affiliate or Sublicensee in such country following receipt of applicable Regulatory Approval of such Licensed Product in such country; *provided, however*, that First Commercial Sale shall not include any transfer of a product (a) between or among GSK and its Affiliates or its Sublicensees, unless the Affiliate or Sublicensee is the last entity in the distribution chain of such product, or (b) for purposes of patient assistance programs, treatment IND sales, named patient sales or compassionate use sales, *provided*, that in case of (b), such product is sold at a price no greater than GSK's Manufacturing Costs for such Licensed Product.
- **1.100** "First No Opt-Out Period" means, with respect to a Licensed Product, the time period commencing on the Effective Date and ending on [\*\*\*].
- **1.101 "Force Majeure"** means any event beyond the reasonable control of the affected Party, including: embargoes; war or acts of war, including terrorism; insurrections, riots, or civil unrest; strikes, lockouts or other labor disturbances; epidemics (including pandemics), the spread of infectious diseases, and quarantines; fire, floods, earthquakes or other acts of nature; impossibility to obtain materials, components, drug substance, utilities, equipment, supplies, fuel or other required materials, receipt of warning letters, or loss, infection or failure of cell banks (in each case, due to reasons other than the affected Party's negligence or willful misconduct or any other cause within the reasonable control of the affected Party); or acts, omissions, or delays in acting by any Governmental Authority (including the refusal of any Regulatory Authority to issue required Regulatory Approvals due to reasons other than the affected Party), and failure of plant or machinery (*provided* that such failure could not have been prevented by the exercise of skill, diligence, and prudence that would be reasonably and ordinarily expected from a skilled and experienced person engaged in the same type of undertaking under the same or similar circumstances). The Parties agree the effects of the COVID-19 pandemic that is ongoing

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as of the Effective Date (including related government orders) may be invoked as a Force Majeure for the purposes of this Agreement even though the pandemic is ongoing and those effects may be reasonably foreseeable (but are not known for certain) as of the Effective Date. In addition, a Force Majeure may include reasonable measures affirmatively taken by a Party or its Affiliates to respond to any epidemic, pandemic, or spread of infectious disease (including the COVID-19 pandemic), such as requiring employees to stay home, closures of facilities, delays of Clinical Trials, or cessation of activities in response to an epidemic or other Force Majeure event.

- **1.102 "FTC**" has the meaning set forth in Section 2.2 (HSR Filing).
- **1.103** "FTE" means, with respect to employees of a Party or its Affiliates, the equivalent of the work of one (1) full time person for one (1) year (consisting of at least [\*\*\*] hours per year). Overtime, and work on weekends, holidays and the like shall not be counted with any multiplier (*e.g.*, time-and-a-half or double time) toward the number of hours that are used to calculate the FTE contribution. If any person works partially on other work in a given Calendar Year, then the full-time equivalent to be attributed to such person's work hereunder shall be equal to the percentage of such person's total work time in such Calendar Year that such person spent working on activities contemplated under this Agreement. FTE efforts shall not include the work of general corporate personnel. Each Party shall track FTEs of its personnel using such Party's standard practices and methodologies and in a manner designed to ensure proper reporting and auditing of such information in accordance with this Agreement.
- **1.104** "FTE Rate" means, unless otherwise agreed by the unanimous decision of the Financial Working Group or by the Parties in writing, commencing on the Effective Date, (a) with respect to Development activities, [\*\*\*] per FTE and (b) with respect to Commercialization activities at a rate to be agreed by the Financial Working Group prior to commencement of Commercialization activities by either Party. The FTE Rate shall be increased or decreased on the first day of every January starting in 2023 by a percentage equivalent to the change over the preceding twelve (12)-month period in the Consumer Price Index for All Urban Consumers (All Items), or any successor to such published measure, not seasonally adjusted, as published by the U.S. Department of Labor Bureau of Labor Statistics. For clarity, the FTE Rate includes "fully burdened" base salary, target bonus (yearly bonus based on achievement of personal/corporate targets), plus benefits including holiday allowance, pension, medical, risk, share-based payments and other remuneration-based benefits, tax and social security; however, the FTE Rate does not include or cover costs for facilities, travel expenses and IT allocation.
- **1.105** "GAAP" means generally acceptable accounting standards, principles, and procedures as issued by the Financial Accounting Standards Board (FASB).
- **1.106** "**GCP**" means all applicable Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials, including, as applicable, (a) FDA regulations and guidelines for good clinical practice, as promulgated by the FDA under 21 CFR Parts 50, 54, 56, 312 and 812, (b) as set forth in European Commission Directive 2001/20/EC relating to the implementation of good

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clinical practice in the conduct of clinical trials on medicinal products for human use, and brought into law by European Commission Directive 2005/28/EC laying down the principles and detailed guidelines for good clinical practice for investigational medicinal products, (c) the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use ("**ICH**") Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any other guidelines for good clinical practice for trials on medicinal products in the EU, (d) the Declaration of Helsinki (2008), and (e) any further amendments or clarifications with respect to any of the foregoing and any equivalents thereto in the country in which clinical studies of a product are conducted.

- **1.107** "Global Development Budget" means the budget of all [\*\*\*] to be incurred from and after the Effective Date in the performance of any Shared Global Development Activities under the Global Development Plan for any Licensed Antibodies and Licensed Products, including (a) a budget, broken down by Calendar Quarters and at a level of detail agreed by the JDC, for the estimated [\*\*\*] expected to be incurred by each Party in the given Calendar Year with respect to such Shared Global Development Activities under the Global Development Plan and (b) for subsequent Calendar Years, a [\*\*\*], of the estimated [\*\*\*] to be incurred in connection with such Shared Global Development Activities under the applicable Global Development Plan [\*\*\*] for such Licensed Antibodies and Licensed Products. The Global Development Budget will not include any costs or expenses to be incurred by GSK in connection with the performance of the GSK Sole Development Activities.
- "Global Development Plan" means the written plan setting forth (a) (i) all Development activities (including Clinical 1.108 Trials) for any Licensed Antibodies and Licensed Products (including Combination Products), in each case, through the completion of Registration Studies and any other Development activities necessary to obtain and maintain Regulatory Approvals for such Licensed Products in the U.S. and the European Union, including process development activities, CMC activities, formulation development, Companion Diagnostic development, and any post-Regulatory Approval studies and other non-clinical and pre-clinical studies and Clinical Trials, activities related to value-evidence outcomes, patient-focused outcomes and epidemiology, in each case, the data from which may be used to obtain or maintain Regulatory Approval in both the U.S. and the European Union (the activities described in this clause (a)(i), the "Shared Global Development Activities"), and (ii) all Development activities (including Clinical Trials), other than activities described in the foregoing clause (a)(i), that are necessary or desirable to obtain and maintain Regulatory Approvals of each Licensed Product in the Net Sales Territory, including all proposed post-Regulatory Approval studies and all other non-clinical and pre-clinical studies and Clinical Trials, activities related to value-evidence outcomes, patient-focused outcomes and epidemiology, in each case, the data from which will be used solely to obtain or maintain Regulatory Approval in the Net Sales Territory (the activities described in this clause (a)(ii), the "GSK Sole Development Activities"), (b) the estimated timelines for the performance and completion of such activities described in clause (a), (c) the regulatory strategy for obtaining and maintaining Regulatory Approval for Licensed Products in the Territory, (d) the supplies of Licensed Antibodies and Licensed Products (or components thereof including Other Components Controlled by GSK), comparator



drugs and placebo, in each case, needed to perform such Development activities, and (e) the Global Development Budget, in each case ((a) through (e)), as the same may be amended from time-to-time in accordance with this Agreement. The initial Global Development Plan is attached as <u>Schedule 3.2</u> of this Agreement.

- **1.109** "Global Strategic Launch Plan" has the meaning set forth in Section 6.1 (Global Strategic Launch Plan).
- **1.110** "GLP" means all applicable Good Laboratory Practice standards, including, as applicable: (a) FDA regulations and guidelines for good laboratory practice, as promulgated by the FDA under 21 CFR Part 58; (b) European Commission Directive 2004/10/EC relating to the application of the principles of good laboratory practices, as may be amended from time to time as well as any Rules Governing Medicinal Products in the European Community Vol. III, ISBN 92.825 9619-2 (ex-OECD principles of GLP); and (c) any further amendments or clarifications with respect to any of the foregoing and any equivalents thereto in the country in which pre-clinical or clinical studies of a product are conducted.
- **1.111** "GMP" means all applicable Good Manufacturing Practices, including: (a) the applicable part of quality assurance to ensure that products are consistently produced and controlled in accordance with the quality standards appropriate for their intended use, as defined in European Commission Directive 2003/94/EC laying down the principles and guidelines of good manufacturing practice; (b) the principles detailed in the U.S. Current Good Manufacturing Practices, 21 C.F.R. Sections 210, 211, 601, 610 and 820; (c) the Rules Governing Medicinal Products in the European Community, Volume IV Good Manufacturing Practice for Medicinal Products; (d) the principles detailed in the ICH Q7A guidelines; and (e) the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time.
- **1.112** "Government Official" (where "government" means all levels and subdivisions of governments, *i.e.*, local, regional, national, administrative, legislative, executive, or judicial, and royal or ruling families) means (a) any officer or employee of a government or any department, agency or instrumentality of a government (which includes public enterprises, and entities owned or controlled by the state); (b) any officer or employee of a public international organization such as the World Bank or United Nations; (c) any officer or employee of a political party, or any candidate for public office; (d) any individual defined as a government or public official under Applicable Laws (including anti-bribery and corruption laws) and not already covered by any of the above; or (e) any individual acting in an official capacity for or on behalf of any of the above. "Government Official" includes any individual with close family members who are Government Officials (as defined above) with the capacity, actual or perceived, to influence or take official decisions affecting the business of a Party.

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- **1.113 "Governmental Authority**" means any multinational, federal, national, state, provincial, local or other entity, office, commission, bureau, agency, political subdivision, instrumentality, branch, department, authority, board, court, arbitral or other tribunal, official or officer, exercising executive, judicial, legislative, police, regulatory, administrative or taxing authority, or functions of any nature pertaining to government.
- **1.114 "GSK"** has the meaning set forth in the preamble.
- **1.115** "GSK Arising Know-How" has the meaning set forth in Section 11.1.3 (Ownership by GSK).
- **1.116** "GSK Arising Patents" has the meaning set forth in Section 11.1.3 (Ownership by GSK).
- **1.117** "GSK Arising Technology" means GSK Arising Know-How and GSK Arising Patents.
- **1.118** "GSK Background Know-How" means any Know-How Controlled by GSK or its Affiliates as of the Effective Date or during the Term, other than pursuant to this Agreement.
- **1.119** "**GSK Background Patents**" means any Patents Controlled by GSK or its Affiliates as of the Effective Date or during the Term, other than pursuant to this Agreement.
- **1.120** "GSK Background Technology" means the GSK Background Know-How and the GSK Background Patents.
- **1.121** "GSK CMO Agreement" has the meaning set forth in Section 5.1.5 (Second Source).
- **1.122** "GSK Indemnitees" has the meaning set forth in Section 15.1.1 (Indemnification by ITEOS).
- **1.123** "GSK Patents" has the meaning set forth in Section 11.2.3 (GSK Patent Prosecution and Costs).
- **1.124** "GSK Sole Development Activities" has the meaning set forth in Section 1.108 (Global Development Plan).
- **1.125** "**GSK Technology**" means (a) all GSK Background Technology, (b) all GSK Arising Technology Controlled by GSK or any of its Affiliates during the Term, and (c) GSK's joint ownership interest in Joint Arising Technology Controlled by GSK during the Term, in each case ((a) through (c)), that [\*\*\*] and the terms of this Agreement.
- **1.126** "Guidelines" has the meaning set forth in Section 6.9.3 (Applicable Laws and Guidelines).
- **1.127 "HSR Act**" has the meaning set forth in Section 2.2 (HSR Filing).
- **1.128** "HSR Clearance Date" has the meaning set forth in Section 2.2 (HSR Filing).
- **1.129** "HSR Filings" has the meaning set forth in Section 2.2 (HSR Filing).

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- **1.130 "Human Biological Samples**" means any human biological material (including any derivative or progeny thereof), including any portion of an organ, any tissue, skin, bone, muscle, connective tissue, blood, cerebrospinal fluid, cells, gametes, or sub-cellular structures such as DNA, or any derivative of such biological material such as stem cells or cell lines; and any human biological product, including hair, nail clippings, teeth, urine, feces, breast milk and sweat.
- **1.131** "**IFRS**" means the International Financial Reporting Standards as adopted by the United Kingdom, applied on a consistent basis.
- **1.132** "Increased Withholding Taxes" has the meaning set forth in Section 8.10.2 (Tax Matters).
- **1.133 "IND"** means an Investigational New Drug Application (including any amendments thereto) filed with the FDA pursuant to 21 CFR Part 312, or any equivalent filing with any relevant Regulatory Authority in any jurisdiction.
- **1.134** "Indemnifying Party" has the meaning set forth in Section 15.1.3 (Indemnification Procedures).
- **1.135 "Indemnitee**" has the meaning set forth in Section 15.1.3 (Indemnification Procedures).
- **1.136** "**Indication**" means a separate and distinct disease, disorder or medical condition that a Licensed Product is intended to treat, prevent, cure or ameliorate in the indications section of the Approved Labeling for such Licensed Product, or that is the subject of a Clinical Trial and where it is intended that the data and results of such Clinical Trial (if successful) will be used to support a Regulatory Filing and Regulatory Approval that is intended to result in distinct labeling in the indications section of the Approved Labeling relevant to usage of such Licensed Product in such disease, disorder or medical condition that is separate and distinct from another disease, disorder, or medical condition. For clarity, each different patient population or line of therapy will be deemed a different Indication.
- **1.137** "**Infringement**" has the meaning set forth in Section 11.3.1 (Notification of Infringement).
- **1.138** "Infringement Notice" has the meaning set forth in Section 11.3.1 (Notification of Infringement).
- **1.139** "**Initiation**" means, with respect to any Clinical Trial, the first patient dosed for the first time in such Clinical Trial.
- **1.140** "**Institutional Review Board**" means an institutional review board ("**IRB**") or independent ethics committee ("**IEC**") that reviews the methods proposed for research and development activities to ensure such methods satisfy ethical requirements.

- **1.141 "Internal Policies**" means, with respect to a Party, such Party's health care compliance, ethical, reputational, antibribery and corruption and other policies applicable to such Party's activities under this Agreement, and any standard operating procedures implementing such policies, including the codes of conduct of any self-regulatory body of which that Party is a member.
- **1.142 "ITEOS**" has the meaning set forth in the preamble.
- **1.143** "ITEOS [\*\*\*] Agreement" means that certain [\*\*\*].
- **1.144** "ITEOS Arising Know-How" has the meaning set forth in Section 11.1.4 (Ownership by ITEOS).
- **1.145** "**ITEOS Arising Patents**" has the meaning set forth in Section 11.1.4 (Ownership by ITEOS).
- **1.146** "**ITEOS Arising Technology**" means ITEOS Arising Know-How and ITEOS Arising Patents.
- **1.147** "**ITEOS Background Agreements**" means, collectively: [\*\*\*].
- **1.148** "**ITEOS Background Know-How**" means any Know-How Controlled by ITEOS or its Affiliates as of the Effective Date or during the Term, other than pursuant to this Agreement.
- **1.149** "**ITEOS Background Patents**" means any Patents Controlled by ITEOS or its Affiliates as of the Effective Date or during the Term, other than pursuant to this Agreement.
- **1.150 "ITEOS Background Technology**" means the ITEOS Background Know-How and the ITEOS Background Patents.
- **1.151** "**ITEOS Indemnitees**" has the meaning set forth in Section 15.1.2 (Indemnification by GSK).
- **1.152 "ITEOS Phase 1 Clinical Study**" means IO-002 Study that is a multicenter, open-label, dose-escalation Phase I/IIa clinical study to evaluate the safety and tolerability, PK, PD, and antitumor activity of EOS884448 in participants with advanced cancers (ClinicalTrials.gov Identifier: NCT04335253).
- **1.153** "**ITEOS Retained Rights**" has the meaning set forth in Section 9.1 (License Grant to GSK).
- **1.154** "**ITEOS Technology**" means (a) all ITEOS Background Technology, (b) all ITEOS Arising Technology Controlled by ITEOS or any Affiliate during the Term, and (c) ITEOS's interest in Joint Arising Technology Controlled by ITEOS during the Term, in each case ((a) through (c)), that are [\*\*\*].
- **1.155** "Joint Arising Technology" has the meaning set forth in Section 11.1.5 (Joint Ownership).

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- **1.156** "Joint Commercialization Budget" has the meaning set forth in Section 6.2 (Joint Commercialization Plans).
- **1.157** "Joint Commercialization Committee" or "JCC" has the meaning set forth in Section 7.3.1 (Establishment of JCC).
- **1.158** "Joint Commercialization Plan" has the meaning set forth in Section 6.2 (Joint Commercialization Plans).
- **1.159** "Joint Development Committee" or "JDC" has the meaning set forth in Section 7.2.1 (Establishment of the JDC).
- **1.160** "Joint Steering Committee" or "JSC" has the meaning set forth in Section 7.1.1 (Establishment of JSC).
- **1.161 "Know-How**" means any information or materials, whether proprietary or not and whether patentable or not, including confidential trade secrets, models, discoveries, inventions, ideas, Data and other types of data, databases, results, assays, instructions, processes, techniques, documentation, equipment, technology, quality control analysis, specifications, transportation and storage requirement, concepts, methods, procedures, designs, compositions, plans, documents, formulas, algorithms, Materials, inventions, computational models, human-relevant disease models, computer software (including source code), predictive model implementations, data analytic tools, biotechnology hardware and associated algorithms and methodologies, methods of use, expert knowledge and information.
- **1.162 "Knowledge of ITEOS"** or **"ITEOS's Knowledge**" means the actual knowledge by ITEOS's senior management [\*\*\*]. For this purpose, "senior management" means ITEOS's officers as defined under Rule 16a-1(f) of the Securities Exchange Act of 1934 (or amendment thereto or replacement or successor law) as of the Execution Date.
- **1.163** "Licensed Antibody" means (a) the EOS-448 Antibody and (b) any other [\*\*\*] in each case ((a) and (b)), that have been generated by or on behalf of ITEOS.
- **1.164** "Licensed Product" means any pharmaceutical product that is comprised of or contains a Licensed Antibody, in all forms, presentations, strengths, doses and formulations, and includes the EOS-448 Sole Active Product and Combination Products.
- **1.165** "Losses" has the meaning set forth in Section 15.1.1 (Indemnification by ITEOS).
- **1.166** "Manufacture" means all activities related to the synthesis, making, production, processing, purifying, formulating, filling, finishing, packaging, serialization, labeling, shipping, and holding of any product, or any component or intermediate thereof, including process qualification and validation, scale-up, qualification, validation, pre-clinical, clinical and commercial capacity reservation, production, and analytic development, product characterization, stability testing, quality assurance, and quality control, but, in each case, excluding activities directed to Development, Medical Affairs, or Commercialization. "Manufacturing" shall have a correlative meaning.



### **1.167** "Manufacturing Cost" means:

- **1.167.1** With respect to GSK as the Manufacturing Party, with respect to a Licensed Product or other compound, antibody, or product Controlled by GSK and supplied to ITEOS pursuant to this Agreement, GSK's reasonable and necessary Standard Costs of Goods Manufactured *plus* Cost Variances and a standard manufacturing markup of [\*\*\*] to cover the costs of global shared services for support activities such as quality, procurement, information technology, human resource, and finance, determined in accordance with applicable Accounting Standards, and the terms and conditions of this Agreement, incurred in Manufacturing or acquisition of such Licensed Product, in each case, to the extent directly attributable and reasonably allocable (subject to discussion and agreement by the Financial Working Group) to such Licensed Product or other compound, antibody, or product Controlled by GSK, which shall include the following costs incurred by a Party or its Affiliates:
  - (a) "Standard Cost of Goods Manufactured" are, as calculated in accordance with applicable Accounting Standards, consistently applied by the Manufacturing Party in accordance with its standard accounting practice for public financial reporting purposes, budgeted unit costs of direct materials, direct labor, Third Party fees, depreciation of Manufacturing equipment (including buildings, fixtures, and fittings and a reasonable allocation of indirect expenses and overhead connected therewith (to the extent allocable to forecasted production of materials for use in or sale of such product recorded as an expense by GSK or its Affiliates)), which allocation is made in a manner consistent with such allocations applied to other products made in the same production center, and consistent with customary practice. Examples of reasonably allocable indirect manufacturing costs include power, rent and rates, quality, and regulatory; and
  - (b) "**Cost Variances**" are actual costs of Manufacturing versus Standard Cost of Goods Manufactured and include direct materials variances (including material usage variances and purchase price variances), direct labor variances, and indirect expenses and overhead variances (to the extent allocable to forecasted production of materials for use in or sale of such product recorded as an expense by GSK or its Affiliates), which allocation is made in a manner consistent with customary practice (including volume variances, variable overhead spending variances and fixed overhead spending variances).
- **1.167.2** To the extent Licensed Products or other compounds, antibodies, or products Controlled by GSK are Manufactured by Third Party contract manufacturing organizations and similar contractors (collectively, "**CMOs**"), the Out-of-Pocket Costs invoiced by and paid to such CMO(s) for the Manufacture of such product, *plus* a Manufacturing mark-up of [\*\*\*].

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**1.167.3** With respect to ITEOS as the Manufacturing Party, (a) for such Licensed Product (or components thereof) Manufactured by a Third Party, the Out-Of-Pocket Costs paid by ITEOS or its Affiliates to a Third Party for Manufacturing of such Licensed Product, or any component thereof; and (b) for such Licensed Product (or components thereof) Manufactured by ITEOS or its Affiliates, the reasonable internal costs and direct Out-of-Pocket Costs recorded as an expense by ITEOS or its Affiliates in connection with the Manufacture, including supply chain management, of such Licensed Product, in each case ((a) and (b)), *plus* a Manufacturing mark-up of [\*\*\*].

Manufacturing Cost shall not include capital costs or costs associated with physical plant improvements. Subject to the foregoing, all Manufacturing Costs shall be calculated on a *pro-rata* basis based on the use of the components of Manufacturing activities devoted to the Licensed Products as opposed to all other products using the same components. In addition, Manufacturing Costs shall exclude costs that result from the gross negligence or willful misconduct of a Party, its Affiliates, Sublicensees or Third Party manufacturers or a failure by a Party, its Affiliates, Sublicensees or Third Party manufacturing process or any other Manufacturing defect arising from such Manufacture of the applicable Licensed Product.

- **1.168** "Manufacturing Tech Transfer Plan" has the meaning set forth in Section 5.2 (Manufacturing Technology Transfer).
- **1.169 "Marketing Approval Application**" or **"MAA**" means a BLA or any corresponding application in the applicable country or jurisdiction outside of the United States, including, with respect to the European Union, an application for Regulatory Approval filed with the EMA pursuant to the centralized approval procedure or with the applicable national Regulatory Authority of a country in the European Union with respect to the mutual recognition procedure, decentralized procedure or any other national approval.
- **1.170** "Marketing Materials" means Promotional Materials, Regulatory Filings relating to Promotional Materials, and training program and related materials contemplated by Section 6.10.4 (Product Specific Training).
- **1.171** "Material Safety or Commercialization Concern" means, with respect to an activity for a Licensed Antibody or Licensed Product, that such activity may [\*\*\*].
- **1.172** "**Materials**" means any chemical or biological substances, including any biological or chemical compounds, drug products, Human Biological Samples, or other materials, regardless of the route of transfer, that are supplied by a Party or its nominee to the other Party or its nominee for use in the conduct of activities under this Agreement, including activities set forth in the Global Development Plan.
- **1.173** "Materials Receiving Party" has the meaning set forth in Section 3.12.1 (Material Transfers).
- **1.174** "Materials Transferring Party" has the meaning set forth in Section 3.12.1 (Material Transfers).

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- **1.175 "Medical Affairs**" means, with respect to a product, any and all activities performed by or on behalf of a Party's or its Affiliates' medical affairs departments interacting with physicians or other healthcare professionals who may utilize or conduct research related to a drug or biological product, including: supporting continuing medical education and other medical programs and communications; Health Economics and Outcomes Research (HECOR, HEMAR); pharmacovigilance, publication and dissemination of publications; fulfillment of medical information responses to external inquiries or complaints; development and execution of disease awareness education including symposia and digital education initiatives; sponsorship and booth exhibition at key congresses; natural history and real world evidence studies; supporting educational fellowships and research grants, scientific research agreements and investigator initiated trials (following Regulatory Approval); medical resourcing, training and allocation; medical and scientific platform and content development; conducting appropriate activities involving opinion leaders (including programs (to the extent related to medical affairs or clinical guidance); field based medical science liaisons, medical affairs clinical trial management, medical doctors in field (separate from medical science liaisons); establishing patient registries and expanded access programs; life cycle management activities and clinical research.
- **1.176 "Medical Affairs Content**" means all written, printed, graphic, electronic, audio or video matter, in each case, intended for use or used by a Party or its Affiliates, Sublicensees or subcontractors in connection with the conduct of Medical Affairs activities related to the Licensed Products in the Profit-Sharing Territory.
- **1.177** "**Medical Affairs Materials**" means the Medical Affairs Content, Regulatory Filings relating to Medical Affairs Content, and training program and related materials contemplated by Section 6.4.4 (Medical Affairs Training).
- **1.178 "More Conservative Approach**" means the approach or position described in the written proposal provided by a Party's Senior Executive to the Designated Executives with respect to the resolution of a Committee Deadlock regarding a Material Safety or Commercialization Concern, which approach or position, in the aggregate, [\*\*\*].
- **1.179** "MTR" has the meaning set forth in Section 3.12.1 (Material Transfers).
- **1.180** "Negotiation Period" has the meaning set forth in Section 3.5.3 (Limitation On Third Party Combinations).

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**1.181** "Net Sales" means, with respect to a Licensed Product during a stated time period, the gross invoiced sales amounts for such Licensed Product sold by or on behalf of GSK, its Affiliates or Sublicensees in arm's length transactions to Third Parties (but not including sales relating to transactions by and between GSK, its Affiliates or Sublicensees unless the Affiliate or Sublicensee is the last entity in the distribution chain of such Licensed Product) less the following deductions from such gross amounts which are actually incurred, allowed, paid, accrued or specifically allocated to the extent that such amounts are deducted from gross invoiced sales amounts as reported by GSK in its financial statements in accordance with IFRS, applied on a consistent basis:

[\*\*\*]

Upon any sale or other disposal of the Licensed Product that should be included within Net Sales for any consideration other than an exclusively monetary consideration on *bona fide* arm's length terms, then for purposes of calculating the Net Sales under this Agreement, the Licensed Product shall be deemed to be sold exclusively for money at the average sales price during the applicable reporting period generally achieved for the Licensed Product in the country in which such sale or other disposal occurred.

Notwithstanding the foregoing, (i) Net Sales shall not include disposals of the Licensed Product for, or use of the Licensed Product in, clinical or pre-clinical trials undertaken as part of Development contemplated under this Agreement, given as free samples, or distributed at no charge to patients unable to purchase the Licensed Product, and (ii) Net Sales shall not include amounts for any Licensed Product distributed for compassionate, named patient or similar use provided at a price no greater than GSK's Manufacturing Costs for such Licensed Product for such purpose.

The Licensed Products that will be Developed under this Agreement are anticipated to be sold either as: (1) a Licensed Product with a sole active ingredient that may be co-administered with other products (for example, the EOS-448 Sole Active Product, which is not a Combination Product under this Agreement), (2) a Combination Product that is in a single formulation finished form (*i.e.*, a co-formulated Licensed Product) (a "**Co-Formulated Product**"), or (3) other Combination Products.

In the event of (X) a Combination Product sale in a country where not all of the active ingredient components in that Combination Product are also sold separately in that country (as sole active ingredient products), or (Y) a Combination Product sale that is a Co-Formulated Product, then the Net Sales of such Combination Product for the purposes of determining royalty payments and ROW Net Sales Milestones and U.S. Net Sales Milestones, as well as with respect to the calculation of Net Sales of Combination Products for the purpose of determining Pre-Tax Profit or Loss for the Profit-Sharing Territory (if applicable), shall be determined by [\*\*\*].

In the event of a sale of a Combination Product that is not a Co-Formulated Product in a country where all of the active ingredient components in that Combination Product are also sold separately in that country (as sole active ingredient products), then the Net Sales of such Combination Product, for the purposes of determining royalty payments and ROW

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Net Sales Milestones and U.S. Net Sales Milestones, as well as also with respect to the calculation of Net Sales of Combination Products for the purpose of determining Pre-Tax Profit or Loss for the Profit-Sharing Territory (if applicable), shall be determined by multiplying the Net Sales of such Combination Product by the fraction, A/(A+B) where A is the weighted (by sales volume) average sale price in a particular country of the Licensed Product containing the relevant Licensed Antibody(ies) as the sole active ingredient(s) when sold separately in finished form in such country and B is the weighted average sale price in that country of the product containing Other Components as the sole active ingredient when sold separately in finished form.

- **1.182** "Net Sales Territory" means the Territory excluding the Profit-Sharing Territory; *provided*, that from and after the Cost Share End Date, "Net Sales Territory" means the entire Territory (including the U.S.).
- **1.183** "Non-Breaching Party" has the meaning set forth in Section 12.3.1 (Termination for Material Breach).
- **1.184 "Notice of Dispute**" has the meaning set forth in Section 16.1.1 (Dispute Resolution).
- **1.185** "Notice Period" has the meaning set forth in Section 3.5.3 (Limitation On Third Party Combinations).
- **1.186** "[\*\*\*] **Agreement**" means that certain [\*\*\*].
- **1.187** "October 2021 Campaign" has the meaning set forth in Section 5.1.2 (Clinical Supply).
- **1.188** "OIG" has the meaning set forth in Section 6.9.3 (Applicable Laws and Guidelines).
- **1.189 "OPDP**" means the FDA's Office of Prescription Drug Promotion (formerly Division of Drug Marketing, Advertising and Communications) or its successor entity.
- **1.190** "**Opt-Out Notice**" has the meaning set forth in Section 6.7.1 (ITEOS Opt-Out Right).
- **1.191** "Other Component(s)" has the meaning set forth in Section 1.41 (Combination Product).
- **1.192** "**Out-Of-Pocket Costs**" means the actual amounts paid by a Party or its Affiliate to a Third Party for specific external activities conducted for the Licensed Antibodies or Licensed Products.
- **1.193 "Party**" or **"Parties**" has the meaning set forth in the preamble.
- **1.194 "Patent Challenge"** has the meaning set forth in Section **Error! Reference source not found.** (Termination for Patent Challenge).
- **1.195** "**Patent Costs**" means all out-of-pocket expenses (including reasonable attorneys' fees) incurred in the preparation, prosecution, filing and maintenance of Patents.
- **1.196** "Patent Liaisons" has the meaning set forth in Section 7.9 (Patent Liaisons).

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- **1.197 "Patents"** means all patents and pending patent applications (including inventor's certificates and utility models) and any patents issuing therefrom, in any country in the Territory, including any and all provisionals, non-provisionals, substitutions, continuations, continuations-in-part, divisional and other continuing applications, supplementary protection certificates, renewals, and any and all reissues, extensions, registrations, reexaminations, confirmations, registrations and patents of addition on any of the foregoing.
- **1.198** "**Payee**" has the meaning set forth in Section 8.10.2 (Tax Matters).
- **1.199** "**Payor**" has the meaning set forth in Section 8.10.2 (Tax Matters).
- **1.200** "**Permitted Overage**" has the meaning set forth in Section 8.2.2(a) (Overruns).
- **1.201** "**Person**" means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government, or any agency or political subdivisions thereof.
- **1.202** "**Personally Identifiable Information (PII)**" means information that can be used to identify an individual, either alone or when combined with other personal or identifying information that is linked or linkable to a specific individual, which may include (alone or in combination): (a) a first and last name; (b) a home or other physical address, including street name and name of city or town; (c) an email address or other online contact information, such as an instant messaging user identifier or a screen name that reveals an individual's email address; (d) a telephone number; (e) a social security number; (f) a bank, loan, or credit card account number; (g) a persistent identifier, such as a customer number held in a "cookie" or processor serial number, that is combined with other available data that identifies an individual consumer; or (h) any information that is combined with any of (a) through (g) above.
- **1.203 "Phase 2 Adaptive Study"** means a Phase 2 Clinical Study that is not considered a Registration Study until it meets the criteria set within the protocol to expand to become a Registration Study at the pre-defined interim analysis (such meeting of such criteria, the "**Expansion**").
- **1.204 "Phase 2 Clinical Study**" means a Clinical Trial of an investigational product in subjects with the primary objective of characterizing its activity in a specific disease state as well as generating more detailed safety, tolerability, pharmacokinetics, pharmacodynamics, and dose finding information as described in 21 C.F.R. 312.21(b), or a comparable Clinical Trial prescribed by the relevant Regulatory Authority in a country other than the Unites States.
- **1.205** "**PhRMA**" has the meaning set forth in Section 6.9.3 (Applicable Laws and Guidelines).
- **1.206** "**PhRMA Code**" has the meaning set forth in Section 6.9.3 (Applicable Laws and Guidelines).
- **1.207** "Potential In-License" has the meaning set forth in Section 9.11.2 (Potential In-License).

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- **1.208** "**Pre-Tax Profit or Loss**" has the meaning set forth in the Pre-Tax Profit or Loss Schedule.
- **1.209** "**Pre-Tax Profit or Loss Schedule**" means the schedule set forth in <u>Schedule 8.3.1</u> attached hereto.
- **1.210 "Product Claims**" means a notice, claim, demand, suit or cause of action alleging or relating to, in whole or in part, bodily injury or personal injury arising from any act or omission connected with the Manufacture, Development, Commercialization or use of a Licensed Product in the Profit-Sharing Territory, including relating to alleged defects in the applicable Licensed Product resulting from an alleged intrinsic or latent problem or defect in the efficacy or safety of such Licensed Product.
- **1.211 "Product Marks**" means the trademarks for use in connection with the Commercialization of any Licensed Product, including trademarks, generic names, international nonproprietary names, trade dress, style of packaging and Internet domain names used in connection with the Commercialization of such Licensed Product.
- **1.212** "**Product Training Materials**" has the meaning set forth in Section 6.10.4 (Product Specific Training).
- **1.213 "Profit-Sharing Term**" means the Term, unless and until the Cost Share End Date occurs.
- **1.214 "Profit-Sharing Territory**" means the United States, unless and until the Cost Share End Date occurs.
- **1.215 "Promotional Materials**" means all written, printed, graphic, electronic, audio or video matter, including journal advertisements, sales visual aids, reprints, direct mail, direct-to-consumer advertising, and digital technologies including Internet and social media postings, Internet sites, email and broadcast advertisements, in each case, intended for use or used by either Party or its Affiliates, Sublicensees or subcontractors in connection with any advertising, marketing or promotion of the Licensed Products or a disease state related to the Licensed Products.
- **1.216 "Proof of Concept Trial**" means a Clinical Trial that is designed to establish, for (a) a Licensed Product as part of a Co-Administration Therapy, or (b) a Licensed Product in a particular Indication, in each case ((a) and (b)), safety and initial evidence of efficacy that would be supportive of moving forward with additional Clinical Trials for such Licensed Product as part of such a Co-Administration Therapy, or for such Licensed Product in such Indication, as applicable.
- **1.217** "**Proposed Additional Development**" has the meaning set forth in Section 3.4.1 (Additional Development Proposals).
- **1.218** "**Publication Strategy**" has the meaning set forth in Section 10.8.1 (Publication Strategy).
- **1.219 "R&D Compliance Officer**" has the meaning set forth in Section 3.13 (R&D Ethics & Compliance).

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- **1.220** "**Receiving Party**" has the meaning set forth in Section 1.56 (Confidential Information).
- **1.221 "Registration Study**" means, with respect to a given Licensed Product, any pivotal Clinical Trial of such Licensed Product designed to establish safety and efficacy of such Licensed Product in patients with the disease or condition being studied for purposes of filing a BLA with the FDA or, with respect to a jurisdiction other than the United States, a similar clinical trial for the purpose of enabling the filing of a Marketing Approval Application equivalent to a BLA with the applicable Regulatory Authority(ies) in such jurisdiction.
- **1.222** "**Regulatory Approval**" means, with respect to a Licensed Product in a particular regulatory jurisdiction in the Territory, all approvals, licenses, registrations or authorizations of any Regulatory Authority, necessary for the Manufacturing, use, storage, import, export, transport, or Commercialization of such Licensed Product in such jurisdiction, including approval of the Marketing Approval Application for such Licensed Product in such jurisdiction.
- **1.223** "**Regulatory Authority**" means the FDA, the EMA or any regulatory body with similar regulatory authority in any other jurisdiction anywhere in the world.
- **1.224 "Regulatory Exclusivity"** means, with respect to a particular Licensed Product in a country in the Territory, exclusive marketing rights conferred by a Regulatory Authority in such country with respect to such Licensed Product, excluding any rights in such country conferred by or based on any Patents.
- **1.225** "**Regulatory Filing**" means any filing, registration, or regulatory application or submission filed with a Regulatory Authority, including authorizations, approvals, Marketing Approval Applications, Regulatory Approvals, or clearances arising from the foregoing, and all notifications, communications, correspondence made to, received from, or otherwise conducted with a Regulatory Authority, as well as minutes of any material meetings, telephone conferences or discussions with such Regulatory Authority, in each case related to Exploiting a pharmaceutical or biologic product in a particular country or jurisdiction.
- **1.226** "**Regulatory Responsible Party**" has the meaning set forth in Section 4.1.3 (Regulatory Responsibilities).
- **1.227** "**Reimbursement Approval**" means an approval, agreement, determination, or other decision by the applicable Governmental Authority that establishes prices charged to end-users for biopharmaceutical products that a pharmaceutical or biologic product will be reimbursed by the Governmental Authorities or Regulatory Authorities in the Territory or any other approvals related to pricing, reimbursement or access to a pharmaceutical or biologic product (including all activities related to tenders and contracts).
- **1.228** "ROW Net Sales Milestones" has the meaning set forth in Section 8.5.1 (ROW Net Sales Milestones).

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- **1.229 "ROW Net Sales Milestone Payments**" has the meaning set forth in Section 8.5.1 (ROW Net Sales Milestones).
- **1.230 "Royalty Term**" has the meaning set forth in Section 8.7.1 (Net Sales Royalties).
- **1.231 "Sales Call"** means a personal visit (whether by face-to-face contact or virtual meetings (such as through videoconference)) by a Sales Representative to (a) one or more healthcare professional(s) having prescribing authority, or (b) key opinion leaders or "thought leaders" that are respected individuals that through their professional status have significant impact or influence on prescribing decisions, in each case ((a) and (b)), with the purpose of promoting the Licensed Product in order to cause such healthcare professional, opinion leader, or thought leader to prescribe such Licensed Product.
- **1.232 "Sales Representatives**" means pharmaceutical sales representatives employed or contracted for by a Party or its Affiliates to conduct Detailing and other marketing efforts with respect to the Licensed Products in accordance with the terms of this Agreement.
- **1.233** "Second No Opt-Out Period" means, with respect to a Licensed Product, the time period commencing on the date that is [\*\*\*] after the first filing date of a BLA in the U.S. for such Licensed Product and ending [\*\*\*] following the First Commercial Sale of such Licensed Product in the Territory.
- **1.234** "Selected Product" has the meaning set forth in Section 9.12.1 (Mutual Exclusivity Covenant).
- **1.235 "Senior Executive**" has the meaning set forth in Section 16.1.1 (Dispute Resolution).
- **1.236** "Shared Commercialization Activities" means all Commercialization activities that the Parties intend to conduct with respect to the Licensed Product in the Profit-Sharing Territory during the Profit-Sharing Term, including activities related to [\*\*\*]. Shared Commercialization Activities exclude [\*\*\*] (collectively, (a) through (f), the "Excluded Commercialization Activities").
- **1.237** "Shared Global Development Activities" has the meaning set forth in Section 1.108 (Global Development Plan).
- **1.238** "Subcommittee" has the meaning set forth in Section 7.5 (Other Subcommittees).
- **1.239** "Subcommittee Deadlock" has the meaning set forth in Section 7.7.1 (Committee Decision Making).
- **1.240** "Subject Patents" has the meaning set forth in Section 11.2.1 (Subject Patents).
- **1.241 "Sublicensee**" has the meaning set forth in Section 9.3 (Sublicenses).
- **1.242 "Target**" means T cell immunoreceptor with Ig and immunoreceptor tyrosine-based inhibition motif domains (also known or referred to as TIGIT).

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- **1.243 "Target BLA Filing Date"** has the meaning set forth in Section 6.2 (Joint Commercialization Plans).
- **1.244 "Tax"** or **"Taxes"** means any present or future taxes, levies, imposts, duties, charges, assessments or fees of any nature (including interest, penalties and additions thereto) imposed by a taxing authority.
- **1.245 "Term**" has the meaning set forth in Section 12.1 (Term).
- 1.246 [\*\*\*]
- **1.247 "Territory**" means all countries and territories in the world.
- **1.248** "Third Party" means a Person other than (a) ITEOS and its Affiliates, and (b) GSK and its Affiliates.
- **1.249 "Third Party Combination Product**" means a Combination Product where one or more Other Components is controlled by a Third Party and licensed to GSK or its Affiliates.
- **1.250 "Third Party Component Contracts"** means those contracts, in existence as of the Effective Date, by and between GSK and a Third Party and listed on <u>Schedule 1.250</u>.
- **1.251** "Third Party Infringement Claim" has the meaning set forth in Section 11.4.1 (Notice; Control).
- 1.252 "Third Party IP" has the meaning set forth in Section 9.11 (New Third Party In-Licenses).
- **1.253 "United States**" or **"U.S.**" means the United States and its territories and possessions.
- 1.254 "U.S. Net Sales Milestones" has the meaning set forth in Section 8.5.2 (U.S. Net Sales Milestones Following Opt-Out).
- **1.255** "U.S. Net Sales Milestone Payments" has the meaning set forth in Section 8.5.2 (U.S. Net Sales Milestones Following Opt-Out).
- **1.256 "Valid Patent Claim"** means a claim of (a) any issued, unexpired Patent that shall not have lapsed, been revoked, cancelled or abandoned, been donated to the public, finally disclaimed, nor held finally invalid or unenforceable by a court of competent jurisdiction in an unappealed or unappealable decision and which has not been held unenforceable through disclaimer or otherwise, or (b) any patent application within such Patents (including patent applications covering or claiming joint inventions) that has been pending for less than [\*\*\*] since the first action on the merits in the relevant jurisdiction.
- **1.257 "VAT"** means any value added, sales, use, purchase, turnover or consumption tax as may be applicable in any relevant jurisdiction, including value added tax chargeable under legislation implementing EU Council Directive 2006/112/EC.

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#### ARTICLE 2 EFFECTIVENESS

- **2.1 Effectiveness of the Agreement**. This Agreement shall become effective as of the HSR Clearance Date (the "**Effective Date**").
- HSR Filing. Both Parties (or their Affiliates) shall file the appropriate notices (the "HSR Filings") under the Hart 2.2 Scott Rodino Antitrust Improvements Act ("HSR Act") within ten (10) Business Days after the Execution Date. The Parties shall promptly make required filings to obtain clearance under the HSR Act for the consummation of this Agreement and the transactions contemplated hereby and shall keep each other apprised of the status of any communications with, and any inquiries or requests for additional information from, the United States' Federal Trade Commission ("FTC") or the Antitrust Division of the United States Department of Justice ("DOJ") and shall comply promptly with any reasonable FTC or DOJ inquiry or request of this nature; provided that [\*\*\*]. Each Party shall be responsible for paying the filing fees it incurs in connection with the HSR Filings. As used herein, the "HSR **Clearance Date**" means the earlier of (a) the date on which the FTC or DOJ shall notify the Parties of early termination of the waiting period under the HSR Act or (b) the date on which the applicable waiting period under the HSR Act expires; provided that, if the FTC or DOJ commences any investigation by means of a second request or otherwise, HSR Clearance Date means the date on which any investigation opened by the FTC or DOJ has been terminated, without action to prevent the Parties from implementing the transactions contemplated by this Agreement with respect to the United States. Notwithstanding any other provisions of this Agreement to the contrary, either Party may terminate its obligation under this Section 2.2 (HSR Filing), and this Agreement shall be void and of no further effect upon notice to the other Party, if the HSR Clearance Date has not occurred on or before the date that is [\*\*\*] after the date on which both Parties have made their respective HSR Filings and the initial waiting period under the HSR Act has commenced.

### ARTICLE 3 DEVELOPMENT PROGRAM

#### 3.1 General.

- **3.1.1 Global Development**. The Party to which a particular Development activity is allocated under the Global Development Plan will lead the performance thereof and all Clinical Trials and Development activities for the Licensed Antibody and Licensed Product in the Territory will be conducted by the Parties as set forth in the Global Development Plan.
- **3.1.2 Development for the Net Sales Territory**. As between the Parties, GSK, either itself or as it may determine, by and through its Affiliates, Sublicensees or subcontractors, will be responsible for performing all GSK Sole Development Activities for the Licensed Antibody and Licensed Products set forth in the Global Development Plan, at GSK's sole cost and expense. Prior to commencing any GSK Sole Development Activities, GSK will include such GSK Sole Development



Activities in the Global Development Plan for each applicable Licensed Product (or an update thereto) and provide such Global Development Plan to the JDC to review, discuss and recommend modifications. ITEOS's representatives on the JDC may comment thereon, and GSK will consider ITEOS's comments in good faith, but the JDC will not have an approval right with respect to any GSK Sole Development Activities included in the Global Development Plan. Notwithstanding the foregoing or any other provision to the contrary set forth in this Agreement, if ITEOS reasonably believes that any GSK Sole Development Activity under the Global Development Plan or update thereto may reasonably give rise to a [\*\*\*]. If the JDC or the Parties' respective [\*\*\*] are unable to resolve such matter, then the matter will be resolved in accordance with Section 7.7.2(c) (Resolution of Material Concerns).

**3.1.3 ITEOS Phase 1 Clinical Study**. ITEOS shall conduct the ITEOS Phase 1 Clinical Study at its sole cost and expense, unless the Parties agree otherwise.

## **3.2** Global Development.

3.2.1 Global Development Plan. Attached as Schedule 3.2 is the initial Global Development Plan for Licensed Antibodies and Licensed Products (including the corresponding Global Development Budget). Such initial Global Development Plan comprises all Development activities contemplated by the Parties with respect to the Licensed Antibodies and Licensed Products as of the Effective Date and the Parties will discuss, through the JDC, and add additional details (including, with respect to Clinical Trials, study design and protocol, proposed enrollment criteria, the number of patients to be included, the endpoints to be measured, and the statistical design and powering, as needed) to the Global Development Plan (and corresponding Global Development Budget) following the Effective Date in accordance with this Agreement, and each update to the Global Development Plan to add any additional Clinical Trials will include such details. The Clinical Trials set forth in the initial Global Development Plan attached hereto (other than any GSK Sole Development Activities therein) are the Clinical Trials that the Parties are committing to conduct as of the Effective Date (the "Committed Studies"). The Parties also plan to add additional non-clinical Development activities to the Global Development Plan following the Effective Date. The Global Development Plan and Global Development Budget will be updated by the Parties and submitted to the JDC for review and comment not less frequently than annually during the Term, in November of each Calendar Year. In addition, either Party may propose updates to the Global Development Plan and corresponding Global Development Budget from time to time during the Term. Each updated Global Development Budget will be provided to the Financial Working Group prior to being reviewed by the JDC or JSC. The JDC will review, discuss and propose modifications to each update to the Global Development Plan and Global Development Budget and, in turn, submit such updates (as such update may be modified on the recommendation of the JDC) to the Global Development Plan and Global Development Budget to the JSC to review, discuss and determine whether to approve. Each such update to the Global Development Plan and corresponding Global Development Budget will

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become effective and will supersede the previous Global Development Plan and corresponding Global Development Budget upon approval thereof by the JSC. Any such updates or amendments to the Global Development Plan and Global Development Budget may be memorialized in the JDC and JSC meeting minutes until the next annual update to the Global Development Plan and Global Development Budget.

- **3.2.2 Performance under Global Development Plan**. Without limiting the JDC's rights to prepare, review and discuss, or the JSC's rights to review, discuss and determine whether to approve each Global Development Plan and update thereto (other than the GSK Sole Development Activities), the Party to whom a particular Development activity is allocated under the Global Development Plan will have the right, without seeking JDC review or JSC approval, to make operational decisions with respect to the implementation and performance of such Development activity to the extent consistent with the then-current Global Development Plan and Global Development Budget.
- **Shared Development Costs**. Except as set forth in Section 3.4 (Additional Development), and further subject 3.2.3 to Section 6.7 (ITEOS Opt-Out), the Parties will share Development Costs incurred in the performance of Shared Global Development Activities undertaken in accordance with the Global Development Plan and Global Development Budget, with GSK bearing sixty percent (60%) of such Development Costs and ITEOS bearing forty percent (40%) of such Development Costs. Reconciliation and sharing of Development Costs shall be managed in accordance with Section 8.2 (Sharing of Development Costs). The Parties agree to initially spend an aggregate amount of [\*\*\*] (the "Committed Development Spend") under the Global Development Budget to undertake the Committed Studies (including as these may be amended or replaced with comparable Clinical Trials of similar scope through an update to the Global Development Plan in accordance with Section 3.2.1 (Global Development Plan)) provided for in the Global Development Plan and any other Clinical Trials that the Parties agree to include in the Global Development Plan that can be conducted within the Committed Development Spend. In addition, if agreed pursuant to an update to the Global Development Plan and Global Development Budget in accordance with Section 3.2.1 (Global Development Plan), then the Parties may also agree to add additional Development activities to the Global Development Plan or spend more than the Committed Development Spend.
- **3.3 Development Diligence**. Each Party will use Commercially Reasonable Efforts to perform the obligations assigned to it under the Global Development Plan. GSK (directly, or through its Affiliates, its or their Sublicensees and subcontractors) will use Commercially Reasonable Efforts to Develop the Licensed Products in the Field in the Territory, including to obtain and maintain Regulatory Approval of Licensed Products in the Field in the United Kingdom, Germany, Italy, France, Spain, China, Japan, and, in the event that ITEOS has delivered an Opt-Out Notice, the United States.

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## 3.4 Additional Development.

- Additional Development Proposals. Subject to Section 3.5 (Limits on Development; No Other 3.4.1 Development), if either Party proposes to Develop a Licensed Product that the Parties previously agreed to Develop under the Global Development Plan (including a Co-Formulated Product), either as (i) a Licensed Product for a new Indication, or (ii) a Licensed Product as part of a Co-Administration Study (*i.e.*, an existing Co-Administration Therapy in a new Indication or a new Co-Administration Therapy in a new or existing Indication), in each case of (i) or (ii), other than in Indications or in Co-Administration Studies set forth in the then-current Global Development Plan (each, "Proposed Additional Development"), then the proposing Party will present to the JDC to review and discuss, and submit, within [\*\*\*], to the JSC to review, discuss and determine whether to approve a proposal to add such Proposed Additional Development to the Global Development Plan, including the countries in which such activities would be conducted (which will include at least the U.S. or the European Union) and the allocation of performance of such activities between the Parties (an "Additional Development Proposal"). Each Additional Development Proposal will describe in reasonable detail the applicable non-clinical studies, pre-clinical studies and Clinical Trials, in each case, that the proposing Party desires to conduct as part of such Proposed Additional Development, including a synopsis of the Clinical Trial or other activities, the proposed enrollment criteria, the number of patients to be included, the endpoints to be measured, and the statistical design and powering (the "Additional **Development** Activities"), as well as a proposed timeline and budget (which budget will include the expected Development FTE Costs, Out-Of-Pocket Costs and Manufacturing Costs to be incurred in the conduct of such Additional Development Activities) and an analysis of the business opportunity and revenue potential for such Additional Development Activities.
- **3.4.2 JSC Decision Regarding Proposed Additional Development**. The JSC will review, discuss and determine whether to approve an Additional Development Proposal within [\*\*\*] after receipt thereof from the JDC.
  - (a) **JSC Approval**. If the JSC approves an Additional Development Proposal (or a modified version thereof), then upon such an approval the JDC will update the Global Development Plan (and corresponding Global Development Budget) to include such Additional Development Activities set forth in such Additional Development Proposal (as the same may be amended by the JDC or JSC upon such approval).

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(b) No JSC Approval. If the JSC fails to approve an Additional Development Proposal (or a modified version thereof) regarding a Licensed Product in a new Indication or any Co-Administration Studies for any Licensed Product or an appropriate update to the Global Development Budget to account for the performance thereof, then such Proposed Additional Development will not be included in the Global Development Plan or corresponding Global Development Budget and the provisions of Section 3.4.3 (Independent Performance of Additional Development) will apply.

## 3.4.3 Independent Performance of Additional Development.

- Independent Development Activities. If the JSC fails to approve for inclusion in the Global (a) Development Plan the Proposed Additional Development proposed by either Party (or any modified version thereof), then the proposing Party will have the right, subject to Section 3.5.2 (Material Adverse Development), upon written notice to the other Party, to conduct such Additional Development Activities set forth in the Additional Development Proposal at its own cost and expense. The proposing Party will conduct such Additional Development Activities in accordance with the applicable Additional Development Proposal (including the budget therein) previously provided to the JDC and JSC that the JSC declined to approve. No Development activities included in an Additional Development Proposal may be included in or contemplated by the Global Development Plan if not approved by the JSC. Each applicable Party undertaking any such Additional Development Activities will keep the JDC reasonably informed of any progress and results of activities for such Additional Development Activities undertaken by it or on its behalf, including any and all Data and intellectual property arising from such activities, through its employees on the JDC and the Patent Liaisons, as applicable, at each regularly scheduled meeting thereof.
- (b) **Proof of Concept Data**. Without limiting any provision of Section 3.4.3(a) (Independent Development Activities), the Party conducting any Additional Development Activities will, following completion of a Proof of Concept Trial included in such Additional Development Activities, share the Data from such Proof of Concept Trial with the JDC. Following receipt of such Data, the JDC may determine to amend the Global Development Plan to include the remainder of the applicable Additional Development Activities and, if the JDC determines to approve such an amendment to the Global Development Plan, then the other Party will reimburse the proposing Party for (i) if the proposing Party is ITEOS, sixty percent (60%), and (ii) if the proposing Party is GSK, forty percent (40%), in each case ((i) and (ii)), of the Out-of-Pocket Costs, Development FTE Costs and Manufacturing Costs incurred by the proposing Party in the performance of such Additional Development Activities solely through completion of the Proof of Concept Trial for the U.S. and the European Union in accordance with the applicable Additional Development Proposal and the budget presented to the JDC in

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the Additional Development Proposal *plus* an amount equal to one-hundred percent (100%) of the applicable amount set forth in the foregoing clause (i) or (ii), as applicable, in consideration for the proposing Party taking the development risk for the new Indication or new Co-Administration Studies (for example, if GSK spent \$100,000 on such Additional Development Activities, and ITEOS was obligated to reimburse GSK for such Additional Development Activities pursuant to this Section 3.4.3(b) (Proof of Concept Data), then ITEOS would owe GSK \$40,000 in reimbursement *plus* \$40,000 in consideration of the development Activities to the Global Development Plan, then the proposing Party may continue to conduct such Additional Development Activities in accordance with the provisions of this Section 3.4 (Additional Development).

(c) Receipt of Regulatory Approval. Subject to Section 6.7.3 (Effects of Opt-Out), upon receipt of Regulatory Approval in the U.S. (if any) for the Licensed Product in the new Indication or as part of a new Co-Administration Therapy, in each case, that was the subject of Additional Development Activities, the other Party will reimburse the proposing Party for (i) if the proposing Party is ITEOS, sixty percent (60%), and (ii) if the proposing Party is GSK, forty percent (40%), in each case ((i) and (ii)), of the Out-of-Pocket Costs, Development FTE Costs and Manufacturing Costs incurred by the proposing Party in the performance of such Additional Development Activities for the U.S. and the European Union in accordance with the applicable Additional Development Proposal and the budget presented to the JDC in the Additional Development Proposal as set forth in Section 3.4.1 (Additional Development Proposals) (provided that the costs incurred by the proposing Party that are subject to reimbursement under this Section 3.4.3(c) (Receipt of Regulatory Approval) shall be capped at [\*\*\*] of such budget) plus an amount equal to [\*\*\*] of the applicable amount set forth in the foregoing clause (i) or (ii), as applicable, in consideration for the proposing Party taking the development risk for the new Indication or new Co-Administration Studies (for example, if GSK spent \$100,000 on Additional Development Activities, and ITEOS was obligated to reimburse GSK for such Additional Development Activities pursuant to this 3.4.3(c) (Receipt of Regulatory Approval), then ITEOS would owe GSK \$40,000 in reimbursement plus \$40,000 in consideration of the development risk, for a total of \$80,000). Following the date of Regulatory Approval for any new Indication or any Licensed Product as part of a new Co-Administration Therapy, the JDC will update the Global Development Plan and Global Development Budget to include any further or remaining Development of such approved new Indication, or Licensed Product as part of a new Co-Administration Therapy (as applicable) for the U.S. or European Union, and the JSC will approve such updates.

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- (d) Supporting Documentation. Upon (i) the JDC's determination to add Additional Development Activities to the Global Development Plan pursuant to Section 3.4.3(b) (Proof of Concept Data) or (ii) receipt of any Regulatory Approval in the U.S. for the Licensed Product in the new Indication or as part of a new Co-Administration Therapy, in each case, that was the subject of such Additional Development Activities, in each case, ((i) and (ii)), the proposing Party shall promptly submit all information and documentation supporting such Out-of-Pocket Costs, Development FTE Costs and Manufacturing Costs to the Financial Working Group in order for the sharing of such Out-of-Pocket Costs, Development FTE Costs and Manufacturing Costs to be managed in accordance with Section 8.2.3 (Reimbursement for Additional Development) after the Financial Working Group receives such information and documentation.
- (e) **No Regulatory Approval**. If such Regulatory Approval is not obtained, then the other Party will not be obligated to reimburse the proposing Party for the Out-of-Pocket Costs, Development FTE Costs or Manufacturing Costs incurred by the proposing Party in the performance of such Additional Development Activities.

## 3.5 Limits on Development; No Other Development.

- **3.5.1** No Fixed-Dose Co-Formulation Products or Other Formulations. Neither Party may conduct Development activities (including as Additional Development Activities hereunder) with respect to (a) any Co-Formulated Products that are not already agreed to be Developed by the Parties under the Global Development Plan or (b) a Licensed Product in a formulation that is not already agreed to be Developed by the Parties under the Global Development Plan. If either Party proposes to Develop any other Co-Formulated Products or a Licensed Product in any other formulation, then, in each case, such Party will propose an applicable update to the Global Development Plan (and corresponding Global Development Budget) to the JDC for the JDC to review and discuss, and submit to the JSC to review, discuss, and determine whether to approve pursuant to Section 3.2.1 (Global Development Plan). If the JSC approves inclusion of such Co-Formulated Product or such other formulation, as applicable, in the Global Development Plan, then the Parties will Develop such Co-Formulated Product or Licensed Products in such formulation, as applicable, in accordance with the Global Development Plan.
- **3.5.2 Material Adverse Development**. Neither Party may conduct Additional Development Activities, that, if conducted, either Party reasonably believes may give rise to a Material Safety or Commercialization Concern. Notwithstanding the foregoing or any other provision to the contrary set forth in this Agreement, if either Party reasonably believes that any Development activity set forth in an Additional Development Proposal or any Additional Development Activities undertaken by the proposing Party subject to Section 3.4.3(a) (Independent Development Activities) may present a Material Safety or Commercialization Concern, then (a) such Party may raise such concern to the JDC in order for the [\*\*\*], and (b) [\*\*\*].

ITEOS's [\*\*\*], as applicable, will promptly meet to discuss such matters. If the JDC or the Parties' respective [\*\*\*] are unable to resolve such matters, then the issue will be resolved in accordance with Section 7.7.2(c) (Resolution of Material Concerns).

## **3.5.3** Third Party Combinations.

(a) Limitation on Third Party Combinations. Except as permitted under this Section 3.5.3 (Limitation On Third Party Combinations), neither Party may conduct Additional Development Activities with respect to a Licensed Product in a Co-Administration Study with a compound, antibody, or product that is owned by a Third Party that modulates the same target as a compound, antibody, or product Controlled by the other Party as of the date such Party wishes to initiate such Additional Development Activities. If either Party proposes to conduct Additional Development Activities with respect to a Licensed Product in a Co-Administration Study with a compound, antibody, or product that modulates the same target as a compound, antibody, or product Controlled by the other Party as of the date such Party wishes to initiate such Additional Development Activities, then such proposing Party will notify the other Party and the JDC in writing of such desire. The JDC shall meet promptly thereafter to discuss the Proposed Additional Development, including all the details to be provided in the Additional Development Proposal as set forth in Section 3.4.1 (Additional Development Proposals). The other Party shall have [\*\*\*] following such written notice to notify the proposing Party in writing whether it is interested in providing the compound, antibody or product Controlled by it to the proposing Party for such Proposed Additional Development (the "Notice Period"), and the Parties will negotiate in good faith regarding the terms and conditions under which the proposing Party might obtain such rights to Develop such compound, antibody, or product in a Co-Administration Study with a Licensed Product, and the supply of such compound, antibody, or product by the other Party, for a period of [\*\*\*] commencing upon the other Party's delivery of written notice to the proposing Party indicating their interest in negotiating such terms (the "Negotiation Period"). If (i) the other Party does not deliver notice to the proposing Party during the Notice Period indicating its interest in negotiating with the proposing Party, (ii) the Parties are unable to reach agreement on terms granting the proposing Party the right to do such Proposed Additional Development and providing for the supply of such compounds, antibodies or products during the Negotiation Period, or (iii) the Parties otherwise agree that the proposing Party should seek rights to the applicable compound, antibody, or product from a Third Party, then in each case ((i) through (iii)), the proposing Party will be permitted to enter into an agreement with a Third Party regarding obtaining rights to Develop the applicable compound, antibody, or product in a Co-Administration Study with a Licensed Product and obtaining supplies of such compound, antibody, or product as long as doing so will not put either Party in breach of any obligations to any Third Parties (including exclusivity obligations



related to the compound, antibody or product Controlled by the other Party) under any agreement with any such Third Parties that are applicable to the other Party's Additional Development Activities (which the proposing Party shall have been made aware of by the other Party together with disclosure of a copy of the relevant agreement(s) with the Third Parties, redacted as reasonably necessary to comply with obligations to such Third Party, *provided* that such redacted copy must include (in unredacted form) those provisions that are relevant to determining what provisions are applicable to the other Party's Additional Development Activities). Notwithstanding any provision to the contrary set forth in this Agreement, the Development of the applicable Third Party compound, antibody, or product in a Co-Administration Study with a Licensed Product will be considered Additional Development Activities under this Agreement and will be treated as such in accordance with Section 3.4 (Additional Development).

- (b) **Third Party Combination Exception**. [\*\*\*].
- **3.5.4 No Other Development**. Except for Additional Development Activities conducted pursuant to Section 3.4 (Additional Development), neither Party will perform Development activities for any Licensed Antibodies or Licensed Products that are not set forth in the Global Development Plan, other than immaterial activities undertaken by or on behalf of a Party directly in support of the activities contemplated by the Global Development Plan or in respect of Additional Development Activities.
- **Development Reporting**. [\*\*\*], with respect to any Development activities conducted by or on behalf of either Party 3.6 with respect to the Licensed Antibodies or Licensed Products under this Agreement, within [\*\*\*] following the end of [\*\*\*], each Party shall prepare and provide to the other Party and the JDC (or the JSC, if the JDC is no longer meeting) a detailed written report that summarizes: (a) the Development activities (including CMC Development and other Manufacturing-related Development activities) performed and the status of activities and progress with respect to the activities set forth in the Global Development Plan (including enrollment data), and shall identify any issues or circumstances of which it is aware that may prevent or adversely affect in a material manner its future performance of activities assigned to it under the then-current Global Development Plan, and (b) all material Data generated since the last [\*\*\*] report (each, a "Development Report"). Solely in the event that, and for so long as, the effects of forced optout set forth in Section 6.7.4 (Effects of Forced Opt-Out) apply, the Development Reports provided by GSK to the JSC pursuant to this Section 3.6 (Development Reporting) will include GSK's [\*\*\*] ITEOS's JSC representatives may review, but will have no right to comment on or approve. Each Party and the JDC (or the JSC, if the JDC is no longer meeting) shall have the right to review all reports and Data related to any Clinical Trials for a Licensed Product, whether such reports are generated by or on behalf of GSK, ITEOS, a Sublicensee or a subcontractor. Each Party will respond to the reasonable questions or requests of the other Party's JDC representatives (or JSC representatives, if the JDC is no longer meeting), as applicable, for additional information relating to such Party's Development activities under this Agreement in a timely manner.



3.7 Performance of Development Activities; Development Records. Each Party will perform, and ensure that their Affiliates, Sublicensees, and subcontractors perform, its Development activities as contemplated under this Agreement in a good scientific manner and in compliance with its Internal Policies, Applicable Law, including (if applicable) laws regarding the environment, safety and industrial hygiene, and GMP, GLP, GCP, informed consent and Institutional Review Board regulations, current standards for pharmacovigilance practice, and all applicable requirements relating to the protection of human subjects. Each Party and its Affiliates will maintain written or electronic records, in sufficient detail, in a good scientific manner (in accordance with GLP, GCP, and GMP, as applicable), and appropriate for regulatory and patent purposes, and that (a) are complete and accurate in all material respects and properly reflect all Development work performed and results achieved, in each case, by or on behalf of such Party and its Affiliates under this Agreement and (b) record only such activities and not include or be commingled with records of activities outside the scope of this Agreement, which records will be retained for at least [\*\*\*] years following expiration or termination of this Agreement, or for such longer period as may be required by Applicable Law or a Party's Internal Policies. The JDC shall have the right, during normal business hours and upon [\*\*\*] Business Days' notice, to inspect and copy any records kept by a Party in accordance with this Section 3.7 (Performance of Development Activities; Development Records). Each Party will provide the other with copies of relevant Internal Policies promptly following the Effective Date or from time-to-time as additional Internal Policies become relevant, and will provide updates of such Internal Policies as appropriate.

# **3.8 Obligations to Third Parties Regarding Combination Products.**

- **3.8.1 Existing** [\*\*\*]. The Parties each acknowledge where a Licensed Product being Developed under this Agreement is a [\*\*\*].
- **3.8.2** [\*\*\*] **Contracts With Third Parties**. If, at any time during the Term, (a) the Parties agree (through the JDC) to Develop a Licensed Product in a Co-Administration Study or as a Combination Product (including a Co-Formulated Product) with a compound, antibody or product that is owned or controlled by a Third Party under the Global Development Plan or (b) either Party proposes to Develop a Licensed Product in a Co-Administration Study or product that is owned or controlled by a Third Party in an Additional Development Proposal and the JSC does not approve the inclusion of such Additional Development Activities in the Global Development Plan under Section 3.4.2(a) (JSC Approval), and, in either case ((a) or (b)), either Party is party to an agreement related to such compound, antibody or product with such Third Party at such time, then such Party will [\*\*\*]. If, at any time during the Term, the Parties agree (through the JDC) to Develop a Licensed Product in a Co-Administration Study or as a Combination Product (including a Co-Formulated Product), including pursuant to 3.4.3(b) (Proof of Concept Data) or 3.4.3(c) (Receipt of Regulatory Approval) with a compound, antibody or product that is owned or controlled by a Third Party under the Global Development Plan and neither Party is party to an agreement with such Third Party at such time, then such or product in a Co-Administration Study or as a Combination Product (including a Co-Formulated Product), including pursuant to 3.4.3(b) (Proof of Concept Data) or 3.4.3(c) (Receipt of Regulatory Approval) with a compound, antibody or product that is owned or controlled by a Third Party under the Global Development Plan and neither Party is party to an agreement with such Third Party related to such compound, antibody or product with such Third Party related to such compound, antibody or product with such Third Party et at such time, then any [\*\*\*].

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**3.9 Pharmacovigilance and Adverse Event Reporting.** The Parties will cooperate with regard to the reporting and handling of safety information involving the Licensed Products in accordance with the Applicable Law, regulatory requirements, and regulations on pharmacovigilance and clinical safety. For each Licensed Product, GSK will be responsible for all processing of information related to any adverse events for such Licensed Product. Each Party will provide to the other Party the relevant safety information it receives (either directly or indirectly) related to a Licensed Product in a timely manner. The drug safety departments from each of the Parties shall meet and agree upon a written pharmacovigilance agreement for exchanging adverse event and other safety information and timelines within [\*\*\*] days of the Effective Date, which pharmacovigilance agreement will provide for the transfer of ITEOS's then-current safety database for Licensed Products to GSK, including the timing for such transfer. Such written pharmacovigilance agreement shall ensure that adverse event and other safety information is exchanged according to a schedule that will permit each Party (and its Sublicensees or designees) to comply with all Applicable Laws. GSK will own and maintain the global safety database for all Licensed Products.

# **3.10** Data Integrity Practices.

- **3.10.1 Requirements**. All activities conducted under the Global Development Plan, including the conduct of any clinical studies, will be conducted in accordance with the following practices:
  - (a) Data will be generated using sound scientific techniques and processes;
  - (b) Data will be accurately recorded by the Persons performing the applicable Development activities in accordance with data integrity practices;
  - (c) Data will be analyzed appropriately without bias in accordance with data integrity practices;
  - (d) Data and results from experiments and clinical studies will be stored securely such that it can be easily retrieved; and
  - (e) Data trails will exist to easily demonstrate or reconstruct key decisions made during the performance of all activities under the Global Development Plan, presentations made about such activities, and conclusions reached with respect to the activities undertaken in the performance of the Global Development Plan.
- **3.10.2** Changes to Data Integrity Requirements. At any time after the Effective Date and for so long as ITEOS is conducting Development of Licensed Products under the Global Development Plan, GSK may request changes to the requirements set forth above in this Section 3.10 (Data Integrity Practices) where GSK reasonably believes such changes are required to ensure that such activities are undertaken in compliance with GSK's Internal Policies or Applicable Law, and ITEOS shall use reasonable efforts to give effect to such changes as soon as reasonably practicable following receipt of GSK's written request, which request will include a copy of

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any updated GSK Internal Policies. GSK shall be permitted, in its sole discretion, to undertake on-site compliance audits of ITEOS's data integrity practices in respect of the activities performed by ITEOS to inspect ITEOS's compliance with the terms of this Section 3.10 (Data Integrity Practices) by providing ITEOS with [\*\*\*] days' written notice of GSK's intent to do so, such audits to be conducted at a time agreed by the Parties and no more frequently than once every [\*\*\*] during the Term.

## 3.11 Animal Welfare.

- **3.11.1** With respect to any activities conducted by or on behalf of either Party under the Global Development Plan or in connection with any Additional Development Activities that involve the use of animals, including any animal studies, such Party agrees to comply with this Section 3.11.1 (Animal Welfare). The Parties shall comply with all Applicable Laws related to the care, welfare and ethical treatment of animals in the country where it is performing Development activities under this Agreement. The Parties further agree to comply with the "3Rs" principles reducing the number of animals used, replacing animals with non-animal methods whenever possible and refining the research techniques used. All work must be conducted in adherence to the core principles for animals set forth below in this Section 3.11 (Animal Welfare). Local customs, norms, practices or Applicable Laws may be additive to the core principles, but the Parties agree to comply and shall procure and ensure each Party's subcontractors comply, at a minimum, with these core principles:
  - (a) Access to species appropriate food and water;
  - (b) Access to species specific housing, including species appropriate temperature and humidity levels;
  - (c) Provision of humane care and a program of veterinary care through guidance of a veterinarian;
  - (d) Animal housing that minimizes the development of abnormal behaviors;
  - (e) Adherence to principles of replacement, refinement and reduction in the design of *in vivo* or *ex vivo* studies with processes to optimize animal use and to ensure effective population management;
  - (f) Work is supported by a relevant scientific justification or rationale, approved by an institutional ethical review process and subjected to independent scientific review;
  - (g) Commitment to minimizing pain and distress during *in vivo* and *ex vivo* studies; and
  - (h) Work is performed by staff documented as trained and competent to conduct the procedures for which they are responsible.



- **3.11.2** All animal study protocols shall undergo an ethical review, whether or not required by Applicable Law, and written documentation confirming ethical review shall be maintained by the applicable Party until three (3) years after the expiration or termination of this Agreement demonstrating that the review was completed. Each Party shall have the right to inspect the other Party's records upon reasonable notice; *provided* that such inspection shall not extend to those parts of the records that the other Party can demonstrate to be subject to confidentiality arrangements with Third Parties. Each Party shall use reasonable efforts to ensure that its subcontractors will materially comply with the obligations identified in this Section 3.11.2 (Animal Welfare).
- **3.11.3** If a Party is currently accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International, then such Party agrees to use reasonable efforts to maintain such accreditation during the Term.
- **3.11.4** Each Party shall have policies or procedures in place to ensure the qualification and training of its employees that work with animals. Each Party shall use reasonable efforts to ensure that its subcontractors will comply with the obligations identified in this Section 3.11.4 (Animal Welfare).
- **3.11.5** Upon reasonable advanced written notice and subject to the agreements each Party has with its subcontractors, each Party (or its subcontractor/delegate) shall have the right to inspect the other Party's records and facilities as they relate to the conduct of animal work under the Global Development Plan or in connection with any Additional Development Activities. The scope of such inspection may include a tour of the facility, the opportunity to view relevant SOPs, training records, building management records, animal health records, ethical review documents, and any other documents in the applicable Party's or its Affiliates' or subcontractors' possession reasonably necessary to assess compliance by such other Party with any of the terms and conditions of this Section 3.11.5 (Animal Welfare); *provided* that such inspection shall not extend to those parts of the records and facilities that the other Party can demonstrate to be subject to confidentiality arrangements with Third Parties. To the extent that any significant deficiencies are identified as the result of such inspection, the other Party shall endeavor in good faith to take reasonable and practical corrective measures to remedy any such material deficiencies.
- **3.11.6** Each Party shall promptly provide to the other Party information regarding any material deficiencies impacting the activities under the Global Development Plan or in connection with any Additional Development Activities regarding its animal care and welfare program and any corrective actions taken. Where relevant to the Global Development Plan or in connection with any Additional Development Activities, each Party shall also provide the other Party copies of any regulatory enforcement action or inspection findings issued to the providing Party (or subcontractor) and relating to a systemic failure in the ethical care and treatment of animals, regardless of whether such enforcement action or inspection finding relates specifically to the conduct of the Global Development Plan or in connection



with any Additional Development Activities. The JDC shall discuss and develop a remediation strategy for any such material deficiencies regarding animal care and welfare. Each Party shall use reasonable efforts to ensure that its subcontractors will comply with the obligations identified in this Section 3.11.6 (Animal Welfare).

**3.11.7** Each Party shall have a procedure in place to assess and approve its external suppliers and distributors who supply animals to such Party to (a) ascertain and confirm the quality of the animals supplied, (b) ensure legal requirements for the care and welfare of animals are met, (c) ensure that only purpose bred animals are used to conduct animal work under the Global Development Plan or in connection with any Additional Development Activities, (d) minimize the distance of suppliers from such Party's test facility (where practicable), (e) ensure minimum stress in transport processes (*e.g.*, stocking densities, carrying crates, food and water), and (f) ensure checks are in place on arrival to confirm only healthy animals are used in the conduct of the Global Development Plan or in connection with any Additional Development Activities. Such Party shall document the approval process for its animal suppliers and distributors, which documentation shall be made available to the other Party upon reasonable request.

#### 3.12 Material Transfers.

- **3.12.1** During the course of the performance of the Global Development Plan, either Party (or such Party's designee) (the "Materials Transferring Party") may transfer to the other Party or its designee (the "Materials Receiving Party") certain Materials for use in connection with activities contemplated under the Global Development Plan. Such Materials will be provided under the terms and conditions of this Agreement and in such amount as described in the material transfer record for the particular transfer ("MTR"), in the form attached hereto as <u>Schedule 3.12</u>, which MTR shall set forth the type and name of the Materials transferred, the amount of the Materials transferred, the date of the transfer of such Materials and the proposed use of such Materials by the Materials Receiving Party. For clarity, this Section 3.12 (Material Transfers) shall not apply to the clinical supply of Licensed Antibodies or Licensed Product, which shall be supplied under a clinical supply agreement or otherwise in accordance with Article 5 (Manufacturing and Supply).
- MATERIALS SUPPLIED BY THE MATERIALS TRANSFERRING PARTY HEREUNDER ARE 3.12.2 SUPPLIED IN "AS IS" CONDITION WITH NO WARRANTY, EXPRESS, IMPLIED OR STATUTORY, INCLUDING WARRANTIES OF MERCHANTABILITY, TITLE, NON-INFRINGEMENT, EXCLUSIVITY, OR FITNESS FOR A PARTICULAR PURPOSE. ANY MATERIAL DELIVERED PURSUANT TO THIS AGREEMENT IS UNDERSTOOD TO BE EXPERIMENTAL IN NATURE AND MAY HAVE HAZARDOUS PROPERTIES. THE MATERIALS RECEIVING PARTY WILL HANDLE THE MATERIAL ACCORDINGLY AND WILL INFORM THE MATERIALS TRANSFERRING PARTY IN WRITING OF ANY ADVERSE EFFECTS EXPERIENCED BY PERSONS HANDLING THE MATERIAL.

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- **3.12.3** The Materials Receiving Party acknowledges that, except for the licenses and other express rights granted herein, it does not have any claim to the Materials supplied by the Materials Transferring Party, or any license or rights to any proprietary information or intellectual property rights in or to the Materials. For clarity, the Materials shall remain the sole and exclusive property of the Materials Transferring Party and shall be returned or destroyed at the request of the Materials Transferring Party.
- **3.12.4** The Materials Receiving Party agrees that the Material(s):
  - (a) will be used solely for, and in compliance with, the activities described in the Global Development Plan;
  - (b) will be used in compliance with all Applicable Laws;
  - (c) will not be used in human subjects, in Clinical Trials, or for diagnostic purposes involving human subjects (except, in each case, as otherwise described in this Agreement);
  - (d) will be used only by the Materials Receiving Party and only in the Materials Receiving Party's laboratory, except with the prior written consent of the Materials Transferring Party;
  - (e) will not be transferred to a Third Party without the prior written consent of the Materials Transferring Party; and
  - (f) the Materials Receiving Party shall not reverse engineer or attempt to determine the chemical structure, make-up or sequence of, or determine the chemical or biological properties of, or make or attempt to make any analogues, progeny or derivatives of, or modifications to, such Materials except as expressly required to carry-out such Party's obligations hereunder, including its activities pursuant to the Global Development Plan.
- **3.12.5** The Materials Receiving Party assumes all liability for damages that may arise from its use, storage or disposal of the Materials. The Materials Transferring Party shall not be liable to the Materials Receiving Party for any loss, claim or demand made by the Materials Receiving Party, or made against the Materials Receiving Party by any Third Party, due to or arising from the use of the Materials, except to the extent permitted by Applicable Law when caused by the negligence, willful misconduct, fraud or fraudulent misrepresentation of the Materials Transferring Party. Upon termination of the relevant Development requiring use of the Materials or the Agreement in its entirety, as applicable, except for any continuing rights as set forth in this Agreement, the Materials Receiving Party, return or destroy (and certify destruction of) any remaining Material in compliance with all Applicable Laws.



**3.13 R&D Ethics & Compliance**. Each Party's compliance officer responsible for Development activities (or other equivalent personnel of either Party) (each, an "**R&D Compliance Officer**") will meet within [\*\*\*] after the Effective Date to (a) review each Party's Internal Policies relevant to Development activities to be undertaken in accordance with this Agreement, (b) discuss implications for the Development Program, and (c) propose to the JDC within [\*\*\*] of the Effective Date (unless otherwise agreed by the Parties in writing) a plan regarding how each Party's R&D Compliance Officer or other appropriate personnel will support the JDC in addressing any ethics or compliance issues and risks for the Development Program. The JDC shall review such plan in good faith and agree to any modifications, with the final agreed plan documented in the JDC minutes.

### ARTICLE 4 REGULATORY MATTERS

# 4.1 General.

- **4.1.1 Shared Global Development Activities.** The Parties will conduct regulatory activities with respect to the Licensed Products in accordance with the regulatory strategy set forth in the Global Development Plan and the terms of this Article 4 (Regulatory Matters) related to the Shared Global Development Activities. The JDC will oversee the implementation of, and discuss progress regarding, such regulatory strategy.
- **4.1.2 GSK Sole Development Activities.** GSK will conduct regulatory activities with respect to the Licensed Products in accordance with the regulatory strategy set forth in the Global Development Plan and the terms of this Article 4 (Regulatory Matters) related to the GSK Sole Development Activities. The JDC will oversee implementation of, and discuss progress regarding such regulatory strategy.
- 4.1.3 **Regulatory Responsibilities**. Subject to the remainder of this Article 4 (Regulatory Matters), each Party will lead all regulatory matters relating to Licensed Products in the countries in which it is responsible for conducting Development, for so long as such Party is responsible for such Development in accordance with the Global Development Plan or as required to conduct Additional Development Activities being conducted by such Party in accordance with Section 3.4 (Additional Development) (such Party, the "Regulatory Responsible Party"). Subject to each Party's right of reference as described in Section 4.5 (Right of Reference), the Regulatory Responsible Party shall file for in its name, and will own, all Regulatory Filings in the countries in which it is responsible for Development and will own all Regulatory Approvals for all Licensed Products in the Territory until such Regulatory Filings are assigned to GSK pursuant to Section 4.2 (Assignment of Regulatory Filings). Subject to this Article 4 (Regulatory Matters), the Regulatory Responsible Party will have the sole responsibility for (a) overseeing, monitoring and coordinating all regulatory actions, communications and filings with, and submissions to, each applicable Regulatory Authority with respect to each Licensed Product; (b) interfacing, corresponding and meeting with each Regulatory Authority in the Territory with respect to each Licensed Product; and (c) seeking

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and maintaining all Regulatory Approvals in the Territory with respect to each Licensed Product, in each case, for so long as such Party is the Regulatory Responsible Party with respect to such Licensed Product. In addition, notwithstanding any provision to the contrary set forth in this Agreement, the Regulatory Responsible Party will (i) not be required to delay any actions, communications, or filings with, or submissions to any applicable Regulatory Authorities in a manner that affects the Regulatory Responsible Party's ability to comply with any Regulatory Authority requirement or deadline or Applicable Law in the applicable jurisdiction or that would delay receipt of Regulatory Approval for a Licensed Product anywhere in the Territory and (ii) have final say on the content of all Regulatory Filings with Regulatory Authorities in the Territory for so long as such Party is the Regulatory Responsible Party with respect to such Licensed Product.

- **4.1.4 Regulatory Cooperation**. As reasonably requested by the Regulatory Responsible Party from time to time during the Term, the other Party shall promptly provide reasonable assistance to the Regulatory Responsible Party with respect to filings and other interactions with Regulatory Authorities regarding Licensed Antibodies and Licensed Products.
- **4.2 Assignment of Regulatory Filings**. Unless otherwise agreed by the Parties, no later than [\*\*\*], if ITEOS holds, in its name, any Regulatory Filings (including INDs) with respect to any Licensed Products as of such date, unless otherwise agreed by the Parties, ITEOS will assign to GSK all rights, title, and interests in and to each such Regulatory Filing (including INDs) filed in the Territory, and will transfer to GSK copies (in electronic or other format) of those Regulatory Filings owned by ITEOS or its Affiliates that are necessary to assign such INDs to GSK, *provided, however*, that ITEOS will not assign Regulatory Filings (including INDs) to GSK regarding Additional Development Activities being conducted by ITEOS in accordance with Section 3.4 (Additional Development) until (a) such Additional Development Activities are added to the Global Development Plan pursuant to Section 3.4.3(b) (Proof of Concept Data) or (b) the applicable Regulatory Approval is obtained in connection with such Additional Development Activities, as described in Section 3.4.3(c) (Receipt of Regulatory Approval), in each case, which assignment of Regulatory Filings shall be in a manner and on the timelines to be agreed by the Parties.
- **4.3 Meetings and Communications**. During the Term, each Party will keep the other Party reasonably informed of any material communications from, or meetings with, any Regulatory Authority pertaining to such Party's Development activities (including Additional Development Activities) performed under this Agreement promptly following receipt thereof. To the extent relating to a Licensed Product, the Regulatory Responsible Party with respect to such Licensed Product, will provide the other Party with: (a) to the extent allowable by Applicable Laws and the relevant Regulatory Authority and to the extent practicable, an opportunity to have one or more of its representatives attend and observe substantive discussions and meetings with the FDA or any other Regulatory Authority with respect to any Clinical Trials or other matters (*e.g.*, CMC or non-clinical issues); (b) a copy of any material documents, reports or correspondence submitted to the



FDA or any other Regulatory Authority (which copies may be redacted as necessary to comply with any confidentiality or information protection requirements under any applicable Third Party Component Contracts); and (c) reasonable advanced notice (to the extent practicable) of substantive meetings, scheduled or unscheduled, with the FDA or any other Regulatory Authority. All such documents or reports described in subclause (b) above will be provided to the non-Regulatory Responsible Party at least [\*\*\*] prior to their submission to the applicable Regulatory Authority (or such later date as the Parties may reasonably agree), and the Regulatory Responsible Party will reasonably consider any comments provided by the non-Regulatory Responsible Party with respect to such documents or reports in good faith. To the extent a Party receives material written or oral communications from the FDA or any other Regulatory Authority relating to a Licensed Product or activities under this Agreement with respect to a Licensed Product, such Party shall notify the other Party and provide a copy of any such written communications to the other Party within [\*\*\*]. In addition, upon a reasonable request from the other Party, each Party shall provide copies of other documents, reports or communications from or to Regulatory Authorities relating to Licensed Products.

- **4.4 Exchange of Development Data**. Without limiting the other provisions of this Agreement, at the request of a Party or upon direction by the JSC or JDC, the other Party shall provide to the requesting Party all pertinent Data developed by or on behalf of such Party, as applicable, in connection with the Development of a Licensed Product under this Agreement or the performance of other activities under the Global Development Plan or Commercialization Plans hereunder subject to any applicable confidentiality arrangements with Third Parties [\*\*\*]. The format of, and media for exchanging, such Data shall be decided by the JDC.
- **4.5 Right of Reference**. Each Party shall have the right, without obtaining the approval of the other Party and without additional payment to such other Party (other than payments expressly provided in this Agreement), to reference (including a "Right of Reference" as that term is defined in 21 C.F.R. § 314.3(b) (or any successor rule), and corresponding rights under the foreign equivalents of 21 C.F.R. § 314.3(b) in the applicable countries in the Territory), copy, access and use Data, and all reports, documents, Regulatory Filings, and other information developed by any Party that is derived from or includes such Data, in each case, that is related to a Licensed Antibody or Licensed Product and that is owned or Controlled by a Party or its Affiliates (a) for purposes of preparing and submitting INDs, NDAs, BLAs and other Regulatory Filings for the Licensed Products, and (b) preparing and filing patent applications, in each case ((a) and (b)) in accordance with this Agreement, and, with respect to such Data, reports, documents and other information developed by the other Party, solely to the extent permitted under this Agreement.

# 4.6 Recall, Withdrawal or Field Alert of a Licensed Product.

**4.6.1 Notification and Determination**. If any Governmental Authority threatens in writing or initiates any action to remove a Licensed Product from the market (in whole or in part) in the Territory, then the Party receiving notice thereof will notify the other Party of such communication immediately, but in no event later than [\*\*\*] after receipt thereof. Notwithstanding the foregoing, in all cases GSK will



determine whether to initiate any recall, withdrawal or field alert of such Licensed Product in the applicable territory, including the scope of such recall or withdrawal (*e.g.*, a full or partial recall, or a temporary or permanent recall) or field alert. Before GSK initiates a recall, withdrawal, or field alert for a Licensed Product in the Territory the Parties will promptly meet and discuss in good faith the reasons therefor, *provided* that such discussions will not delay any action that GSK reasonably believes should be taken in relation to any actual or potential recall, withdrawal or field alert. In the event of any such recall, withdrawal, or field alert, GSK will determine the necessary actions to be taken and will implement such action. Without limiting the foregoing, either Party will have the right to propose that a recall, withdrawal or field alert for a Licensed Product should be initiated by such Party, but GSK will have the right to make the final decision as to whether or not to initiate the recall, withdrawal or field alert. Notwithstanding the foregoing, if ITEOS notifies GSK of a Manufacturing issue related to a Licensed Product that ITEOS had Manufactured during the October 2021 Campaign and that ITEOS reasonably believes could give rise to a recall, withdrawal or field alert, then GSK will initiate such recall, withdrawal, or field alert in accordance with ITEOS's request.

**4.6.2 Recall Cost Allocation**. All costs and expenses associated with implementing a recall, withdrawal, or field alert with respect to a Licensed Product will be allocated between ITEOS and GSK as follows: (a) subject to clause (b)(ii) below, such costs and expenses included in Recall Expenses will be shared equally (50:50) by the Parties as Allowable Expenses, in accordance with Section 8.3 (Pre-Tax Profit or Loss Sharing) in the event of such a recall, withdrawal, or field alert with respect to a Licensed Product in the Profit-Sharing Territory, (b) GSK will be responsible for such costs and expenses (i) in the event of such a recall of a Licensed Product in the Net Sales Territory and (ii) that are associated with any recall, withdrawal, or field alert of a Licensed Product that is due to the negligence or willful misconduct of GSK, its Affiliates, Sublicensees or its Third Party contractors, including due to Manufacturing (including labeling) of such Licensed Product, and (c) ITEOS will be responsible for such costs and expenses that are associated with any recall, withdrawal or field alert of a Licensed Product that is due to the negligence or willful misconduct of ITEOS, its Affiliates, Sublicensees or its Third Party contractors in the Net Sales Territory.

### ARTICLE 5 MANUFACTURING AND SUPPLY

### 5.1 Manufacturing.

**5.1.1 JDC Oversight; Efforts.** The JDC, in consultation with the Financial Working Group, shall oversee CMC Development, supply chain strategy, establishment of Manufacturing sources, capacity, supply chains, and Manufacture of Licensed Antibodies and Licensed Products, subject to the provisions of this Article 5 (Manufacturing and Supply). Each Party shall use reasonable efforts to execute and to perform, or cause to be performed through its Affiliates, the Existing CMO,

or GSK CMO, the Manufacturing activities assigned to it under this Agreement and by the JDC, and to cooperate with the other Party in carrying out such Manufacturing activities. If the JDC is unable to resolve any dispute regarding the activities described in this Section 5.1.1 (JDC Oversight; Efforts), then the issue will be resolved in accordance with Section 7.7 (Decision-Making).

**5.1.2 Clinical Supply**. Subject to the terms of [\*\*\*] ("**Existing CMO Agreement**"), ITEOS shall be solely responsible, through its Existing CMO, for Clinical Manufacture and supply of Licensed Antibodies and Licensed Products required for the performance of activities under the Global Development Plan from the Effective Date until completion [\*\*\*] (the "**October 2021 Campaign**"), after which GSK shall be solely responsible for Clinical Manufacture and supply of Licensed Antibodies and Licensed Products throughout the Territory (including for the performance of activities under the Global Development Plan).

[\*\*\*]

- **5.1.3 Commercial Supply**. Subject to Section 5.1.5 (Second Source), GSK shall be solely responsible for all Commercial Manufacture and supply of Licensed Products throughout the Territory.
- **5.1.4 Request to Supply**. If ITEOS requests supply of Licensed Product from GSK for Development activities (including Additional Development Activities) conducted hereunder, then prior to any such supply, the Parties will enter into a clinical supply agreement and quality agreement under which GSK will, subject to Section 5.3 (Prioritization of Supply), supply Licensed Product to ITEOS at a supply price equal to [\*\*\*]. Any requests for supply of Licensed Product by ITEOS from GSK will be ordered under such clinical supply agreement pursuant to the terms thereof and the Parties will not be obligated to enter into any additional supply agreements. The clinical supply agreement shall include terms for the required lead time from the date GSK receives the purchase order from ITEOS and the requested delivery date in the purchase order and will be on terms customary for supply agreements between collaboration partners with respect to Development of products.
- **5.1.5** Second Source. The Parties agree that GSK will maintain a supply relationship with ITEOS's Existing CMO with respect to the supply of Licensed Products during the Term, *provided*, *however*, that [\*\*\*] ("GSK CMO Agreement"). [\*\*\*].
- **5.1.6 Supply Price Updates.** For purposes of determining GSK's Manufacturing Costs with respect to Licensed Products, the Standard Cost of Goods Manufactured will be updated annually as part of GSK's customary practice for its other products.
- **5.2 Manufacturing Technology Transfer**. Within [\*\*\*] following the Effective Date, (a) the JDC will prepare and approve a Manufacturing technology transfer plan for the transfer from ITEOS or its Existing CMO of Know-How within the ITEOS Technology related to Manufacturing the Licensed Antibodies and Licensed Products, which plan will include a reasonable allocation of costs between the Parties (the "**Manufacturing Tech Transfer**

**Plan**") and (b) the Parties will initiate performance of technology transfer activities to enable GSK to conduct Clinical Manufacturing and supply of Licensed Product or Licensed Antibodies. The JDC will manage and oversee the transfer of Know-How within the ITEOS Technology set forth in the Manufacturing Tech Transfer Plan. Without limiting the foregoing, ITEOS will use reasonable efforts to facilitate GSK's and ITEOS's shared goal of an orderly transition and successful Manufacturing technology transfer in accordance with the timelines set forth in the Manufacturing Tech Transfer Plan and uninterrupted Development of the applicable Licensed Antibodies and Licensed Products in compliance with GMP requirements. The format of, and media for exchanging, any of the foregoing information shall be decided by the JDC and described in the Manufacturing Tech Transfer Plan. The Parties will complete the transfer of Manufacturing responsibility to GSK no later than [\*\*\*].

- **5.3 Prioritization of Supply**. Allocation of supply of any Licensed Antibodies or Licensed Products to either Party for Additional Development Activities shall be [\*\*\*].
- **5.4 Supply of Other Products by GSK**. If the Global Development Plan includes Clinical Trials to be conducted by ITEOS for the Development of a [\*\*\*], then (a) GSK will be responsible for supplying such [\*\*\*], for use under the Global Development Plan and (b) the Parties will enter into a clinical supply agreement and a quality agreement (or add such [\*\*\*] to the supply agreement previously entered into by the Parties pursuant to Section 5.1.4 (Request to Supply)), as necessary for GSK to [\*\*\*] to ITEOS for the purpose of conducting the applicable Clinical Trials in accordance with the Global Development Plan. [\*\*\*].

### ARTICLE 6 COMMERCIALIZATION; MEDICAL AFFAIRS

Global Strategic Launch Plan. No later than [\*\*\*] prior to the Target BLA Filing Date, GSK will prepare a 6.1 reasonably detailed written plan for the Licensed Product with respect to the [\*\*\*] plans for the Licensed Product that sets out the [\*\*\*] with respect to Licensed Products throughout the Territory, which plan will include at a minimum: (a) [\*\*\*] (the "Global Strategic Launch Plan"). The Global Strategic Launch Plan will serve as the basis for the Joint Commercialization Plan. The Global Strategic Launch Plan will be prepared having at least the same level and quality of information and in the same format as GSK ordinarily prepares for its own internal management for purposes of standard budget and portfolio reviews and project management, *provided* that GSK will not be obligated to include information that does not relate to the Licensed Products. At least once per Calendar Year, GSK will review and update, as appropriate, the Global Strategic Launch Plan. GSK will provide the initial Global Strategic Launch Plan for each Licensed Product, and each annual update thereto, to the JCC and the JSC for review and comment. ITEOS's representatives on the JCC and the JSC may comment thereon and GSK will consider ITEOS's comments in good faith, but the JCC and the JSC will not have an approval right with respect thereto. Notwithstanding the foregoing or any other provision to the contrary set forth in this Agreement, if ITEOS reasonably believes that any activity under a Global Strategic Launch Plan or update thereto or otherwise proposed to be conducted by GSK in the Net Sales Territory may reasonably give rise to a Material Safety or Commercialization Concern described in Section 1.171(b) or (c) (and excluding Section 1.171(a)) based on information known at the time, then ITEOS may raise such concern to the JCC and the JCC will promptly discuss and determine whether such activity may present a Material Safety or Commercialization Concern described in Section 1.171(b) or (c) (and excluding Section 1.171(a)), and whether such Material Safety or Commercialization Concern described in Section 1.171(b) or (c) (and excluding Section 1.171(a)) may be appropriately addressed in an update to the Joint Commercialization Plan. If ITEOS reasonably believes that any activity under a Global Strategic Launch Plan or update thereto or otherwise proposed to be conducted by GSK in the Net Sales Territory may reasonably give rise to a Material Safety

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or Commercialization Concern [\*\*\*] for the Licensed Product or [\*\*\*] to discuss and determine whether such activity may present a Material Safety or Commercialization Concern described in Section 1.171(a). If the JCC is unable to reach a decision that the resolution of such matter is appropriately addressed in the Joint Commercialization Plan within thirty (30) days of ITEOS raising such a Material Safety or Commercialization Concern described in described in Section 1.171(b) or in Section 1.171(c), then the issue will be resolved in accordance with Section 7.7.2(c) (Resolution of Material Concerns) or if the [\*\*\*] are unable to resolve a Material Safety or Commercialization Concern described in Section 1.171(a), then, in each case, the issue will be resolved in accordance with Section 7.7.2(c) (Resolution of Material Concerns).

6.2 Joint Commercialization Plan. The JDC shall determine a target filing date of the BLA for the most advanced Licensed Product being Developed under this Agreement (the "Target BLA Filing Date"). No later than [\*\*\*] of a Licensed Product in the Profit-Sharing Territory, GSK will provide to the JCC a draft initial joint commercialization plan and budget that sets out the Commercialization and Medical Affairs activities to be conducted by the Parties with respect to the Licensed Products in the Profit-Sharing Territory (the "Joint Commercialization Plan"). The Joint Commercialization Plan will be based upon and consistent with the Global Strategic Launch Plan for the applicable Licensed Product. Promptly thereafter, the JCC, with the support and direct involvement of the Financial Working Group with regard to preparation of the Joint Commercialization Budget, will review, discuss and recommend modifications to the draft Joint Commercialization Plan (provided, that only the medical representatives on the JCC may recommend modifications to the Medical Affairs activities set forth in the Joint Commercialization Plan), and the JCC will, in turn, provide such Joint Commercialization Plan (as such plan may be modified on the recommendation of the JCC) and Joint Commercialization Budget to the JSC to review, discuss and determine whether to approve. The Joint Commercialization Plan will (a) include matters similar to those included in the Global Strategic Launch Plan but revised to specifically support launch of the Licensed Product in the Profit-Sharing Territory, (b) [\*\*\*] included in such plan to be undertaken for the upcoming Calendar Year which budget will be broken down by Calendar Quarter, for the estimated Commercial FTE Costs (for Commercialization activities), estimated Development FTE Costs (for Medical Affairs activities), Manufacturing Costs, and Out-Of-Pocket Costs expected to be incurred by each Party in the given Calendar Year with respect to such Medical Affairs and Commercialization activities set forth in such plan (such budget the "Joint Commercialization Budget"). So long as ITEOS is Commercializing with GSK the Licensed Products in the Profit-Sharing Territory under this Agreement, on at least an annual basis during the Term (or more frequently as may be

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required), GSK will review and update each Joint Commercialization Plan (and Joint Commercialization Budget therein) based on the currently available information and data. GSK will provide to the JCC a copy of each such update to the Joint Commercialization Plan to (together with the Financial Working Group) review, discuss, and recommend modifications (provided, that only the medical representatives on the JCC may recommend modifications to the Medical Affairs activities set forth in the Joint Commercialization Plan), and the JCC will, in turn, provide such update to the Joint Commercialization Plan (as such update may be modified on the recommendation of the JCC) to the JSC to review, discuss and determine whether to approve. The initial Joint Commercialization Plan and each such update to the Joint Commercialization Plan will become effective and will supersede the previous Joint Commercialization Plan only upon approval thereof by the JSC. Any such updates or amendments to the Joint Commercialization Plan and Joint Commercialization Pla

# 6.3 Commercialization Responsibilities.

- **6.3.1** Net Sales Territory. During the Term, GSK, either itself or as it determines, by and through its Affiliates, Sublicensees or subcontractors, will be solely responsible for all Commercialization activities (including booking of sales) with respect to the Licensed Products throughout the Net Sales Territory, at GSK's sole cost and expense, in accordance with the Global Strategic Launch Plan and this Article 6 (Commercialization; Medical Affairs). GSK will keep ITEOS reasonably informed, through periodic updates to the JSC, regarding key pricing and patient support programs in major countries or regions in the Net Sales Territory.
- 6.3.2 **Profit-Sharing Territory.** The Parties will jointly Commercialize the Licensed Products in the Profit-Sharing Territory in accordance with the Joint Commercialization Plan and this Article 6 (Commercialization; Medical Affairs). The Party to which a particular Commercialization activity is allocated under the Joint Commercialization Plan will lead the performance thereof and, without seeking JCC or JSC review or approval, but subject to this Article 6 (Commercialization; Medical Affairs), will have the right to make operational decisions with respect to the implementation and performance of such Commercialization activities to the extent consistent with the then-current Joint Commercialization Plan and this Article 6 (Commercialization; Medical Affairs). If a particular Commercialization activity is allocated to both Parties to perform jointly under the Joint Commercialization Plan, then both Parties will conduct such activity in collaboration with each other. GSK will book sales of all Licensed Products in the Profit-Sharing Territory and will be responsible for performing or approving, as applicable, the Excluded Commercialization Activities. Unless otherwise agreed by the JCC, the Joint Commercialization Plan will assign to ITEOS [\*\*\*] percent [\*\*\*] of the Shared Commercialization Activities for such Licensed Products in the Profit-Sharing Territory each Calendar Quarter. Without limiting the foregoing, ITEOS will have the right to participate in the [\*\*\*]. Each



Party will conduct all Commercialization activities in the Profit-Sharing Territory in accordance with the Joint Commercialization Plan and this Article 6 (Commercialization; Medical Affairs).

### 6.4 Medical Affairs Responsibilities.

- **6.4.1 Net Sales Territory**. During the Term, GSK, either itself or by and through its Affiliates, Sublicensees or subcontractors, will be solely responsible for all Medical Affairs activities with respect to the Licensed Products throughout the Net Sales Territory, at GSK's sole cost and expense, in accordance with the Global Strategic Launch Plan and this Article 6 (Commercialization; Medical Affairs).
- **6.4.2 Profit-Sharing Territory**. The Party to which a particular Medical Affairs activity is allocated under a Joint Commercialization Plan will lead the performance thereof, and, without seeking JCC or JSC review or approval, will have the right to make operational decisions with respect to the implementation and performance of such Medical Affairs activities to the extent consistent with the then-current Joint Commercialization Plan and this Article 6 (Commercialization; Medical Affairs). If a particular Medical Affairs activity is allocated to both Parties to perform jointly under a Joint Commercialization Plan, then both Parties will conduct such activity in collaboration with each other. Each Party will use reasonable efforts in the Profit-Sharing Territory to [\*\*\*] is permitted under Applicable Law and Guidelines. Each Party will conduct all Medical Affairs activities in the Profit-Sharing Territory in accordance with the Joint Commercialization Plan and this Article 6 (Commercialization; Medical Affairs).
- **6.4.3 Medical Affairs Materials.** GSK shall prepare and produce all Medical Affairs Materials for the Licensed Products in the Territory in accordance with the Global Strategic Launch Plan and the Joint Commercialization Plan, which Medical Affairs Materials GSK will share with ITEOS for ITEOS's review and comment, which comments GSK will consider in good faith. GSK will be solely responsible for legal and regulatory review of such Medical Affairs Materials through its normal internal review process, and submission of Medical Affairs Content to applicable Regulatory Authorities for comments or approval as required. GSK shall own all rights, title and interests in and to any and all such Medical Affairs Materials. Neither Party shall use any materials other than the Medical Affairs Materials that have undergone GSK's internal review and approval process for use in connection with the conduct of Medical Affairs activities related to the Licensed Products under this Agreement; *provided* that, ITEOS will not be required to use any Medical Affairs Materials that ITEOS's compliance team has not also approved. GSK shall be responsible for providing and shipping to ITEOS all Medical Affairs Materials in quantities necessary for ITEOS to perform its activities under the Joint Commercialization Plan.
- **6.4.4 Medical Affairs Training**. GSK shall be responsible for preparing the training programs and materials relating to Medical Affairs activities for the Licensed Product ("**Medical Affairs Training Materials**") for the Parties' Medical Affairs

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personnel, which Medical Affairs Training Materials GSK will share with ITEOS for ITEOS's review and comment, which comments GSK will consider in good faith. GSK shall conduct training programs regarding Medical Affairs activities for the Licensed Products based on such Medical Affairs Training Materials for all such Medical Affairs personnel of the Parties. The Medical Affairs Training Materials will be updated annually taking into account any areas identified through internal monitoring of activities by each Party for enhanced or refreshed training. Following the initial training of Medical Affairs personnel, each Party shall be responsible for, and shall conduct, regular training programs for its own Medical Affairs personnel using the most up-to-date Medical Affairs Training Materials. GSK shall have the right to join ITEOS Medical Affairs training on the USPPs. GSK shall own all rights in the Medical Affairs Training Materials in all formats (*e.g.*, print, video, audio, digital, computer) including all applicable copyrights, trademarks, program names, domain names and Internet sites. Each Party shall be responsible for the performance of its own Medical Affairs representatives.

- **6.5 Limited Disclosure**. Nothing in this Agreement shall require GSK to disclose to ITEOS (a) [\*\*\*] or (b) information pertaining to [\*\*\*].
- **6.6 Diligence**. Each Party will use Commercially Reasonable Efforts to perform the obligations assigned to it under the Joint Commercialization Plan. Upon receipt of the Regulatory Approval for a Licensed Product in the Field in a given country in the Territory, GSK (directly, or through its Affiliates, its or their Sublicensees or subcontractors) will use Commercially Reasonable Efforts to Commercialize such Licensed Product in the Field in such country in the Territory.

# 6.7 ITEOS Opt-Out.

- **6.7.1 ITEOS Opt-Out Right**. Subject to Section 6.7.3 (Effects of Opt-Out), at any time during the Term, ITEOS may provide GSK with written notice indicating that ITEOS elects, in its discretion, not to Commercialize with GSK the Licensed Products in the Profit-Sharing Territory in accordance with the Joint Commercialization Plan and the requirements of this Agreement or share Development Costs or Pre-Tax Profit or Loss under this Agreement (such notice, an "**Opt-Out Notice**"). For the avoidance of doubt, any Opt-Out Notice shall terminate ITEOS's right to both Commercialize and provide Medical Affairs activities in the Profit-Sharing Territory.
- **6.7.2 Forced Opt-Out**. If (i) in connection with its conduct of Commercialization activities in the Profit-Sharing Territory, ITEOS materially breaches its obligations under Section 6.9 (Regulatory Compliance) and Section 6.10 (Marketing) to comply with the Anti-Kickback Statute (42 U.S.C. § 1320a-7b et seq.) or any Applicable Laws, Guidelines or USPPs governing off-label promotion, pre-approval promotion or disguised promotion of pharmaceutical products in the Profit-Sharing Territory, (ii) ITEOS delivers less than [\*\*\*] of the Details required



to be delivered by ITEOS under the Joint Commercialization Plan in any [\*\*\*] Calendar Quarters, or (iii) ITEOS otherwise fails to provide such Commercialization activities that are specifically allocated to ITEOS under the Joint Commercialization Plan in any [\*\*\*] Calendar Quarters where ITEOS's failure to do so is a material failure under ITEOS's overall contribution of Commercialization activities as contemplated under the then-current Joint Commercialization Plan, then GSK will provide written notice to ITEOS of the occurrence of any such event described under clause (i), (ii) or (iii). Such notice will, in each case, expressly reference this Section 6.7.2 (Forced Opt-Out), reasonably describe the alleged breach or failure, and state GSK's intent to terminate ITEOS's right to Commercialize Licensed Products under this Agreement if such breach or failure is not cured or remediated in accordance with this Section 6.7.2 (Forced Opt-Out).

(a) With respect to a material breach described in clause (i) of this Section 6.7.2 (Forced Opt-Out), ITEOS shall immediately cease its Commercialization activities relating to the alleged material breach, and propose to GSK within [\*\*\*] after receipt of GSK's notice of breach a comprehensive remediation plan designed to avoid similar breaches in the future and ensure compliance with such Applicable Laws, Guidelines and USPPs, which plan shall provide for immediate termination (at ITEOS's sole cost and expense) of the employment of any ITEOS employees and contract with any Subcontractor, in each case, that have violated such Applicable Laws, Guidelines or USPPs, which remediation plan the Parties will discuss in good faith and agree upon. If GSK does not agree to ITEOS's proposed remediation plan, then GSK will provide to ITEOS, [\*\*\*], a comprehensive remediation plan (which may be a modified version of ITEOS's proposed remediation plan) designed to avoid similar breaches in the future and ensure compliance with such Applicable Laws, Guidelines and USPPs. ITEOS will not resume the ceased Commercialization activities in the Profit-Sharing Territory until a comprehensive remediation plan has been agreed between the Parties or has been provided by GSK to ITEOS, as applicable. If ITEOS does not comply with the foregoing requirement to cease the applicable Commercialization activities and provide a remediation plan designed to avoid similar breaches in the future and ensure compliance with such Applicable Laws, Guidelines and USPPs, then, subject to Section 6.7.2(c), GSK may terminate ITEOS's right to Commercialize in the Profit-Sharing Territory by providing written notice to ITEOS of such failure to comply with the provisions of this Section 6.7.2(a), and ITEOS's right to Commercialize in the Profit-Sharing Territory will terminate [\*\*\*] days after the breach notice has been provided for such material breach described in clause (i) of this Section 6.7.2 (Forced Opt-Out). Further, if ITEOS materially breaches any such comprehensive remediation plan agreed by the Parties or provided by GSK, as applicable, or otherwise materially breaches its obligations to comply with the Anti-Kickback Statute (42 U.S.C. § 1320a-7b et seq.) or any Applicable Laws, Guidelines or USPPs governing off-label promotion, pre-approval promotion or disguised promotion of

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pharmaceutical products in the Profit-Sharing Territory in respect of any resumed Commercialization activities in the Profit-Sharing Territory that were to be conducted under such an agreed or provided comprehensive remediation plan, then, subject to Section 6.7.2(c), GSK may terminate ITEOS's right to Commercialize in the Profit-Sharing Territory immediately notice to ITEOS of such further material breach.

- (b) With respect to a failure described in clause (ii) or (iii) of this Section 6.7.2 (Forced Opt-Out), if by the end of the next [\*\*\*] Calendar Quarters following the [\*\*\*] Calendar Quarters in which the failure described in clause (ii) or (iii) of this Section 6.7.2 (Forced Opt-Out) occurred, ITEOS does not perform at least [\*\*\*] percent [\*\*\*] of the Details required to be delivered by it during such next [\*\*\*] Calendar Quarters as set forth in the then-current Joint Commercialization Plan or ITEOS otherwise materially fails to perform its other Commercialization Plan for such next [\*\*\*] Calendar Quarters, then ITEOS's right to Commercialize in the Profit-Sharing Territory will terminate upon [\*\*\*] notice provided by GSK following such subsequent failures in such subsequent [\*\*\*] Calendar Quarters.
- (c) If there is a good faith dispute with respect to the existence of a material breach or failure or whether such material breach has been remediated or failure has been cured, and if such alleged material breach or failure to cure is contested in good faith by ITEOS in writing within [\*\*\*] after the delivery of the notice of material breach or failure from GSK, then the dispute resolution procedure set forth in Article 16 (Dispute Resolution) may be initiated by ITEOS to determine whether a material breach or failure, or a failure to remediate or cure, has actually occurred. If either Party so initiates such dispute resolution procedure, then the applicable cure period and the corresponding occurrence of the Cost Share End Date, as applicable, will be tolled until such time as the dispute is finally resolved pursuant to Article 16 (Dispute Resolution).
- **6.7.3 Effects of Opt-Out**. If ITEOS has delivered an Opt-Out Notice pursuant to Section 6.7.1 (ITEOS Opt-Out Right), or if ITEOS's right to Commercialize in the Profit-Sharing Territory has terminated pursuant to Section 6.7.2 (Forced Opt-Out), then, notwithstanding any provision to the contrary set forth in this Agreement, the following effects of such opt-out will apply beginning: (i) (A) if delivered during the First No Opt-Out Period, then the later of [\*\*\*] following delivery of the Opt-Out Notice or the day following end of the First No Opt-Out Period, (B) if delivered after the end of the First No Opt-Out Period but prior to Second No Opt-Out Period, then [\*\*\*] following delivery of the Opt-Out Notice, (C) if delivered during or following the Second No Opt-Out Period, then the later of [\*\*\*] following delivery of the Opt-Out Notice or the day following the second No Opt-Out Period, then the later of [\*\*\*] following delivery of the opt-Out Notice of the termination of ITEOS's right



to Commercialize in the Profit-Sharing Territory as set forth in Section 6.7.2 (Forced Opt-Out) ((i) or (ii), as applicable, the "**Cost Share End Date**"):

- sharing of Development Costs incurred in connection with the performance of Shared Global (a) Development Activities under the Global Development Plan and of the Pre-Tax Profit or Loss in the Profit-Sharing Territory in accordance with the relevant provisions of this Agreement will no longer apply with respect to any of the Licensed Antibodies and Licensed Products; provided that ITEOS shall continue to be responsible for its portion of the Development Costs up to the Committed Development Spend that has not yet been expended in connection with the Committed Studies (whether or not such Committed Studies have commenced as of the Cost Share End Date and as these may be amended or replaced with comparable Clinical Trials of similar scope through an update to the Global Development Plan in accordance with Section 3.2.1 (Global Development Plan)) and any other Clinical Trials that the Parties agree to include in the Global Development Plan prior to the Cost Share End Date that can be conducted within the Committed Development Spend; provided, further that the maximum amount of the Committed Development Spend to be incurred by ITEOS is [\*\*\*], and if the Committed Studies and other Clinical Trials that the Parties agreed to include in the Global Development Plan prior to the Cost Share End Date cost less than the Committed Development Spend, then ITEOS shall be responsible for only its portion of such lesser amount;
- (b) with respect to any on-going Additional Development Activities conducted by GSK, the costs of undertaking such Development would not be subject to sharing between the Parties;
- (c) the Net Sales Territory will automatically be amended to include the entire Territory;
- (d) obligations under this Agreement relating solely to the Profit-Sharing Territory, including obligations regarding the preparation and approval of the Joint Commercialization Plan and corresponding Joint Commercialization Budget, will no longer be applicable;
- (e) where the JSC, JCC, or JDC, respectively, had an approval right, such approval right will automatically be converted into a review and comment, but not approval, right.
- **6.7.4 Effects of Forced Opt-Out**. Notwithstanding any provision to the contrary set forth in this Agreement, if ITEOS's right to Commercialize Licensed Products in the Profit-Sharing Territory is terminated pursuant to Section 6.7.2(a), then the effects of opt-out set forth in Section 6.7.3 (Effects of Opt-Out) will apply, except that, (a) [\*\*\*]. If, following ITEOS's right to Commercialize Licensed Products in the Profit-Sharing Territory being terminated pursuant to Section 6.7.2(a), ITEOS delivers an Opt-Out Notice pursuant to Section 6.7.1 (ITEOS Opt-Out Right), then

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all effects of opt-out set forth in Section 6.7.3 (Effects of Opt-Out) will apply in accordance with their terms, and the effects of forced opt-out set forth in this Section 6.7.4 (Effects of Forced Opt-Out) will no longer apply.

**6.8 Commercialization Reporting**. During the Term, with respect to any Medical Affairs and Commercialization activities conducted by or on behalf of either Party with respect to the Licensed Products under this Agreement, within [\*\*\*] following the end of each [\*\*\*], each Party shall prepare and provide to the other Party and the JCC (or the JSC, if the JCC is no longer meeting) a written report that summarizes the material Medical Affairs and Commercialization activities performed with respect to the Licensed Products in the Territory and the status of activities and progress with respect to the information included in each applicable Commercialization Plan, and shall identify any issues or circumstances of which it is aware that may prevent or adversely affect in a material manner its future performance of activities assigned to it under the then-current Commercialization Plans (each, a "**Commercialization Report**"). Solely in the event that, and for so long as, the effects of forced opt-out set forth in Section 6.7.4 (Effects of Forced Opt-Out) apply, the Commercialization Reports provided by GSK to the JSC pursuant to this Section 6.8 (Commercialization Reporting) will include GSK's [\*\*\*] ITEOS's JSC representatives may review, but will have no right to comment on or approve. Each Party will respond to the reasonable questions or requests of the other Party's JCC representatives (or JSC representatives, if the JCC is no longer meeting), as applicable, for additional information relating to such Party's Medical Affairs or Commercialization activities under this Agreement in a timely manner.

### 6.9 Compliance.

- **6.9.1 Establishment of Compliance Program**. The compliance officers (or equivalent personnel) from each Party with responsibility for Commercialization and Medical Affairs (the "**Compliance Officers**") will meet to align on a compliance program applicable to the Licensed Products in the Profit-Sharing Territory, that will include the concepts set forth in this Section 6.9 (Compliance) along with the requirement to perform regular risk assessments relating to the Commercialization and Medical Affairs activities undertaken by the applicable Party in the Profit-Sharing Territory (the "**Compliance Program**"). The Compliance Program will be presented to the JCC for review and discussion. Each Party will ensure that it will perform, and will ensure that each of its Affiliates, Sublicensees, and subcontractors perform, all Commercialization and Medical Affairs activities in a professional and ethical business manner and in compliance with the Compliance Program and the Approved Labeling and each Party will provide appropriate training to its employees, Sales Representatives, Affiliates, Sublicensees and subcontractors on the foregoing, except where GSK provides such training to ITEOS under this Article 6 (Commercialization; Medical Affairs).
- **6.9.2 Compliance Resourcing**. In order to ensure adherence to the Compliance Program across all Commercialization and Medical Affairs activities, each Party will maintain resources sufficient to conduct at least the following activities: (a) assess such Party's compliance with any pre-established criteria set forth in the

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Compliance Program, (b) ensure upward reporting and escalation processes that provide positive assurance regarding the management of significant risks that are communicated to senior leadership or risk oversight committees, (c) provision of training on Commercialization and Medical Affairs activities within the scope of such Party's responsibilities under the applicable Joint Commercialization Plan, including on Applicable Laws, Guidelines and USPPs, as applicable, as set out in this Article 6 (Commercialization; Medical Affairs) (d) monitoring and updating of training programs described under (c), and provision of refresher training on a regular basis, (e) maintenance of a speak-up hotline to report violations of compliance, and (f) conducting robust investigations of any suspected compliance violations by trained independent individuals with relevant functional experience and skill.

- 6.9.3 Applicable Laws and Guidelines. Each Party shall conduct its Commercialization activities under this Agreement in accordance with the requirements of this Agreement, Applicable Laws and Guidelines and shall cooperate with one another in any efforts toward ensuring that government reporting (including price and honoraria reporting), sales, marketing and promotional practices in respect of the Licensed Products meet the standards required by: (a) Applicable Laws; and (b) applicable guidelines concerning the advertising and promotion of prescription drug products, including the Office of the Inspector General's ("**OIG**") Compliance Guidance Program issued in 2003, the American Medical Association (the "AMA") Guidelines on Gifts to Physicians, the Pharmaceutical Research and Manufacturers of America ("PhRMA") Code on Interactions with Healthcare Professionals, as hereafter amended from time to time (the "PhRMA Code"), the PhRMA Principles on Conduct of Clinical Trials and Communication of Clinical Trial Results, and the standards set forth by the Accreditation Council for Continuing Medical Education relating to educating the medical community in the United States ("ACCME Standards"), in each case, to the extent applicable to the Parties' activities hereunder and as may be amended or supplemented from time to time (such guidelines as set forth in this Section 6.9(b), the "Guidelines"). In addition, each Party shall obtain and maintain all licenses, permits, approvals and other authorizations applicable to it in order to enable it to perform its respective obligations hereunder. The Parties shall cooperate in good faith to update their obligations under this Section 6.9 (Compliance) from time to time to reflect any changes in any of the foregoing (a) – (b) or to resolve any conflicts in any of the foregoing standards as applied to the Parties' activities under this Agreement. Each of the Parties agrees and acknowledges that it shall comply, and shall ensure that its applicable Affiliates and its and their respective employees, officers, directors and consultants comply, with the applicable requirements of this Section 6.9.3 (Applicable Laws and Guidelines).
- **6.9.4 Business Practices**. The Parties shall perform all of their Commercialization and Medical Affairs activities undertaken in the Profit-Sharing Territory in accordance with GSK's policies regarding the same, known as of the Effective Date as the US Practices Policies, that are provided to ITEOS by GSK, along with any updates thereto (the "**USPPs**"); *provided* that, with respect to updates to the USPPs, ITEOS



shall use reasonable efforts to give effect to any updates to the USPPs as soon as reasonably practicable following receipt of such updates from GSK. Notwithstanding anything to the contrary in this Agreement, neither Party nor any of its Affiliates shall be required to take, or shall be deemed in breach of this Agreement for not taking, any action that is not in compliance with such Party's Internal Policies (so long as such action is still compliant with Applicable Laws and Guidelines) or that such Party reasonably believes is not in compliance with Applicable Laws, Guidelines or the USPPs.

- **6.9.5 Reporting**. Each Party shall be responsible for calculating, tracking and reporting transfers of value initiated and controlled by its employees or contractors pursuant to its respective obligations under the requirements of Section 6002 (Transparency Reports and Reporting of Physician Ownership and Investment Interest) of the Patient Protection and Affordable Care Act, commonly referred to as the "Sunshine Act", and applicable state marketing reporting laws. Subject to Applicable Laws and Guidelines, the value reported to the Centers for Medicare & Medicaid Services ("CMS") shall be the amount expended by the controlling Party, irrespective of the division of or reconciliation of expenses between the Parties.
- **6.9.6 Information**. Each of GSK and ITEOS shall reasonably cooperate with the other Party to provide the other Party reasonable access to information and reports related to the Licensed Products reasonably required by the other in order to comply with the relevant provisions of the Medicare Modernization Act, as amended from time to time, and any other Applicable Laws and Guidelines, including reporting requirements, in a timely and appropriate manner. Each Party shall ensure that its reporting to CMS and other federal and state healthcare programs related to the Licensed Products is true, complete and correct in all material respects; *provided, however,* that neither Party shall be held responsible for submitting erroneous reports if such deficiencies result from information provided by the other Party which itself was not true, complete and correct. Each Party shall notify the other Party promptly upon becoming aware of any Licensed Product-related inquiries or document requests by any Regulatory Authority, or claims or threatened claims related to the Licensed Product.
- 6.9.7 **Cooperation**. At the request of either Party, the Parties' Compliance Officers will convene for purposes of discussing the Compliance Program and resourcing and to share best practices, and if such discussions result in modifications to the Compliance Program, then such modifications shall be presented to the JCC for accordance Section (Establishment review and discussion in with 6.9.1 of Compliance Program). Notwithstanding the foregoing, if a Party becomes aware of an allegation of a significant violation of Applicable Laws or Guidelines or USPPs, such Party shall promptly investigate and timely notify the other Party's Compliance Officer and General Counsel of the commencement of the investigation. If the investigation is conducted in accordance with the attorney-client privilege, then such notification shall be made pursuant to a joint-defense agreement in order to maintain all attorney-client privilege protections. Such notification shall occur within two (2) Business Days of a Party becoming aware of an allegation of such a violation.

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- **6.9.8** Audit and Monitoring Rights. GSK shall have the following rights with respect to ITEOS's performance of Commercialization and Medical Affairs activities:
  - GSK or its duly authorized Third Party auditor shall upon [\*\*\*] notice and no more frequently than (a) once every [\*\*\*] have the right during normal business hours at a time to be agreed by the Parties for the duration of the Profit-Sharing Term and for a period of [\*\*\*] following the termination or expiration of the Profit-Sharing Term for any reason, to examine and copy such books and records and all other documents and materials in the possession of or under the control of ITEOS relating to the conduct of all Commercialization and Medical Affairs activities undertaken by ITEOS under this Agreement. ITEOS shall ensure that GSK has similar audit rights for any subcontractor used by ITEOS to perform Detailing activities as described in Section 6.12 (Subcontracting). GSK or its third-party auditor shall have access to ITEOS's facilities, shall be allowed to interview current or former employees of ITEOS with respect to the conduct of Commercialization and Medical Affairs activities under of this Agreement, shall have access to all applicable necessary records and shall be furnished adequate and appropriate workspace in order to perform the examinations provided for herein. GSK's costs for any such on-site audit shall be borne by GSK. Notwithstanding the foregoing, where GSK has a good faith belief that a violation of the Compliance Program has occurred or will occur if appropriate actions are not taken then GSK or its duly authorized thirdparty auditor may request an audit with only [\*\*\*] notice regardless of the timing or occurrence of any previous audit; and
  - (b) GSK shall have the right to monitor Sales Representatives and Medical Affairs personnel of ITEOS in the field to assess, *inter alia*, compliance with Applicable Laws, Guidelines and USPPs and to identify gaps or weaknesses in knowledge or application of Applicable Laws, Guidelines and USPPs to the conduct of the applicable activity (the "**Field Monitoring**"). Such Field Monitoring shall be conducted on regular intervals as agreed by the Parties but at least quarterly and shall be at GSK's cost. Notwithstanding the foregoing, where GSK has a good faith belief that that a violation of the Compliance Program has occurred or will occur if appropriate actions are not taken then GSK may request to conduct Field Monitoring outside of the quarterly assessments on only [\*\*\*] notice regardless of the timing or occurrence of any previous Field Monitoring session.
  - (c) Any and all reports from the audits set forth in (a) above or from the Field Monitoring sessions set forth in (b) above shall be shared with ITEOS and discussed by the Compliance Officers as set forth in Section 6.9.7 (Cooperation).

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## 6.10 Marketing.

- 6.10.1 Advertising and Promotional Materials. GSK shall prepare and produce all Marketing Materials (including Promotional Materials) for the Licensed Products in the Territory in accordance with the Global Strategic Launch Plan and the Joint Commercialization Plan and as otherwise agreed by the JCC. ITEOS may also propose Promotional Materials for Licensed Products in the Profit-Sharing Territory in accordance with the Joint Commercialization Plan and as otherwise agreed by the JCC. Each Party will share Promotional Materials with the other Party for consideration, and will reasonably consider the input from the other Party in good faith. Notwithstanding the foregoing, GSK will be solely responsible for legal and regulatory review of all such Marketing Materials (regardless of which Party created such materials) through the GSK standard copy approval process and submission of materials to applicable Regulatory Authorities for comments or approval as required. GSK shall own all rights, title and interests in and to any and all such Marketing Materials (including Promotional Materials). Neither Party shall use any materials other than the Marketing Materials (including Promotional Materials) that have undergone GSK's copy approval process for use in connection with the Commercialization and Detailing of the Licensed Products under this Agreement; provided that ITEOS will not be required to use any Marketing Materials (including Promotional Materials) that ITEOS's compliance team has not also approved. GSK shall be responsible for providing and shipping to ITEOS all Marketing Materials (including Promotional Materials) in quantities necessary for ITEOS to perform its activities under the Joint Commercialization Plan.
- **6.10.2 Branding**. The Marketing Materials (including Promotional Materials) will contemplate branding that acknowledges ITEOS's role in discovering the Licensed Products, [\*\*\*] in the Profit-Sharing Territory where permitted by Applicable Law. GSK will use reasonable efforts to include an agreed-upon standard [\*\*\*].
- **6.10.3 Sales Representatives.** Each Party shall have sole responsibility for all costs and expenses in connection with its own Sales Representatives and its related management, including salaries, travel expenses and other expenses, credentialing, licensing, providing benefits, deducting federal, state and local payroll taxes, Federal Insurance Contributions Act contributions, Federal Unemployment Insurance, State Unemployment Insurance and any similar taxes and paying workers' compensation premiums, unemployment insurance contributions and any other payments required by Applicable Laws to be made on behalf of its employees. Notwithstanding the foregoing, the Parties will share (50:50) Commercial FTE Costs incurred in connection with Commercializing the Licensed Products in the Profit-Sharing Territory as set forth on <u>Schedule 8.3.1</u> (Pre-Tax Profit and Loss Sharing). Nothing in this Agreement shall be construed to conclude that any of a Party's Sales Representatives or any other agents or employees of such Party are agents or employees of the other Party or subject to such other Party's direction and control. Each Party shall have sole authority over the terms and conditions of employment of its own Sales Representatives, including their selection, management, compensation (*provided* that the basis on which Sales



Representatives are compensated shall be aligned between the Parties to ensure compliance with the USPPs) and discharge. Any and all Detailing performed by a Party hereunder shall be tracked using such Party's internal recording of such activity; *provided* that such tracking shall be on the same basis as such Party's measurement for its Sales Representatives detailing of its other products, consistently applied throughout the Term and such tracking will be shared at the JCC for review and discussion to measure compliance with each Party's obligations under the Joint Commercialization Plan.

- **6.10.4 Product Specific Training.** GSK shall be responsible for preparing the initial Licensed Product training programs and materials ("**Product Training Materials**") for both its own Sales Representatives as well as the ITEOS's Sales Representatives, and shall conduct such training programs for all Sales Representatives prior to the launch of the applicable Licensed Product; *provided* that thereafter each Party shall be responsible for, and shall conduct, training programs using the most up-to-date Product Training Materials for its own Sales Representatives who will participate in Detailing the Licensed Product using the Product Training Materials to ensure a consistent, focused promotional strategy between the Parties that is consistent with the Approved Labeling for the applicable Licensed Product. The Product Training Materials will be updated annually taking into account any areas identified through internal monitoring of activities by each Party for enhanced or refreshed training. For the avoidance of doubt, the Product Training Materials will include training on the USPPs. GSK shall own all rights in the Product Training Materials in all formats (*e.g.*, print, video, audio, digital, computer) including all applicable copyrights, trademarks, program names, domain names and Internet sites. Each Party shall be responsible for the performance of its own Sales Representatives.
- **6.11 Product Marks**. GSK shall select, obtain and maintain any Product Marks for Licensed Products. Prior to selecting any Product Marks for Licensed Products, GSK will present the trademarks that it is considering for selection along with any relevant related reports or information to the JCC for review and discussion at a regularly scheduled meeting of the JCC. In addition, upon reasonable request of GSK, ITEOS shall provide reasonable assistance in the selection of Product Marks for a Licensed Product. As between the Parties, GSK shall be the owner of the Product Marks for any Licensed Product. GSK will and hereby does grant ITEOS the right to use such Product Marks, and the Marketing Materials (including Promotional Materials), to perform Medical Affairs activities and to Commercialize the Licensed Products in the Profit-Sharing Territory in accordance with this Agreement and as set forth in the Joint Commercialization Plan.
- **6.12 Subcontracting**. ITEOS may engage a Third Party subcontractor to provide Sales Representatives to conduct Detailing activities solely in accordance with the terms set forth in this Section 6.12 (Subcontracting). ITEOS shall not engage any Third Party subcontractors to perform any of its obligations under the Joint Commercialization Plan without the prior written consent of GSK. Any subcontractor approved by GSK that performs Detailing activities in the Profit-Sharing Territory during the Term prior to the Cost Share End Date will be set forth in the Joint Commercialization Plan and shall meet



the qualifications typically required by GSK for Sales Representatives employed or engaged by GSK. Prior to executing an agreement with a Third Party subcontractor that will perform Detailing activities on behalf of ITEOS hereunder, ITEOS will (a) provide GSK with an opportunity to review and comment on the material terms, (b) ensure that such agreement includes all of the requirements and obligations of Article 6 (Commercialization; Medical Affairs), including compliance, use of materials, training obligations, and ability to terminate in accordance with the provisions of Section 6.7 (ITEOS Opt-Out), and (c) require the Third Party subcontractor to comply with Applicable Law, Guidelines and USPPs and affords GSK the right to audit and perform Field Monitoring with respect to such subcontractor's Detailing activities in substantially the same manner as provided in Section 6.9.8 (Audit and Monitoring Rights). Upon execution of any such contract with such Third Party subcontractor, ITEOS will provide GSK with a copy of such agreement.

#### ARTICLE 7 MANAGEMENT OF THE COLLABORATION

#### 7.1 Joint Steering Committee.

- **7.1.1 Establishment of JSC**. No later than [\*\*\*] after the Effective Date, the Parties shall establish a Joint Steering Committee ("Joint Steering Committee" or "JSC"), which shall be constituted in accordance with Section 7.6 (Membership, Meetings, and Meeting Minutes). The JSC shall operate in accordance with the provisions of Section 7.6 (Membership, Meetings, and Meeting Minutes) and Section 7.7 (Decision-Making). At its meetings, the JSC shall review, discuss and determine whether to approve (as appropriate and necessary), the matters described in Section 7.1.2 (Responsibilities of the JSC) or such other matters as are reasonably requested by either Party.
- **7.1.2 Responsibilities of the JSC**. The JSC shall perform the following functions:
  - (a) oversee and guide the overall strategic direction of the Development Program (but without modifying or limiting the rights or obligations of either Party as otherwise set forth herein);
  - (b) establish, as appropriate, additional Subcommittees or working groups responsible for managing specific aspects of the Development Program as contemplated herein;
  - (c) oversee and supervise the Subcommittees and resolve issues or Disputes elevated to it by the JDC, JCC, Financial Working Group, or any subcommittee the JSC may establish;
  - (d) review, discuss and determine whether to approve the Global Development Plan and Global Development Budgets and all updates thereto, as submitted by the JDC, as described in Section 3.2.1 (Global Development Plan);

- (e) resolve any dispute of the JDC regarding whether any GSK Sole Development Activity raised by ITEOS presents a Material Safety or Commercialization Concern described in Section 1.171(b) or (c) (and excluding Section 1.171(a)), as provided in Section 3.1.2 (Development for the Net Sales Territory);
- (f) resolve any dispute of the JDC regarding whether any Development activity set forth in an Additional Development Proposal and raised by either Party presents a Material Safety or Commercialization Concern, described in Section 1.171(b) or (c) (and excluding Section 1.171(a)), as provided in Section 3.5.2 (Material Adverse Development);
- (g) review, discuss and determine whether to approve Additional Development Proposals, as described in Section 3.4.1 (Additional Development Proposals);
- (h) review, discuss and comment on the Global Strategic Launch Plan and updates thereto, as described in Section 6.1 (Global Strategic Launch Plan);
- review, discuss and determine whether to approve the Joint Commercialization Plan and Joint Commercialization Budget and all updates thereto, as submitted by the JCC, as described in Section 6.2 (Joint Commercialization Plans);
- (j) resolve any disputes of the JCC regarding whether any Medical Affairs or Commercialization activity set forth in a Global Strategic Launch Plan and raised by ITEOS presents a Material Safety or Commercialization Concern, described in Section 1.171(b) or (c) (and excluding Section 1.171(a)), as provided in Section 6.1 (Global Strategic Launch Plan);
- (k) coordinate with the Financial Working Group, JDC or JCC, as appropriate, with respect to the reconciliation or approval, as applicable, of Development Costs, Development Excess Costs, Commercialization Excess Costs, and the Pre-Tax Profit or Loss;
- (l) provide a forum for GSK to update ITEOS on key [\*\*\*] in major countries or regions in the Net Sales Territory, with respect to each Licensed Product; and
- (m) perform such other functions as are assigned to the JSC in this Agreement, or otherwise agreed by the Parties in writing.
- **7.1.3 Term of the JSC**. The JSC shall meet in accordance with Section 7.6.2 (Meetings) for the Term.

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#### 7.2 Joint Development Committee.

- **7.2.1 Establishment of the JDC**. No later than [\*\*\*] after the Effective Date, the Parties shall establish a joint development committee (the "Joint Development Committee" or "JDC") to oversee the conduct of, and coordinate the Parties' activities with respect to the Development of Licensed Antibodies and Licensed Products under this Agreement (the "Development Program"), and coordinate on the execution of the Global Development Plan (in accordance with the Global Development Budget).
- **7.2.2 Responsibilities of the JDC**. The JDC shall perform the following functions for the Development Program:
  - (a) oversee, review, discuss and coordinate the conduct and progress of the Development activities (including Manufacturing-related Development activities) of the applicable Licensed Antibody or Licensed Product, as described in the Global Development Plan (in accordance with the Global Development Budget), as well as any identified issues or circumstances that may prevent or adversely affect in a material manner a Party's future performance of activities assigned to it under the then-current Global Development Plan;
  - (b) review, discuss, and propose modifications to, the Global Development Plan and Global Development Budgets and all updates thereto, and submit such plans, budgets, and updates to the JSC for approval, as described in Section 3.2 (Global Development Plan);
  - (c) determine whether any GSK Sole Development Activity raised by ITEOS presents a Material Safety or Commercialization Concern, as described in Section 3.1.2 (Development for the Net Sales Territory);
  - (d) review and discuss the Data from Proof of Concept Trials conducted by a Party as Additional Development Activities and determine whether to amend the Global Development Plan to include the remainder of the applicable Additional Development Activities, as further described in Section 3.4.3(b) (Proof of Concept Data);
  - (e) determine whether any Development activity set forth in an Additional Development Proposal and raised by either Party presents a Material Safety or Commercialization Concern, as described in Section 3.5.2 (Material Adverse Development);
  - (f) review and discuss Additional Development Proposals, as described in Section 3.4.1 (Additional Development Proposals) and Section 3.5.3 (Limitation On Third Party Combinations) and Data and intellectual property arising out of Additional Development Activities, as described in Section 3.4.3(a) (Independent Development Activities);



- (g) discuss and develop a remediation strategy for material deficiencies regarding animal care and welfare, as described in Section 3.11.6.
- (h) review the compliance plan submitted to the JDC pursuant to Section 3.13 (R&D Ethics & Compliance) and agree to any modifications, and document the final agreed Development compliance plan in the JDC minutes;
- (i) oversee the implementation of the Global Development Plan, and monitor whether activities thereunder are performed in accordance with the timelines set forth therein and the terms set forth in Article 3 (Development Program);
- (j) review and discuss Data and information arising from Development activities for the Licensed Antibodies and Licensed Products, including Additional Development Activities, undertaken under this Agreement;
- (k) review and discuss regulatory matters relating to Development activities for the Licensed Antibodies and Licensed Products, including Additional Development Activities, undertaken under this Agreement and oversee the implementation of, and discuss progress regarding, the regulatory strategy set forth in the Global Development Plan;
- (l) coordinate with the Financial Working Group with respect to the reconciliation of Development Costs, and review and determine whether to approve Excess Development Costs and other budget overruns in consultation with the Financial Working Group, in accordance with Section 8.2 (Sharing of Development Costs);
- (m) review and discuss Development Reports;
- in consultation with the Financial Working Group, oversee CMC Development, supply chain strategy, establishment of Manufacturing sources, capacity, supply chains, and Manufacture of Licensed Antibodies and Licensed Products, as described in Section 5.1.1 (JDC Oversight; Efforts);
- (o) prepare and determine whether to approve the Manufacturing Tech Transfer Plan (including choosing the format and media for such transfer) and manage and oversee the transfer of Know-How set forth in the Manufacturing Tech Transfer Plan, as described in Section 5.2 (Manufacturing Technology Transfer);
- (p) prepare the Publication Strategy, and, with consultation from the Patent Liaisons, where applicable, review and approve such Publication Strategy, and amend it from time to time upon agreement of the Parties, as described in Section 10.8.1 (Publication Strategy); and

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- (q) perform such other functions as are specifically designated to the JDC in this Agreement, or as the Parties otherwise agree in writing are appropriate to further the purposes of this Agreement.
- **7.2.3 Term of the JDC**. The JDC for the Development Program shall meet in accordance with Section 7.6.2 (Meetings) for so long as GSK and ITEOS are sharing Development Costs under the Global Development Plan. Following the Cost Share End Date, any [\*\*\*], and any responsibilities of the [\*\*\*].
- **7.3 Joint Commercialization Committee**. The JCC shall perform the following functions:
  - **7.3.1 Establishment of JCC**. No later than the [\*\*\*] for a Licensed Product, the JSC will establish a joint commercialization committee (a "Joint Commercialization Committee" or "JCC") for the Licensed Products. The JCC will be composed of both medical and commercial representatives from each Party. It is expected that the JCC will create a collaborative forum for sharing of information and robust discussions and input on the activities set forth in Section 7.3.2 (Responsibilities of the JCC), as well as Shared Commercialization Activities. Such information and activities are expected to include, for example, [\*\*\*].

## 7.3.2 **Responsibilities of the JCC**.

- (a) review, discuss and, solely with respect to medical representatives on the JCC, propose modifications to, the Medical Affairs activities set forth in the Joint Commercialization Plan and all updates thereto, as described in Section 6.2 (Joint Commercialization Plan);
- (b) review, discuss and recommend modifications to, each Joint Commercialization Plan (including the Joint Commercialization Budget therein), and all updates thereto, and submit such Joint Commercialization Plans and updates to the JSC to review, discuss, and determine whether to approve, as described in Section 6.2 (Joint Commercialization Plan);
- (c) review, discuss and comment on the Global Strategic Launch Plan and updates thereto, as described in Section 6.1 (Global Strategic Launch Plan);
- (d) discuss and determine whether any Medical Affairs or Commercialization activity set forth in a Global Strategic Launch Plan raised by ITEOS may reasonably give rise to a matter covered in Section 1.171(b) or (c) (Material Safety or Commercialization Concern), as described in Section 6.1 (Global Strategic Launch Plan);
- (e) review and discuss the details regarding the [\*\*\*] for each Licensed Product in the major countries of the Net Sales Territory provided by GSK to the JCC in advance, as described in Section 6.3.1 (Net Sales Territory);



- (f) review and discuss the material Medical Affairs and Commercialization activities performed with respect to Licensed Products in the Territory and the status of activities and progress with respect to the information included each applicable Commercialization Plan, and any issues or circumstances which may prevent or adversely affect in a material manner a Party's future performance of activities assigned to it under the then-current Commercialization Plans;
- (g) review and discuss each Commercialization Report;
- (h) review and discuss each Detailing tracking report, as described in Section 6.10.3 (Sales Representatives);
- (i) review and discuss the Compliance Program submitted to the JCC pursuant to Section 6.9.1 (Establishment of Compliance Program);
- (j) [\*\*\*] prior to GSK's selection thereof, and related materials, as described in Section 6.11 (Product Marks); and
- (k) The JCC shall liaise with the Financial Working Group with respect to the calculation of the Pre-Tax Profit or Loss and shall perform such other functions as the Parties may agree in writing are appropriate to further the purposes of this Agreement.
- **7.3.3 Term of the JCC**. The JCC shall meet in accordance with Section 7.6.2 (Meetings) during the Term prior to the Cost Share End Date. Following the Cost Share End Date, [\*\*\*].
- **Financial Working Group**. No later than [\*\*\*] after the Effective Date, the Parties will establish a financial working 7.4 group subcommittee ("Financial Working Group"), which shall work with the JDC, the JCC and the JSC, and will be responsible for (a) initially reviewing all budgets included as part of each Global Development Plan and each Joint Commercialization Plan, (b) establishing the FTE Rate with respect to Commercialization activities hereunder, (c) agreeing upon a new [\*\*\*] when required as set forth in Section 1.181 (Net Sales), (d) agreeing upon any reasonably allocable costs to be included in Development Costs, Manufacturing Costs, or Allowable Expenses hereunder, (e) overseeing the operational aspects of all co-funding and payment activities under this Agreement, and (f) such other responsibilities expressly assigned to the Financial Working Group under this Agreement. The Financial Working Group shall include individuals from each Party with reasonable expertise in the areas of accounting, cost allocation, budgeting and financial reporting. The Parties shall determine the appropriate number of representatives of each Party that will constitute the Financial Working Group, which shall be an equal number, and the frequency of meetings thereof. Each Party shall designate their respective initial representatives to the Financial Working Group to allow such Financial Working Group to begin organizing information for the initial meetings of the JDC and the JSC. The Financial Working Group shall operate generally in accordance with the provisions of Section 7.6 (Membership, Meetings, and Meeting Minutes). The

Financial Working Group shall meet in accordance with Section 7.6.2 (Meetings) for so long as either (i) the Parties are engaging in sharing of Development Costs for the Development Program, or (ii) ITEOS Commercializes the Licensed Products with GSK or its Affiliates in the Profit-Sharing Territory or shares Pre-Tax Profit or Loss with GSK hereunder.

**7.5 Other Subcommittees.** From time to time, the JSC may establish other subcommittees of the JSC to oversee particular projects or activities under this Agreement, and such subcommittees shall be constituted and have such responsibility as the JSC approves (such subcommittees, along with the other subcommittees established hereunder (each referred to herein as a "**Subcommittee**")). The Subcommittees shall operate in accordance with the provisions of Section 7.6 (Membership, Meetings, and Meeting Minutes), and shall have no authority to alter or amend the terms and conditions of this Agreement.

#### 7.6 Membership, Meetings and Meeting Minutes.

- 7.6.1 **Membership**. Except as otherwise stated herein, each Committee shall be composed of [\*\*\*] representatives (or such other equal number of representatives as the Parties may agree) from each of ITEOS and GSK. Either Party may replace its respective Committee representatives at any time with prior written notice to the other Party, provided that such replacement is of comparable authority and scope of functional responsibility within that Party's organization as the person he or she is replacing. Each Partv's representatives to each Committee shall be individuals suitable in seniority, experience, and relevant decisionmaking authority to make decisions within the scope of the applicable Committee's responsibilities; provided that it is understood that such representatives may need to seek appropriate authority from the relevant Party with respect to certain matters. For each Committee, each Party shall designate one of its representatives on such Committee to co-chair the meetings for such Committee (each, a "Co-Chair"). The Co-Chairs shall coordinate and prepare the agenda for, and ensure the orderly conduct of, the meetings of such Committee and solicit applicable items from Committee members and provide an agenda, along with appropriate information, reasonably in advance of any meeting. Such agenda shall include all items requested by either Co-Chair for inclusion therein. If the Co-Chairs or another Committee member from either Party is unable to attend or participate in a meeting of such Committee, then the Party whose Co-Chair or member is unable to attend may designate a substitute co-chair or other representative for the meeting, provided that such substitute is of comparable authority and scope of functional responsibility within that Party's organization as the person he or she is substituting. The Alliance Managers shall assist the Co-Chairs of the JSC with respect to the foregoing activities, and attend all meetings of the JSC as non-voting members; provided that attendance by the Alliance Manager does not count towards either Party's representation on the JSC.
- **7.6.2 Meetings.** During the Term, the JSC shall meet [\*\*\*] (or more or less frequently as agreed by the Parties in writing). JSC meetings may be called at other times to resolve Committee Deadlocks in accordance with Section 7.7.1 (Committee Decision-Making). At least one JSC meeting per year will be in-person, unless the

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Parties agree to meet by an alternative mechanism (*e.g.*, telephone or videoconference). The JDC, JCC, the Financial Working Group and other Subcommittees, if any, shall each meet at least quarterly after the Subcommittee is formed, or as more or less often as otherwise agreed by the Parties in writing. Committee meetings may be conducted by telephone, videoconference or in person. Any in-person Committee meetings shall be held on an alternating basis between ITEOS's and GSK's facilities, unless otherwise agreed by the Parties in writing. Each Party shall be responsible for its own expenses in attending such meetings and those expenses will not be included in Development Costs or Allowable Expenses hereunder. As appropriate, the Committee may invite a reasonable number of non-voting employees, consultants, and scientific advisors to attend its meetings as nonvoting observers, *provided* that such invitees are bound by appropriate confidentiality obligations substantially similar to the ones set forth in this Agreement. Each Party may also call for special meetings of a Committee to discuss matters requested by such Party. The Alliance Managers shall provide the members of the JSC with no less than [\*\*\*] notice of each regularly scheduled meeting and, to the extent reasonably practicable under the circumstances, no less than [\*\*\*] notice of any special meetings of the JSC called by either Party.

7.6.3 **Meeting Minutes**. Minutes will be kept of all Committee meetings. Minutes will be sent to all members of the Committee by e-mail for review and approval within [\*\*\*] after each meeting. The Alliance Managers will be responsible for taking and circulating minutes of each JSC meeting and for all other Committees the Co-Chairs will be responsible for taking and circulating minutes, in each case on an alternating basis for each meeting (commencing with the Alliance Manager of GSK and the Co-Chair of each other Committee designated by GSK). If a Party's Alliance Manager (or his or her designee) is not present at a JSC meeting and that Party is responsible for keeping minutes, such Party shall designate one of its JSC members to keep minutes. Minutes shall record all action items and decisions of the applicable Committee. The Committee shall formally accept the minutes of the previous Committee meeting at or before the next Committee meeting. Minutes will be deemed approved unless any member of the Committee objects to the accuracy of such minutes by providing written notice to the other members of the Committee prior to the next meeting of such Committee. Minutes shall list action items and shall designate any issues that need to be resolved by the JSC (or applicable escalation process as set forth in this Agreement). In the event of any such objection to the minutes that is not resolved by agreement of the Parties, such minutes will be amended to reflect the details of such unresolved dispute.

## 7.7 Decision-Making.

**7.7.1 Committee Decision Making.** Decisions of each Committee shall be made by unanimous vote, with each Party having one vote. In order to make any decision, any Committee must have present (in person or via telephone or videoconference) at least one representative of each Party. Except as otherwise expressly set forth in this Agreement, the phrase "determine," "designate," "agree upon," "approve," or "determine whether to approve" by the JSC, JDC, JCC, Financial Working Group,

or any Subcommittee and similar phrases used in this Agreement will mean approval in accordance with this Section 7.7 (Decision-Making), including the escalation and tie-breaking provisions herein. For the avoidance of doubt, matters that are specified in Section 7.1.2 (Responsibilities of the JSC), Section 7.2.2 (Responsibilities of each JDC), 7.3.2 (Responsibilities of the JCC) to be reviewed, discussed, and commented on (as opposed to reviewed, discussed, and approved) do not require any agreement or decision by the JSC, JDC, JCC, Financial Working Group, or any Subcommittee, as applicable, and are not subject to the voting and decision-making procedures set forth in this Section 7.7 (Decision-Making). Unless otherwise specified by the JSC, in the event that the JDC, JCC, the Financial Working Group or any other Subcommittee cannot or does not reach consensus with respect to a particular matter within the authority of such Subcommittee (a "**Subcommittee Deadlock**") after endeavoring for [\*\*\*] days to agree, such matter shall be referred to the JSC for discussion and attempted resolution. In the event that the JSC does not reach a decision with respect to a Subcommittee Deadlock, or if the JSC cannot or does not reach consensus with respect to any other matter within its authority, in each case, after endeavoring for [\*\*\*] days to agree, then such matter (a "**Committee Deadlock**") shall be decided in accordance with Section 7.7.2 (Resolution of Committee Deadlocks).

- **7.7.2 Resolution of Committee Deadlocks.** Each Committee Deadlock shall be submitted by either Party to the Senior Executives of both Parties. The Senior Executives of each Party shall attempt to resolve such Committee Deadlock within [\*\*\*] days of submission. If the Senior Executives cannot resolve the Committee Deadlock within such [\*\*\*]-day period, then, such Committee Deadlock shall be resolved as follows:
  - (a) **No Change; Status Quo**. Neither Party will have final decision-making authority with respect to any Committee Deadlocks regarding [\*\*\*], which will require agreement of the Parties to make any change from the then-current *status quo*.
  - (b) **GSK Final Decision Making Authority**. GSK will have the right to make the final decision regarding [\*\*\*].
  - (c) **Resolution of Material Concerns.** If the Parties disagree as to whether an activity may result in a Material Safety or Commercialization Concern and the Senior Executives were not able to agree on a resolution pursuant to Section 7.7.2 (Resolution of Committee Deadlocks), as applicable, then [\*\*\*].
- **7.7.3 Day-to-Day Decision-Making Authority**. Each Party shall have decision making authority with respect to the day-to-day operational and tactical activities of such Party (and such Party's employees, agents and subcontractors) under this Agreement, provided that such decisions are not inconsistent with the terms and conditions of this Agreement (including any Global Development Plan or



Commercialization Plan) or the decisions and actions of the JSC, the JDC, the JCC, Financial Working Group or any other Subcommittee, as applicable.

- **7.7.4 Limitation of Powers**. Each Committee will have only the powers as are specifically delegated to it under this Agreement. The JSC is not a substitute for the rights of the Parties under this Agreement and is intended to coordinate and facilitate the activities of the Parties. The JSC will not be involved with the day-to-day management of activities to be performed by a Party under this Agreement. Matters explicitly reserved to the consent, approval or other decision-making authority of one or both Parties, as expressly provided in this Agreement, are outside the jurisdiction and authority of the JSC, including amendment, modification or waiver of compliance with the Agreement, which shall be made by the Parties only in accordance with Section 17.10 (Entire Agreement). The JSC, the JDC, the JCC, the Financial Working Group, and the Subcommittees will not have the power to: (a) with respect to the calculation or reconciliation of Development Costs and the Pre-Tax Profit or Loss, which for clarity any disagreement by a Committee or by the Parties with respect thereto shall be resolved in accordance with Sections 8.17 (Resolution of Financial Disputes) and 8.18 (Specific Finance Disputes); (b) resolve disputes arising out of the interpretation of this Agreement, which for clarity shall be resolved in accordance with Article 16 (Dispute Resolution); or (c) alter or amend the terms and conditions of this Agreement, or waive compliance with this Agreement.
- **7.8** Alliance Managers. Promptly following the Effective Date, each Party shall designate an individual to serve as the main point of contact for each Party to exchange information, facilitate communication and coordinate the Parties' activities hereunder (each, an "Alliance Manager"). The Alliance Managers shall attend the meetings of the JSC. For all other Committees, the Alliance Managers may participate in meetings but are not required to participate. The Alliance Managers shall not be counted as members of any Committee (and shall not vote on matters discussed at any Committee meeting). Each Party may change its designated Alliance Manager from time to time upon written notice to the other Party.
- **7.9 Patent Liaisons**. No later than [\*\*\*] after the Effective Date, the Parties shall each designate representative(s) to consult with the other Party's representative(s) with respect to Patent prosecution, maintenance, enforcement and defense matters (the "**Patent Liaisons**") as more fully described in this Section 7.9 (Patent Liaisons). The Patent Liaisons shall discuss, at such times, places and frequencies as either Patent Liaison determines is necessary, material issues and provide input to each other regarding determination of inventorship of Know-How hereunder, and the prosecution, maintenance, enforcement or defense of Patents included in the ITEOS Technology, Joint Arising Technology as more fully described in Article 11 (Intellectual Property). All final decisions related to the prosecution, maintenance, enforcement or defense of any Patents included in the ITEOS Technology, Joint Arising Technology or GSK Technology shall be made by the Party with the right to control such prosecution, maintenance, enforcement or defense, as applicable, as set forth in Article 11 (Intellectual Property) and subject to the terms and conditions therein.



#### ARTICLE 8 FINANCIAL PROVISIONS

**8.1 Upfront Payment**. In partial consideration of the licenses granted to GSK under Section 9.1 (License Grant to GSK), GSK shall pay ITEOS Six Hundred Twenty-Five Million Dollars (\$625,000,000.00) within [\*\*\*] after the Effective Date and upon receipt of a valid invoice from ITEOS. Such payment shall be non-creditable and non-refundable.

### 8.2 Sharing of Development Costs.

- 8.2.1 Reports; Reconciliation Payments. Subject to this Section 8.2 (Sharing of Development Costs), with respect to Development Costs incurred by the Parties in connection with the performance of activities under the Global Development Plan, within [\*\*\*] days following the end of each Calendar Quarter during which any such Development Costs are incurred, each of ITEOS and GSK (as applicable), in accordance with its Accounting Standards, shall submit to the Financial Working Group a written report setting forth in reasonable detail all Development Costs incurred by each such Party over such Calendar Quarter, provided, *however*, that a preliminary estimate of the Development Costs, in a format agreed by the Financial Working Group, shall be provided by each of ITEOS and GSK by the [\*\*\*] of each Calendar Quarter for purposes of financial statement close process. For clarity, such estimate may be based on forecasted numbers and the Parties agree that the final actual amounts may differ from this estimate. Within [\*\*\*] Business Days following the receipt by the Financial Working Group of such written reports setting forth the actual amounts of Development Costs incurred by each Party, the Financial Working Group shall prepare and submit to each Party a written report setting forth in reasonable detail (i) the calculation of all such Development Costs incurred by both Parties over such Calendar Quarter and any deviations from the Global Development Budget, and (ii) the calculation of the net amount owed by GSK to ITEOS or by ITEOS to GSK in order to ensure the appropriate sharing of such Development Costs in accordance with Section 3.2.3 (Shared Development Costs). The Party that is due for reimbursement of Development Costs shall invoice the other Party within [\*\*\*] Business Days of receipt of such report from the Financial Working Group. Such payments by one Party to reimburse the other Party's expenditures for Development Costs shall be payable [\*\*\*] days following receipt of the invoice. Any Development Costs incurred in excess of the agreed upon Global Development Budget in any Calendar Quarter will be subject to the terms set forth in Section 8.2.2 (Overruns).
- **8.2.2 Overruns**. Each Party shall notify the other Party promptly upon becoming aware that the anticipated Development Costs to be incurred by such Party under the Global Development Plan for a given Calendar Year shall be in excess of the applicable approved Global Development Budget. Thereafter, the following shall apply:
  - (a) Following such notification, the Financial Working Group, in consultation with the JDC (as and if needed), shall discuss the causes of any such

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increase and evaluate potential mitigation measures to prevent a further increase of Development Costs. To the extent, based on this discussion, that the Financial Working Group concludes that the anticipated amount of the Development Costs is likely not to exceed [\*\*\*] of the amounts budgeted for a given Calendar Year (the "**Permitted Overage**") as set forth in the then-current applicable Global Development Budget, such anticipated or actual Development Costs shall be included in the calculation of the applicable Development Costs for the purposes of determining the amounts to be paid from one Party to the other Party to reflect the sharing percentages set forth in Section 3.2.3 (Shared Development Costs), *provided* that such costs are not incurred as a result of any breach of this Agreement by a Party.

- (b) If the Financial Working Group, in consultation with the JDC, concludes that the anticipated amount of the applicable Development Costs is likely to exceed the Permitted Overage (such amount the "**Development Excess Costs**") and there are no mitigation measures to prevent such Development Excess Costs, then such Development Excess Costs shall not be included in the calculation of the Development Costs and shall be borne by the Party incurring them, unless agreed by the Parties through the JSC to be shared. Notwithstanding the foregoing, to the extent that Development Excess Costs are directly attributable to a change in Applicable Laws, a requirement of a Regulatory Authority, a change required to mitigate a safety issue or a Force Majeure event, or are otherwise agreed by the Parties, then such costs shall not be borne solely by the Party incurring them and shall be included in the calculation of Development Costs for the purposes of determining the amounts to be paid from one Party to the other Party for the applicable Calendar Year.
- (c) **Budget Carry Forward**. To the extent the Development Costs for a given Calendar Year are less than the Development Costs included in the Global Development Budget for such Calendar Year, because Development activities planned for such Calendar Year have been delayed to a subsequent Calendar Year, the Financial Working Group shall agree upon an appropriate adjustment to the Global Development Budget for subsequent Calendar Years to reflect such delay (but without increasing the total cumulative Development Costs under the Global Development Budget).
- **8.2.3 Reimbursement for Additional Development**. With respect to any reimbursement of Out-Of-Pocket Costs, Development FTE Costs, and Manufacturing Costs, and the corresponding premium, required by Section 3.4.3(b) (Proof of Concept Data) or Section 3.4.3(c) (Receipt of Regulatory Approval), following the end of the Calendar Quarter during which either the JDC determines to add further Additional Development Activities to the Global Development Plan following completion of a Proof of Concept Trial or receipt of Regulatory Approval with respect to such Additional Development Activities, as applicable, ITEOS or GSK (as applicable), in accordance with its Accounting Standards, shall submit to the Financial Working Group a written report setting forth in reasonable detail all



Out-Of-Pocket Costs, Development FTE Costs, and Manufacturing Costs required to be reimbursed in accordance with 3.4.3(b) (Proof of Concept Data) or Section 3.4.3(c) (Receipt of Regulatory Approval), as applicable. Within [\*\*\*] Business Days following the receipt by the Financial Working Group of such written reports setting forth the actual amounts of such reimbursable Out-Of-Pocket Costs, Development FTE Costs, and Manufacturing Costs incurred by a Party, the Financial Working Group shall prepare and submit to each Party a written report setting forth in reasonable detail (i) the calculation of all such reimbursable Out-Of-Pocket Costs, Development FTE Costs, and Manufacturing Costs and any deviations from the budget set forth in the applicable Additional Development Proposal, and (ii) the calculation of the net amount owed by GSK to ITEOS or by ITEOS to GSK in order to ensure the appropriate reimbursement of Out-Of-Pocket Costs, Development FTE Costs, and Manufacturing Costs and the corresponding premium in accordance with Section 3.4.3(b) (Proof of Concept Data) or Section 3.4.3(c) (Receipt of Regulatory Approval), as applicable. The Party that is due for reimbursement shall invoice the other Party within [\*\*\*] Business Days of receipt of such report from the Financial Working Group. Such payments by one Party to reimburse the other Party's expenditures for such Additional Development Activities shall be payable on the [\*\*\*] following receipt of the invoice. Any Out-Of-Pocket Costs, Development FTE Costs, and Manufacturing Costs incurred in excess of [\*\*\*] the budget set forth in the applicable Additional Development Proposal will be the responsibility of the proposing Party.

### 8.3 Pre-Tax Profit or Loss Sharing.

Pre-Tax Profit or Loss. Subject to Section 6.7 (ITEOS Opt-Out), in partial consideration for the licenses 8.3.1 granted to GSK under Section 9.1 (License Grant to GSK), the Parties shall share, on a Licensed Product-by-Licensed Product basis, the Pre-Tax Profit or Loss in the Profit-Sharing Territory with respect to the Licensed Antibodies and Licensed Products, as follows: ITEOS shall bear (and be entitled to) fifty percent (50%), and GSK shall bear (and be entitled to) fifty percent (50%), commencing in the earlier to occur of the first Calendar Quarter in which either Party incurs any Allowable Expenses or the First Commercial Sale of a Licensed Product occurs in the Profit-Sharing Territory (the "Cost Share Start Date") and continuing until the Cost Share End Date. Procedures for reporting, quarterly reconciliation and other finance and accounting matters will be as set forth in this Section 8.3 (Pre-Tax Profit or Loss Sharing) and the Pre-Tax Profit or Loss Schedule. Any Balancing Payment made by GSK to ITEOS to effectuate the sharing of Pre-Tax Profit or Loss in the Profit-Sharing Territory set forth in this Section 8.3.1 (Pre-Tax Profit or Loss) will be considered a royalty paid in partial consideration for the licenses granted to GSK under Section 9.1 (License Grant to GSK) hereunder, and any Balancing Payment made by ITEOS to GSK to effectuate the sharing of Pre-Tax Profit or Loss in the Profit-Sharing Territory set forth in this Section 8.3.1 (Pre-Tax Profit or Loss) will be considered a royalty rebate paid by ITEOS.

- **Reporting Generally**. Beginning with the Cost Share Start Date, within [\*\*\*] days after the end of each 8.3.2 Calendar Quarter, each Party shall provide to the Financial Working Group a report of its calculation of actual Pre-Tax Profit or Loss with respect to such Licensed Product for such Calendar Quarter (each, a "Financial **Report**"), in such reporting format as the Financial Working Group shall establish for use, which reporting format shall be consistent with the categories calculated by the reporting Party in accordance with its Accounting Standards; provided, that the Financial Report of a Party's calculation of Pre-Tax Profit or Loss for the Calendar Quarter that is the Cost Share Start Date will include the first Allowable Expenses incurred by such Party with respect to such Licensed Product, provided, however, that a preliminary estimate of the Allowable Expenses, in a format agreed by the Financial Working Group, shall be provided by each of ITEOS and GSK by the [\*\*\*] of each Calendar Quarter for purposes of financial statement close process. Each Financial Report shall specify in reasonable detail any Net Sales, Other Income or Allowable Expenses for such Licensed Product in the corresponding Calendar Quarter received and incurred by the reporting Party or any of its Affiliates, Sublicensees or subcontractors in accordance with this Agreement in such Calendar Quarter. If requested by the other Party or by the Financial Working Group, the reporting Party will provide invoices or other supporting documentation within a reasonable time period on reasonable level of detail to permit the other Party to confirm the accuracy of the reported cost, provided that a minimum threshold of [\*\*\*] per line item will be applied to such a request.
- **8.3.3** Net Sales Reporting. Without limiting the generality of Section 8.3.2 (Reporting Generally) or Section 8.7.6 (Royalty Reporting), within [\*\*\*] days after the end of each Calendar Quarter, beginning with the first Calendar Quarter in which the First Commercial Sale of such Licensed Product occurs, GSK shall provide the Financial Working Group with a report of the Net Sales for the preceding Calendar Quarter on a Licensed Product-by-Licensed Product for the Profit-Sharing Territory. The Financial Working Group may agree from time-to-time on the form and level of detail of such report.
- **8.3.4** Flash Sales Reports. As soon as reasonably practicable, but in no event later than the [\*\*\*] after the end of each Calendar Quarter, on a Licensed Product-by-Licensed Product basis, beginning with the Calendar Quarter in which the First Commercial Sale of such Licensed Product occurs, GSK will provide to the Financial Working Group a flash report providing a good faith, non-binding estimate of Net Sales accrued during the respective Calendar Quarter in the Profit-Sharing Territory. Such flash report shared prior to public announcement would be provided to ITEOS on a strictly confidential basis such that it will only be available to the Financial Working Group. The flash report may be based on forecasted numbers and the Parties agree that the final Net Sales reported in the Financial Reports for reconciliation may differ from these flash sales reports.

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#### 8.3.5 **Reconciliation and Payment**.

- (a) Reconciliation Discussion. In the event that either Party has any questions or concerns regarding the Development Costs or calculation of Pre-Tax Profit or Loss reported by the other Party in a Financial Report pursuant to Section 8.2.1 (Reports; Reconciliation Payments) and Section 8.3.2 (Reporting Generally), the Financial Working Group shall endeavor to resolve such questions and concerns of either Party within [\*\*\*] days after the end of each Calendar Quarter. Additionally, the Financial Working Group may by mutual agreement adjust the timing for notification or payment of any reconciliation payments hereunder.
- (b) Quarterly Reconciliation Payment. Unless such timing is otherwise modified by the Financial Working Group, within [\*\*\*] Business Days after receipt of each Party's Financial Report provided pursuant to Section 8.2.1 (Reports; Reconciliation Payments) or Section 8.3.2 (Reporting Generally), as applicable, the Financial Working Group shall confer and agree in writing on a reconciliation report setting out the calculation of any payment to be paid by ITEOS to GSK or by GSK to ITEOS, as the case may be, ("Balancing Payment") in order to effect the sharing of Development Costs in accordance Sections 8.2.1 (Reports; Reconciliation Payments) and the sharing of Pre-Tax Profit or Loss in accordance with Section 8.3.1 (Pre-Tax Profit or Loss). Within [\*\*\*] Business Days of receipt of such report from the Financial Working Group, each Party that is owed a Balancing Payment shall invoice the other Party for the amount of the Balancing Payment due and the other Party shall pay such invoiced amount within [\*\*\*] days after delivery of such invoice; provided that, in the event of any dispute regarding the Balancing Payment due, the undisputed portion of such Balancing Payment shall be paid in accordance with the foregoing timetable by the applicable Party, and the remaining, disputed portion shall be paid in accordance with Sections 8.17 (Resolution of Financial Disputes) and 8.18 (Specific Finance Disputes) of the Agreement.
- (c) **Overruns**. Each Party shall notify the other Party promptly after becoming aware that the anticipated Allowable Expenses to be incurred by such Party for a Licensed Product for a given Calendar Year shall be in excess of the applicable approved Joint Commercialization Budget for such Licensed Product for such Calendar Year. Following such notification, the Financial Working Group shall discuss the causes of any such increase and evaluate potential mitigation measures to prevent a further increase of Allowable Expenses, as applicable. To the extent, based on this discussion, the Financial Working Group mutually concludes that the anticipated amount of Allowable Expenses is likely not to exceed [\*\*\*] of the amounts budgeted (the "**Commercialization Permitted Overage**") to be incurred by or on behalf of such Party for its activities for the Licensed Product in such Calendar Year as set forth in the then-current applicable Joint Commercialization Budget, then such anticipated costs or expenses shall be

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included in the calculation of the applicable Allowable Expenses for the purposes of calculating the Pre-Tax Profit or Loss hereunder.

- (d) If the Financial Working Group, in consultation with the JSC, concludes that the anticipated amount of the applicable Allowable Expenses is likely to exceed the Commercialization Permitted Overage (such amount the "**Commercialization Excess Costs**") and there are no mitigation measures to prevent such Commercialization Excess Costs, then such Commercialization Excess Costs shall not be included in the calculation of the applicable Allowable Expenses for the purposes of calculating the Pre-Tax Profit or Loss, unless agreed by the Parties through the JSC to be shared. However, to the extent that Commercialization Excess Costs are directly attributable to and required by a change in Applicable Laws, a requirement of a Regulatory Authority, a change reasonably required to mitigate a safety issue or a Force Majeure event, or are otherwise agreed by the Parties, then such Commercialization Excess Costs shall not be borne solely by the incurring Party and shall be included in the calculation of the applicable Allowable Expenses.
- (e) Notwithstanding the foregoing, any Allowable Expenses that are incurred by either Party as a result of such Party's failure to use Commercially Reasonable Efforts in connection with performing its obligations hereunder or due to the gross negligence or willful misconduct of such Party or its Affiliates, Sublicensees, or Third Party contractors, whether or not such Allowable Expenses are in excess of [\*\*\*] of the applicable Joint Commercialization Budget for the applicable Calendar Quarter, shall be borne entirely by such Party.
- **8.3.6 Income Taxes.** Subject to Section 8.10 (Tax Matters), income and withholding Taxes imposed on either of the Parties hereunder shall not be included in Pre-Tax Profit or Loss hereunder.



**8.4 Development and Filing Milestones**. In partial consideration for the licenses granted to GSK under Section 9.1 (License Grant to GSK), GSK shall make the non-refundable, non-creditable milestone payments to ITEOS that are set forth in <u>Table 8.4</u> below (the "**Development and Filing Milestone Payments**") upon the first achievement by GSK, or its Affiliates or Sublicensees of the milestone events set forth in <u>Table 8.4</u> below with respect to the Licensed Products Developed under the Global Development Plan ("**Development and Filing Milestone**"). Each milestone shall be payable only once per Indication for the first Licensed Product to achieve it, up to a maximum of three (3) Indications as set forth in <u>Table 8.4</u> below. [\*\*\*].

<u>Table 8.4</u> – Development and Filing Milestones					
	Milestone Event	First	Second	Third	
		Indication	Indication	Indication	
(1)	[***]	[***]	[***]	[***]	
(2)	[***]	[***]	[***]	[***]	
(3)	[***]	[***]	[***]	[***]	
(4)	[***]	[***]	[***]	[***]	

For the avoidance of doubt, the total amount of potential milestone payments payable if all milestones are achieved for all three (3) Indications is Five Hundred and Fifty Million Dollars (\$550,000,000.00). In the event that a given Licensed Product achieves a Development and Filing Milestone for more than one Indication (*e.g.*, Initiation of a Registration Study of a Licensed Product for two Indications) then all relevant preceding Development and Filing Milestone payments for such Licensed Product shall become due and payable by GSK (*e.g.*, [\*\*\*]).

If either Party achieves any of the Development and Filing Milestones for a particular Licensed Product in an Indication but without the prior achievement of any corresponding earlier listed Development and Filing Milestone for such Licensed Product in such Indication, then GSK will pay to ITEOS the applicable Development and Filing Milestone for such Licensed Product at the same time as GSK pays the applicable Development and Filing Milestone Payment due upon achievement of such later Development and Filing Milestone. Solely by way of example, if Development and Filing Milestone (1) in <u>Table 8.4</u> above has not been achieved by a Licensed Product in such Indication, then GSK will pay to ITEOS the Development and Filing Milestone (2) in <u>Table 8.4</u> above is achieved for a Licensed Product in such Indication, then GSK will pay to ITEOS the Development and Filing Milestone (2) in <u>Table 8.4</u> above is achieved for a Licensed Product in such Indication, then GSK will pay to ITEOS the Development and Filing Milestone (2) in <u>Table 8.4</u> above is achieved for a Licensed Product in such Indication, then GSK will pay to ITEOS the Development and Filing Milestone (2) in <u>Table 8.4</u> above is achieved for a Licensed Product in such Indication, then GSK will pay to ITEOS the Development and Filing Milestone Payment to be made with respect to such Development and Filing Milestone (1) at the same time as GSK pays the Development and Filing Milestone Payment due upon achievement of such Development and Filing Milestone (2).

### 8.5 Net Sales Milestones.

**8.5.1 ROW Net Sales Milestones.** In partial consideration for the licenses granted to GSK under Section 9.1 (License Grant to GSK), GSK shall pay to ITEOS the Net Sales-based milestone payments as set forth in <u>Table 8.5.1</u> below (the "**ROW Net Sales Milestones Payments**") the first time the aggregate Net Sales for all Licensed



Products within any Calendar Year in the Territory outside of the U.S. meets the corresponding threshold set forth in <u>Table 8.5.1</u> below (the "**ROW Net Sales Milestones**"):

<u>Table 8.5.1</u> – ROW Net Sales Milestones				
Milestone Event	Milestone Payment			
Aggregate Net Sales in a Calendar Year of all Licensed Products in the Territory outside of the U.S. are [***]	[***]			
Aggregate Net Sales in a Calendar Year of all Licensed Products in the Territory outside of the U.S. are [***]	[***]			
Aggregate Net Sales in a Calendar Year of all Licensed Products in the Territory outside of the U.S. are [***]	[***]			
Aggregate Net Sales in a Calendar Year of all Licensed Products in the Territory outside of the U.S. are [***]	[***]			

**8.5.2 U.S. Net Sales Milestones Following Opt-Out**. If the Cost Share End Date occurs, then, following the Cost Share End Date, in addition to the ROW Net Sales Milestones set forth in <u>Table 8.5.1</u> above, GSK shall, in partial consideration for the licenses granted to GSK under Section 9.1 (License Grant to GSK), pay to ITEOS the Net Sales-based milestone payments as set forth in <u>Table 8.5.2</u> below (the "**U.S. Net Sales Milestones Payments**") the first time the aggregate Net Sales for all Licensed Products within any Calendar Year in the U.S. meets the corresponding threshold set forth in <u>Table 8.5.2</u> below (the "**U.S. Net Sales Milestones**"):

Table 8.5.2 – U.S. Net Sales Milestones				
Milestone Event	Milestone Payment			
Aggregate Net Sales in a Calendar Year of all Licensed Products in the U.S. are [***]	[***]			
Aggregate Net Sales in a Calendar Year of all Licensed Products in the U.S. are [***]	[***]			
Aggregate Net Sales in a Calendar Year of all Licensed Products in the U.S. are [***]	[***]			

8.6 Milestone Payment Terms. GSK shall notify ITEOS in writing promptly, but in no event later than [\*\*\*] Business Days after each achievement of each milestone set out in Section 8.4 (Development and Filing Milestones). GSK shall pay all such milestone payments due in Dollars by the [\*\*\*] from GSK's receipt of an invoice from ITEOS therefor following the achievement of the corresponding milestone event. GSK shall notify ITEOS in writing promptly, but in no event later than [\*\*\*] Days after the end of the Calendar Quarter in which the achievement of each milestone set out in Section 8.5 (Net Sales Milestones) of this Agreement occurs. GSK shall pay all such milestone payments due in Dollars by the [\*\*\*] Business Day from GSK's receipt of an invoice from ITEOS therefor following the achievement of the corresponding milestone event. GSK shall pay all such milestone payments due in Dollars by the [\*\*\*] Business Day from GSK's receipt of an invoice from ITEOS therefor following the achievement of the corresponding milestone event. GSK shall pay all such milestone payments due in Dollars by the [\*\*\*] Business Day from GSK's receipt of an invoice from ITEOS therefor following the achievement of the corresponding milestone event. GSK shall also notify ITEOS in writing promptly, but in no event later than [\*\*\*] Business Days after each achievement of each milestone in the [\*\*\*] that triggers a payment, [\*\*\*].

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## 8.7 Royalties and Payments.

8.7.1 Net Sales Royalties. In partial consideration for the licenses granted to GSK under Section 9.1 (License Grant to GSK), GSK will pay ITEOS royalties on aggregate Net Sales of all Licensed Products, on a country– by–country basis, in the Net Sales Territory in each Calendar Year at the royalty rates set out in <u>Table 8.7.1</u> below. The period in which royalties are payable for any Licensed Product in a country within the Net Sales Territory commences with the First Commercial Sale of the Licensed Product in such country within the Net Sales Territory and ends, with respect to that Licensed Product in that country upon the latest to occur of: (a) expiration of the last to expire Valid Patent Claim of any Patent within the [\*\*\*], (b) twelve (12) years from such First Commercial Sale of that Licensed Product in that country or (c) expiration of Regulatory Exclusivity for that Licensed Product in that country (the "**Royalty Term**") [\*\*\*]. Further and for clarity, once the Royalty Term has expired in a given country in the Net Sales Territory, Net Sales in such country will not be included in the calculation of aggregate annual Net Sales used to determine the royalty rate.

<u>Table 8.7.1</u> – Net Sales Royalties				
Calendar Year Net Sales	<b>Royalty Rate</b>			
For that portion of aggregate Net Sales in a Calendar Year of all Licensed Products in the Net Sales	[***]			
Territory up to and including [***]	[]			
For that portion of aggregate Net Sales in a Calendar Year of all Licensed Products in the Net Sales	[***]			
Territory greater than [***] up to and including [***]	[]			
For that portion of aggregate Net Sales in a Calendar Year of all Licensed Products in the Net Sales	[***]			
Territory greater than [***] up to and including [***]	LJ			
For that portion of aggregate Net Sales in a Calendar Year of all Licensed Products in the Net Sales	[***]			
Territory greater than [***] up to and including [***]				
For that portion of aggregate Net Sales in a Calendar Year of all Licensed Products in the Net Sales	20%			
Territory greater than [***]	2070			

**8.7.2** No Valid Patent Claim. The foregoing provisions of Section 8.7.1 (Net Sales Royalties) notwithstanding, the royalties payable with respect to Net Sales of Licensed Products shall be reduced, on a Licensed Product–by–Licensed Product and country–by–country basis, after expiration of the last-to-expire Valid Patent Claim of any Patent within the [\*\*\*], by [\*\*\*] of the amounts otherwise payable pursuant to Section 8.7.1 (Net Sales Royalties) and subject to Section 8.7.5 (Royalty Floor) during the remainder of the Royalty Term for such Licensed Product, as applicable, only for so long as such Licensed Product is not Covered by a Valid Patent Claim of any Patent within the [\*\*\*].

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**8.7.3 Biosimilar Step-Down**. Subject to Section 8.7.5 (Royalty Floor), if, on a Licensed Product-by-Licensed Product and country-by-country basis, one or more Biosimilar Products of such Licensed Product are sold in such country, and Net Sales of such Licensed Product in such country in any Calendar Quarter following the first sale of such Biosimilar Product(s) are (a) less than[\*\*\*] of the average Net Sales of such Licensed Product as compared to the Net Sales for such Licensed Product in such country in the [\*\*\*] Calendar Quarters prior to approval of such Biosimilar Product, then for such Calendar Quarter and thereafter the royalties payable with respect to Net Sales of such Licensed Product in such country pursuant to Section 8.7.1 (Net Sales Royalties) or (b) less than [\*\*\*] of the average Net Sales of such Licensed Product as compared to the Net Sales and [\*\*\*] of the average Net Sales of such Licensed Product as compared to the Net Sales of such Licensed Product in such country pursuant to Section 8.7.1 (Net Sales Royalties) or (b) less than [\*\*\*] of the average Net Sales of such Licensed Product as compared to the Net Sales for such Licensed Product in such country in the [\*\*\*] Calendar Quarters prior to approval of such Biosimilar Product, then for such Calendar Quarters prior to approval of such Biosimilar Product in such country in the [\*\*\*] Calendar Quarters prior to approval of such Biosimilar Product in such country in the [\*\*\*] Calendar Quarters prior to approval of such Biosimilar Product, then for such Calendar Quarter and thereafter the royalties payable with respect to Net Sales of such Licensed Product as compared to the Net Sales of such Licensed Product in such country in the [\*\*\*] Calendar Quarters prior to approval of such Biosimilar Product, then for such Calendar Quarter and thereafter the royalties payable with respect to Net Sales of such Licensed Product in such country pursuant to Section 8.7.1 (Net Sales Royalties) shall be reduced to [\*\*\*] of the royalties otherwise payable pu

# 8.7.4 Third Party Payments.

- (a) **ITEOS Existing Agreements**. With respect to the Net Sales Territory, ITEOS shall be solely responsible for payment of all financial obligations (including all royalties and milestone payments) and otherwise performing, at its sole cost and expense, all obligations under all agreements it or its Affiliates have entered into with Third Parties as of the Effective Date, including the ITEOS Background Agreements. With respect to the Profit-Sharing Territory, the Parties will share (50:50) as Third Party Licensing Payments as part of the Pre-Tax Profit or Loss all financial obligations (including all royalties and milestone payments) under the ITEOS Background Agreements that relate to Exploitation of the Licensed Products in the Profit-Sharing Territory.
- (b) **Offset for Third Party Royalties**. Subject to Section 8.7.4(a) (ITEOS Existing Agreements) and to the extent not included in the Third Party Licensing Payments shared by the Parties as part of the Pre-Tax Profit or Loss, GSK shall be entitled to, on a country-by-country basis, credit against the royalties due to ITEOS upon Net Sales of a Licensed Product in a country solely in the Net Sales Territory an amount equal to [\*\*\*] of the total royalties paid by GSK to Third Parties with respect to license rights to Patents (or Know-How that is licensed together with such Patents) controlled by Third Parties that are necessary to avoid infringement of such Third Party Patents (or misappropriation of such Third Party Know-How related to such Third Party Patents) in the manufacture, use, offer for sale, sale or importation of Licensed Antibodies solely in the Net Sales Territory.

- **8.7.5 Royalty Floor.** All royalty reductions and credits provided for in Section 8.7.2 (No Valid Patent Claim) through Section 8.7.4 (Third Party Payments) shall not cumulatively reduce the royalties payable to ITEOS with respect to a Licensed Product in any country to less than [\*\*\*] percent [\*\*\*] of the royalties otherwise due to ITEOS pursuant to Section 8.7.1 (Net Sales Royalties) in a given Calendar Quarter. Any amount that is not so reduced or credited due to the limitation in the immediately preceding sentence, shall be carried forward for application against royalties payable to ITEOS with respect to Net Sales of such Licensed Product in such country in the Net Sales Territory in future Calendar Quarters for application as a royalty reduction, subject in each case to the foregoing [\*\*\*] percent [\*\*\*] floor, until exhausted.
- **8.7.6 Royalty Reporting.** Each Calendar Quarter following the First Commercial Sale of a Licensed Product in the Net Sales Territory, GSK shall furnish to ITEOS a written report showing on a Licensed Product–by–Licensed Product and country-by-country basis (a) the Net Sales and (b) the calculation of the royalties payable under this Agreement on account of those Net Sales. GSK will keep and cause its Affiliates to keep, complete and accurate records in sufficient detail to enable the royalties payable to be determined and the information provided to be verified. Each royalty report along with the royalties shown to have accrued on that report are due and payable to ITEOS within [\*\*\*] days following the end of such Calendar Quarter. All payments due under this Section 8.7 (Royalties and Payments) shall be made by bank wire transfer in immediately available funds to an account designated by ITEOS.
- **8.7.7 Expiration of Royalty Term**. On a Licensed Product-by-Licensed Product and country-by-country basis in the Net Sales Territory, upon expiration of the Royalty Term with respect to such Licensed Product in such country in the Net Sales Territory, GSK will have a non-exclusive, fully-paid, royalty-free right and license, with the right to grant sublicenses, under the ITEOS Technology, to continue to make, have made, use, sell, offer to sell and import such Licensed Product in the Field in such country in the Net Sales Territory.
- **8.8** Audits. Each Party shall, and shall ensure that its Affiliates and Sublicensees, keep complete and accurate records of the items underlying Development Costs, and GSK shall, and shall ensure that its Affiliates and Sublicensees, keep complete and accurate records of Net Sales (for any royalty-bearing Licensed Products hereunder and for calculation of Pre-Tax Profit or Loss as applicable), and, in the case in which the Parties are sharing Pre-Tax Profit or Loss, Allowable Expenses and Other Income, including the number of FTEs (or portion thereof) used to determine Development FTE Costs and Commercial FTE Costs hereunder. Each Party will have the right, at its own expense and no more frequently than once in any twelve (12)-month period (except in the case of fraud), to have an independent, certified public accountant, selected by such Party from nationally reputable accounting firms in the United States or the United Kingdom and reasonably acceptable to the other Party, review any such records of the other Party in the location(s) where such records are maintained by the other Party upon [\*\*\*] days' prior written notice and during regular business hours and under obligations of confidentiality, for the sole purpose of verifying

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the basis and accuracy of payments made under this Agreement, with respect to any Calendar Year ending not more than [\*\*\*] years prior to the request of the auditing Party. If the review of such records reveals that the other Party has failed to accurately report financial information required to be reported hereunder, or to make any payment (or portion thereof) required under this Agreement, then the other Party shall pay to the auditing Party any underpaid amounts due hereunder together with interest calculated in the manner provided in Section 8.12 (Late Payments) within [\*\*\*] days. If any such discrepancies are greater than [\*\*\*] of the amounts actually due for the audited period, then the other Party shall pay all reasonable costs incurred in conducting such review. Once a Party has conducted a review and audit of the other Party pursuant to this Section 8.8 (Audits) in respect of any given period, it may not subsequently reinspect the other Party's records in respect of such period, unless a subsequent audit of a separate reporting period uncovers fraud on the part of the audited Party that is reasonably expected to have been occurring during the prior audited period. For clarity, however, if a discrepancy is identified by the accountant during the course of an audit and the Parties do not agree upon a resolution of such discrepancy, then the auditing Party's accountant may re-inspect the books and records to the extent reasonably relevant to resolving such discrepancy. Unless otherwise defined or stated, financial terms shall be calculated by the accrual method under the applicable Party's Accounting Standards. Financial records related to the foregoing shall be maintained (in such form as may be available) by each Party for a period of no less than [\*\*\*] years following the end of the period to which they pertain.

- **8.9** Accounting Standards. Each Party shall promptly notify the other Party in the event that such Party changes the Accounting Standards pursuant to which such Party's records are maintained, and it being understood that each Party may only use internationally recognized accounting principles (*e.g.*, IFRS, GAAP).
- **8.10 Tax Matters.** Each Party will make all payments to each other under this Agreement without deduction or withholding for Taxes except to the extent that any such deduction or withholding is required by Applicable Law in effect at the time of payment. The Parties shall reasonably cooperate with one another to reduce, minimize or eliminate any such deduction or withholding required by Applicable Law, including by providing reasonable advance notice of such deduction or withholding and by providing any information, forms or other certifications necessary to reduce or eliminate the amount of such withholding.
  - **8.10.1** Any amount payable by one Party to the other under this Agreement is deemed to be exclusive of any amount in respect of any VAT chargeable on the supply for which that sum is the consideration (in whole or in part) for VAT purposes. If anything done by one Party under this Agreement constitutes, for VAT purposes, the making of a supply to the other Party and VAT is or becomes chargeable on that supply, the Party receiving the supply shall, in any event, receive a valid VAT invoice and shall pay the other Party, in addition to any amount otherwise payable under this Agreement by the Party receiving the supply, a sum equal to the amount of the VAT chargeable on that supply against delivery of a valid VAT invoice to the Party receiving the supply, if applicable.

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- 8.10.2 Any Tax required to be withheld on amounts payable under this Agreement will promptly be paid by the Party making the payment (the "Payor") on behalf of the Party receiving the payment (the "Payee") to the appropriate governmental authority, and Payor will furnish Payee with proof of payment of such Tax. Any such Tax required to be withheld will be treated for all purposes of this Agreement as having been paid to the Party with respect to which such withholding was made. The Payor will provide the Payee with prompt written notice of the required withholding (and in any event, no later than [\*\*\*] Business Days) prior to making such payment. Notwithstanding any provision to the contrary in this Agreement, if a Payor assigns, transfers or otherwise disposes of some or all of its rights and obligations to any Person (without the prior written consent of the Pavee) and if, as a result of such action (or as a result of a subsequent transfer following such assignment, transfer or disposition), the withholding or deduction of tax required by Applicable Law with respect to payments under this Agreement is increased (the "Increased Withholding Taxes"), then any amount payable to the Payee under this Agreement shall be increased to take into account such Increased Withholding Taxes as may be necessary so that, after making all required withholdings (including withholdings on the withheld amounts), the Payee receives an amount equal to the sum it would have received had no such Increased Withholding Taxes been made; provided, however, that the parties shall cooperate to reduce, minimize or eliminate such withholding or deduction in accordance with this the provisions of this Section 8.10 (Tax Matters).
- **8.10.3** The Parties will cooperate with respect to all documentation required by any taxing authority or reasonably requested by either Party to secure a reduction in the rate of applicable withholding Taxes or an exemption from withholding Taxes. If a Party is entitled under any applicable tax treaty to a reduction of rate of, or the elimination of, or recovery of, applicable withholding tax, then it may deliver to the other Party or the appropriate governmental authority the prescribed forms necessary to reduce the applicable rate of withholding or to relieve the Payor of its obligation to withhold tax. If a Payee timely delivers to the Payor a validly executed form establishing a reduced rate or exemption from withholding, the Payor shall apply the reduced rate of withholding, or not withhold, as the case may be, *provided* that the Payor is in receipt of evidence, in a form reasonably satisfactory to the Payoe. If, in accordance with the foregoing, the Payor withholds any amount, then it will pay to the Payee the balance when due, timely remit to the proper taxing authority of the withheld amount, and send the Payee proof of such remittance within [\*\*\*] days following that remittance.
- **8.10.4** No Partnership. Nothing contained in this Agreement shall be deemed or construed by the Parties, any of their Affiliates or any third person to treat the relationship between the Parties contemplated by this Agreement as a partnership, joint venture or other business entity under Treasury Regulations Section 301.7701-1(a)(2) (or any corresponding provision under state, local or non-U.S. tax law) (an "Entity"). No Party (or successor or assignee) intends, for Tax purposes, on reporting the relationships established by this Agreement as an Entity, including either (a) making any disclosure that the relationships established by this



Agreement may give rise to an Entity (whether on a U.S. Internal Revenue Service Form 8275 or otherwise) or (b) withholding any amounts from payments made to the other Party pursuant to Section 1446 of the Code (or any corresponding provision under state, local or non-U.S. tax law), unless required by a tax authority on audit or other examination. Notwithstanding the foregoing, in the event that the arrangement between the Parties as contemplated by this Agreement is determined to constitute an Entity under Applicable Law (as determined based on the opinion (on a "should" basis) of a nationally recognized law or accounting firm) or by a tax authority on audit or other examination, the Party that is aware of such determination shall provide notice to the other Party regarding such treatment and the Parties will reasonably cooperate with one another to satisfy any tax filing or reporting obligation arising as a result of such determination, including by providing any information, forms or other certifications necessary to satisfy such obligations.

- **8.11 Invoicing**. To the extent an invoice is required to be submitted to GSK hereunder, such invoice shall include the information set forth in <u>Schedule 8.11</u>.
- **8.12** Late Payments. Without limiting either Party's remedies under this Agreement, any undisputed payments or portions thereof due hereunder that are not paid on the date such payments are due under this Agreement shall bear interest at a rate equal to [\*\*\*] percentage points above the prime rate as published by Citibank, N.A., New York, New York, or any successor thereto, at 12:01 a.m. on the first day of each Calendar Quarter in which such payments are overdue, calculated on the number of days such payment is delinquent. Where the late payment is caused by the Party that is owed the payment, including for reasons such as failure to communicate in a timely manner changes to bank details, or failure to respond to communications from the Party owing the payment regarding the interpretation or dispute of the terms of such payment, then no interest will be payable by the Party owing the payment.
- **8.13 Currency Conversion**. Except as otherwise agreed by the Parties, all payments to be made by either Party to the other Party under this Agreement shall be made by such Party or its Affiliate in U.S. Dollars to the account designated by the Party to which the relevant payment is due. In the case of any amounts designated in another currency, then each Party shall convert such foreign currency into U.S. Dollars using its standard conversion method consistent with its applicable Accounting Standard in a manner consistent with the respective Party's customary and usual conversion procedures used in preparing its audited financial reports applied on a consistent basis, provided that such procedures use a widely accepted source of published exchange rates. [\*\*\*].
- **8.14 Blocked Payments.** In the event that, by reason of Applicable Laws in any country, it becomes impossible or illegal for a Party or its Affiliate to transfer, or have transferred on its behalf, payments to the other Party, such Party shall [\*\*\*] notify the other Party of the conditions preventing such transfer and such payments shall [\*\*\*].
- **8.15 Disclaimer**. ITEOS and GSK each acknowledge and agree that nothing in this Agreement will be construed as representing any estimate or projection of (a) the successful



Development or Commercialization of any Licensed Product under this Agreement, (b) if Commercialized, that any Licensed Product will achieve any particular pricing or reimbursement amount or any particular sales level, or (c) anticipated sales or the actual value of any Licensed Product that may be successfully Developed or Commercialized under this Agreement.

- **8.16 Cooperation on Inter-Party Structure**. The Parties will reasonably cooperate to establish or facilitate an optimal inter-Party financial operational structure (including, if necessary, procedures and agreements among the various Affiliates of the Parties) which is consistent with the economic result contemplated herein, consistent to the extent feasible with each Party's internal structures and procedures, and not adverse to the Parties financial, economic, or tax positions.
- **8.17 Resolution of Financial Disputes.** If a Party has a dispute, claim or controversy relating to calculation or reconciliation of (a) Development Costs or (b) (i) Net Sales, (ii) Allowable Expenses, or (iii) Other Income, as each (i) through (iii) relates to the calculation or reconciliation of Development Costs or under the Pre-Tax Profit or Loss Schedule, such Party shall provide such other Party with a written notice setting forth in reasonable detail the nature and factual basis for such good-faith dispute and each Party agrees that it shall seek to resolve such dispute within [\*\*\*] Business Days through the Financial Working Group after the date such written notice is received. If no such resolution is reached by the Parties, then the dispute shall be referred to the JSC for resolution. If the JSC is unable to reach resolution within [\*\*\*] Business Days, then the dispute shall be resolved in accordance with the procedures set forth in Section 8.18 (Specific Finance Disputes). Notwithstanding any other provision of this Agreement to the contrary, the obligation to pay any reasonably disputed amount shall not be deemed to have been triggered until such dispute is resolved hereunder, *provided* that any undisputed portion of such payment shall be paid by the paying Party in accordance with the payment terms set forth in this Agreement. Any disputed portion of any payment shall be paid by the resolves the dispute.
- **8.18** Specific Finance Disputes. If the Parties are unable to reach a mutually acceptable resolution of any dispute falling within Section 8.17 (Resolution of Financial Disputes) as set forth therein, then the dispute shall be submitted for resolution to [\*\*\*] (the "Finance Expert"). [\*\*\*]. Any amounts owed by one Party to the other Party as a result of such resolution shall be paid or reimbursed by the owing Party within [\*\*\*] days following the applicable decision of the Finance Expert and receipt of a valid invoice.

## ARTICLE 9 LICENSES; EXCLUSIVITY

**9.1 License Grant to GSK**. Subject to the terms and conditions of this Agreement, ITEOS or its Affiliates hereby grant to GSK and its Affiliates, as of the Effective Date, a royalty-bearing, sublicensable through multiple tiers (subject to Section 10.3 (Sublicenses)) license under the ITEOS Technology to make, have made, use, sell, offer for sale, import, Develop, Manufacture, perform Medical Affairs with respect to and Commercialize Licensed

Products in the Field in the Territory during the Term in accordance with this Agreement, the Global Development Plan and the Commercialization Plans, or pursuant to Section 3.4 (Additional Development), which license will be exclusive (even as to ITEOS, subject to the ITEOS Retained Rights) in the Net Sales Territory and co-exclusive (together with ITEOS and its Affiliates) in the Profit-Sharing Territory during the Profit-Sharing Term; *provided* that ITEOS reserves (a) the right to (i) Develop the Licensed Antibodies and Licensed Products as set forth in the Global Development Plan or pursuant to Section 3.4 (Additional Development) or Section 3.5.3(b) (Third Party Combination Exception) and (ii) Manufacture Licensed Antibodies and Licensed Products as set forth in this Agreement, and (b) a co-exclusive (together with GSK and its Affiliates) right under all such ITEOS Technology to perform Medical Affairs for and Commercialize the Licensed Products in the Field in the Profit-Sharing Territory during the Profit-Sharing Term in accordance with the Joint Commercialization Plan and the terms of this Agreement ((a) and (b), collectively, the "**ITEOS Retained Rights**").

- **9.2 License Grant to ITEOS.** Subject to the terms and conditions of this Agreement, GSK or its Affiliates hereby grants to ITEOS as of the Effective Date, a non-exclusive, royalty-free, worldwide license under the GSK Technology (with the right to grant sublicenses solely to subcontractors set forth in the Global Development Plan or Joint Commercialization Plan) solely for the purpose of and solely to (a) Develop the Licensed Products as set forth in the Global Development Plan or pursuant to Section 3.4 (Additional Development), (b) Manufacture Licensed Antibodies and Licensed Products as set forth in this Agreement, (c) perform Medical Affairs with respect to the Licensed Products as set forth in the Joint Commercialization Plan and (d) Commercialize the Licensed Products in the Field, in the case of (c) and (d) solely in the Profit-Sharing Territory during the Profit-Sharing Term and in accordance with the then-current Joint Commercialization Plan and the terms of this Agreement.
- **9.3 Sublicenses.** GSK shall have the right to grant sublicenses to its Affiliates and shall have the further right to grant sublicenses to Third Parties of the license granted to GSK by ITEOS under Section 9.1 (License Grant to GSK) (each, a "**Sublicensee**"), and any such sublicenses shall be subject to the conditions set forth in this Article 9 (Licenses; Exclusivity), *provided* that during the Term prior to the [\*\*\*]. Any and all sublicenses shall be in writing and shall be subject to, and consistent with, the terms and conditions of this Agreement. GSK shall be responsible for ensuring the compliance of its Sublicensees with all obligations owed to ITEOS under this Agreement, shall remain liable to ITEOS for all acts and omissions of such Sublicensees and shall remain responsible for performance of all of its obligations under this Agreement. If GSK grant of any sublicense will not relieve GSK or its Affiliates from any of its obligations under this Agreement. If GSK grants an exclusive sublicense to any Sublicensee of any rights licensed from ITEOS hereunder (an "**Exclusive Sublicense**"), then GSK shall promptly notify ITEOS thereof and shall promptly thereafter provide ITEOS with a copy of such Exclusive Sublicense, which copy may be reasonably redact the detailed financial terms of such Exclusive Sublicense agreement and which will be considered the Confidential Information of GSK. As a condition precedent to and requirement of any such Exclusive Sublicense, if sales by such Sublicensee are included in Net Sales hereunder, then such Sublicensee shall permit

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audit rights with respect to its reporting of Net Sales that are consistent with those given by GSK hereunder with respect to its sales included in Net Sales.

- **9.4 Subcontracting.** GSK may engage its Affiliates or Third Party subcontractors (including distributors, contract research organizations and contract manufacturing organizations) to perform certain of its obligations under the Global Development Plan, Global Strategic Launch Plan, Joint Commercialization Plan, or otherwise in connection with its obligation to Develop, Manufacture, and Commercialize Licensed Antibodies and Licensed Products under this Agreement, *provided* that any such subcontractors (a) performing activities under the Global Development Plan will be set forth in the Global Development Plan, and (b) performing Commercialization activities in the Profit-Sharing Territory during the Term prior to the Cost Share End Date will be set forth in the Joint Commercialization Plan. Any Third Party subcontractor to be engaged by GSK to perform GSK's obligations under this Agreement shall meet the qualifications typically required by GSK for the performance of work similar in scope and complexity to the subcontracted activity.
- **9.5 Requirements of Sublicensees and Subcontractors**. GSK's use of Affiliates, Sublicensees or subcontractors shall not relieve GSK of any obligation hereunder and GSK shall cause its Affiliates, Sublicensees or subcontractors to comply with its applicable obligations under this Agreement. GSK shall remain responsible under this Agreement for ensuring the compliance of Affiliates, Sublicensees and subcontractors with this Agreement.
- **9.6 No Implied Licenses; Retained Rights**. Each Party acknowledges that the licenses granted under this Article 9 (Licenses; Exclusivity) are limited to the scope expressly granted, and all other rights to Patents and Know-How licensed hereunder are expressly reserved to the Party granting the license to such Patents or Know-How. Nothing in this Agreement will be interpreted to grant a Party any rights under any intellectual property rights owned or Controlled by the other Party that are not expressly granted herein, whether by implication, estoppel, or otherwise. GSK will not Develop, Manufacture, perform Medical Affairs with respect to, or Commercialize Licensed Antibodies or Licensed Products other than as expressly licensed and permitted under this Agreement. Without limiting the foregoing, it is understood that where an exclusive license under Patents or Know-How is granted to a Party under this Article 9 (Licenses; Exclusivity) for a particular purpose, the Party granting such license retains all of its rights to such Patents or Know-How for all purposes not expressly licensed. Without limiting the foregoing, ITEOS expressly retains the ITEOS Retained Rights.
- **9.7 Rights in Bankruptcy**. The Parties intend to take advantage of the protections of Section 365(n) (or any successor provision) of the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction to the maximum extent permitted by Applicable Law. All rights and licenses granted under or pursuant to this Agreement, but only to the extent they constitute licenses of a right to "intellectual property" as defined in Section 101 of the U.S. Bankruptcy Code, shall be deemed to be "intellectual property" for the purposes of Section 365(n) or any analogous provisions in any other country or jurisdiction. The non-bankrupt Party shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code or any analogous provisions in any other

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country or jurisdiction, including the right to obtain such intellectual property from another entity. In the event of the commencement of a bankruptcy proceeding by or against a Party under the U.S. Bankruptcy Code or any analogous provisions in any other country or jurisdiction, the non-bankrupt Party shall be entitled to a complete duplicate of (or complete access to, as appropriate) all such intellectual property (including all embodiments of such intellectual property), which, if not already in the non-bankrupt Party's possession, shall be promptly delivered to it upon its's written request (a) upon commencement of a bankruptcy proceeding, unless the bankrupt Party continues to perform all of its obligations under this Agreement, or (b) if not delivered pursuant to clause (a) because the bankrupt continues to perform, upon the rejection of this Agreement by or on behalf of the bankrupt Party. Unless and until the bankrupt Party rejects this Agreement, the bankrupt Party shall perform this Agreement or provide such intellectual property (including all embodiments of such intellectual property) to the non-bankrupt Party, and shall not interfere with the rights of the non-bankrupt Party to such intellectual property, including the right to obtain the intellectual property from another entity. In the case of an insolvency that is governed by non-U.S. bankruptcy law, the Parties agree that, to the extent not prohibited by the applicable insolvency law, the non-bankrupt Party will be entitled to at least the same rights and protections afforded by the U.S. Bankruptcy Code, including survival of the licenses granted hereunder even if the bankrupt Party revokes or terminates this Agreement and a copy of the embodiments of such intellectual property, without conditions other than any legally required payment of royalties. Further, each Party agrees and acknowledges that all payments by GSK to ITEOS hereunder, including under Section 8.4 (Development and Filing Milestones), Section 8.5 (Net Sales Milestones), and Section 9.7 (Royalties and Payments), constitute royalties within the meaning of Section 365(n) of the Bankruptcy Code and relate to licenses of intellectual property hereunder.

- **9.8 Technology Transfer**. Promptly following the Effective Date, ITEOS shall transfer and deliver to GSK (in order to enable GSK to practice under the licenses granted to GSK under Section 9.1 (License Grant to GSK)), Know-How within the ITEOS Technology (including Materials) to enable GSK to Develop, Manufacture and Commercialize Licensed Antibodies and Licensed Products as contemplated under this Agreement.
- **9.9 Existing Third Party Agreements.** All licenses granted by a Party to the other Party in this Article 9 (Licenses; Exclusivity) shall be subject to the licensing restrictions set forth in the Third Party agreements between such Party and any Third Party existing as of the Execution Date. Without limiting the foregoing, the licenses granted by ITEOS to GSK under 9.1 (License Grant to GSK) shall be subject to the ITEOS Background Agreements, for so long as such ITEOS Background Agreements are in effect. [\*\*\*].
- 9.10 [\*\*\*]
- 9.11 New Third Party In-Licenses.
  - 9.11.1 Identified Third Party IP. [\*\*\*] ("Third Party IP") [\*\*\*].
  - **9.11.2 Potential In-Licenses.** Prior to executing an agreement with a Third Party to acquire or license any Third Party IP (any such agreement, a "**Potential In-**"

**License**"), the contracting Party will (a) [\*\*\*], and (c) ensure that such Potential In-License includes the right to grant a sublicense to the other Party under such Third Party IP such that the contracting Party Controls such rights as GSK Background Technology or ITEOS Background Technology, as applicable. Upon execution of such Potential In-License, the contracting Party will notify the other Party in writing and will provide a copy of the final terms thereof that are material, including applicable payment terms. The contracting Party will not enter into a Potential In-License if the terms of such Potential In-License are [\*\*\*] pursuant to the review and comment process set forth in this Section 9.11.2 (Potential In-Licenses).

**9.11.3** New Collaboration In-Licenses. With respect to any Potential In-License entered into between a Party and Third Party in accordance with this Section 9.11 (New Third Party In-Licenses), the Parties will negotiate in good faith and agree upon an equitable allocation of the costs of Third Party IP under each Potential In-License, including upfront fees, milestones, royalties and other payments between the Parties in accordance with the allocation principles set forth in Section 9.11.4 (Payment Allocation Principles under Collaboration In-Licenses), and subject to such agreement on sharing of such costs, (i) each such Potential In-License will be deemed to be a "Collaboration In-License" hereunder, and (ii) the Third Party IP licensed under such Potential In-License will be included in the GSK Background Technology (if GSK is the contracting Party) or the ITEOS Background Technology (if ITEOS is the contracting Party) under this Agreement and, accordingly, included in the licenses granted under Section 9.1 (License Grant to GSK) or Section 9.2 (License Grant to ITEOS), as and if applicable. If the Parties are unable to agree on an equitable allocation of costs for any Third Party IP in accordance with the allocation principles set forth in Section 9.11.4 (Payment Allocation Principles under Collaboration In-Licenses), then either Party may submit the resolution of such equitable allocation to be determined in accordance with Article 16 (Dispute Resolution).

### 9.11.4 Payment Allocation Principles under Collaboration In-Licenses.

- (a) **In the Profit-Sharing Territory.** The Parties will share all costs of Third Party IP (including upfront fees, milestones, royalties and other payments) under Collaboration In-Licenses that arise as a result of the exercise of rights thereunder to the extent specific to the Exploitation of Licensed Products in the Profit-Sharing Territory equally (50:50) as Third Party Licensing Payments, in accordance with Pre-Tax Profit or Loss.
- (b) **In the Net Sales Territory**. GSK will be responsible for 100% of any other costs of Third Party IP (including upfront fees, milestones, royalties and other payments) under the Collaboration In-Licenses that arise as a result of the exercise of rights thereunder to the extent related to the Exploitation of Licensed Products in the Net Sales Territory, which payments GSK will have the right to offset to the extent set forth in Section 8.7.4(b) (Offset for Third Party Royalties).



(c) Allocation of Payments. To the extent that a payment made under any Collaboration In-License is attributable to the Exploitation of a Licensed Product in both the Profit-Sharing Territory and the Net Sales Territory, a *pro rata* portion of such payment will be considered Third Party Licensing Payments for purposes of this Agreement and borne by the Parties as provided under 9.11.4(a) (In the Profit-Sharing Territory) and the *pro rata* portion that will be borne by GSK for the Net Sales Territory as provided under Section 9.11.4(b) (In the Net Sales Territory). If the Party that enters into such Collaboration In-License also intends to use the Patent Rights or Patent Rights and Know-How licensed thereunder for products other than a Licensed Product outside of this Agreement, then the Parties will agree upon a different equitable allocation of payments due under such Agreement.

## 9.12 Exclusivity.

- **9.12.1 Mutual Exclusivity Covenant**. Commencing on the Effective Date, except with respect to the Licensed Antibodies and Licensed Products in accordance with and pursuant to this Agreement, neither Party nor any of its Affiliates shall, alone or with or for any Third Party, (a) during the time period commencing on the Effective Date and lasting solely during the Term until the [\*\*\*] anniversary of the earlier of (i) the first BLA approval of the Licensed Product for the first indication in U.S. or (ii) the first MAA approval of the Licensed Product for the first of any of Germany, France, United Kingdom, Spain, or Italy, engage in, or obtain rights from a Third Party to engage in, Development of a monospecific, monoclonal antibody that inhibits or is an antagonist of the Target through direct physical interaction therewith (a "Selected Product"), or (b) lasting during the Term, Commercialize (or Manufacture for such purposes), or obtain rights from a Third Party to Commercialize (or Manufacture for such purposes) any Selected Product.
- **9.12.2** Limited Development Exception. Notwithstanding Section 9.12.1 (Mutual Exclusivity Covenant), (a) if, [\*\*\*] (b) Development of a Selected Product owned or controlled by a Third Party for use as a comparator solely for purposes of conducting the Development Program will not constitute a breach by such Party of its exclusivity obligations set forth in Section 9.12.1 (Mutual Exclusivity Covenant), and (c) [\*\*\*].
- **9.12.3** New Affiliate Exception. Notwithstanding Section 9.12.1 (Mutual Exclusivity Covenant), if (1) a Third Party becomes an Affiliate of a Party during the Term through merger, acquisition, consolidation, Change of Control, or other similar transaction (any such Third Party, a "New Affiliate") and (2) such New Affiliate, as of the execution date of the definitive agreement with respect to such transaction, is engaged in Exploitation activities that, if conducted by such Party, would cause

such Party to violate the exclusivity obligations set forth in Section 9.12.1 (Mutual Exclusivity Covenant) (such activities, a "**Competing Program**"), then:

- (a) [\*\*\*].
- (b) [\*\*\*].

## ARTICLE 10 CONFIDENTIALITY; PUBLICATIONS AND PRESENTATIONS

- **10.1 Confidential Information**. It is understood and agreed by the Parties that (a) all reports, information, and data provided by a Party to the other Party or its Affiliates or representatives hereunder, including information regarding the scientific, regulatory or business affairs or other activities of the Disclosing Party, will be considered such owning, Controlling, or providing Party's Confidential Information, (b) information relating to the GSK Technology disclosed by GSK hereunder will be GSK's Confidential Information, (c) information relating to the ITEOS Technology disclosed by ITEOS hereunder will be ITEOS's Confidential Information, and (d) the terms of this Agreement, the Global Development Plan, the Global Strategic Launch Plan and the Joint Commercialization Plan, and the results of any audit conducted hereunder, in each case, will be considered the Confidential Information of both Parties.
- **10.2 Confidentiality.** Except to the extent expressly authorized by this Agreement or otherwise agreed by the Parties in writing, during the Term and for a period of [\*\*\*] years following termination or expiration thereof (*provided* that with respect to any such Confidential Information which constitutes a bona fide trade secret of such Party as specifically identified by such Party as a trade secret to the other Party, in writing during the Term, such obligations shall continue for as long as such Confidential Information remains a trade secret), each Party will be obligated to keep confidential and not publish or otherwise disclose to a Third Party, and not to use, directly or indirectly, for any purpose, any Confidential Information furnished or otherwise made known to it, directly or indirectly, by the other Party, except to the extent such disclosure or use is expressly permitted by the terms of this Agreement or is reasonably necessary or useful for the performance of a Party's obligations, or the exercise of such Party's rights under, this Agreement. The confidentiality and non-use obligations with respect to a Party's Confidential Information in this Section 10.1 (Confidentiality) will not include any information (and such information will not be considered Confidential Information) that a Party can show my competent written evidence:
  - **10.2.1** is or becomes part of the public domain through no wrongful act, fault or negligence on the part of the Receiving Party;
  - **10.2.2** was in the Receiving Party's possession prior to initial disclosure by the Disclosing Party without any obligation of confidentiality with respect to such information;
  - **10.2.3** is subsequently received by the Receiving Party from a Third Party who is not bound by any obligation of confidentiality with respect to such information;



- **10.2.4** has been published by a Third Party or otherwise enters the public domain through no fault of the Receiving Party in breach of its contractual obligations to the Disclosing Party; or
- **10.2.5** was independently developed (outside the scope of this Agreement) by or for the Receiving Party without reference to or use of the Disclosing Party's Confidential Information.
- **10.3 Authorized Disclosure**. The Receiving Party may disclose Confidential Information of the Disclosing Party to the extent that such disclosure is:
  - (a) made in response to a valid order of a court or other governmental authority or, if in the reasonable opinion of the Receiving Party's legal counsel, such disclosure is otherwise required by Applicable Law, including by reason of filing with securities regulators; *provided* that the Receiving Party shall, where practicable, first have given notice to the Disclosing Party and given the Disclosing Party a reasonable opportunity to quash such order or to obtain a protective order or confidential treatment; and *provided further* that the Confidential Information disclosed in response to such court or governmental order shall be limited to that information which is legally required to be disclosed in response to such court or governmental order;
  - (b) made by or on behalf of the Receiving Party to Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval for the Licensed Products as permitted by this Agreement; *provided* that reasonable measures shall be taken to assure confidential treatment of such information to the extent practicable and consistent with Applicable Law;
  - (c) made by or on behalf of the Receiving Party to a patent authority as may be reasonably necessary for purposes of obtaining a Patent as permitted by this Agreement; *provided* that reasonable measures shall be taken to assure confidential treatment of such information, to the extent such protection is available; or
  - (d) made by the Receiving Party to its attorneys, auditors, advisors, consultants, contractors, existing or prospective collaboration partners, licensees, sublicensees, existing or prospective investors, prospective acquirers, prospective lenders, prospective financing sources (including, in each case, in connection with any royalty factoring transaction) or other Third Parties as may be necessary in connection with the performance of or exercise of rights under this Agreement or as required under the terms of agreements with Third Parties (including such agreements with Third Parties relating to Other Components included in Combination Products), in each case, for the limited purpose of such collaboration, license, sublicense, financing or acquisition activities; *provided* that such persons shall be subject to obligations of confidentiality and non-use with respect to such Confidential



Information substantially similar to the obligations of confidentiality and non-use of the Receiving Party set forth herein.

- **10.4 Injunctive Relief.** Each Party, as a Receiving Party, acknowledges and agrees that due to the unique nature of a Disclosing Party's Confidential Information, there may be no adequate remedy at law for any breach of its obligations hereunder and that any such breach may allow a Receiving Party or Third Parties unfairly to compete with the Disclosing Party, resulting in irreparable harm to the Disclosing Party. Therefore, notwithstanding the provisions of Section 16.1 (Dispute Resolution), the Parties agree that upon any such breach or any threat thereof, the Disclosing Party shall be entitled to seek appropriate equitable relief at the Disclosing Party's option in either (a) a court of competent jurisdiction where such Disclosing Party resides, or (b) as provided in Section 16.1 (Dispute Resolution), as applicable, in addition to whatever remedies it might have at law in connection with any breach or enforcement of a Receiving Party's obligations hereunder for the unauthorized use or release of any such Confidential Information.
- **10.5 Data Breach**. When transferring Confidential Information, all communications between GSK and ITEOS will use encryption methods agreed to by the Parties. Upon discovering any suspected or actual unauthorized disclosure, loss or theft of Confidential Information (a "**Data Security Breach**") [\*\*\*]. The Parties shall work with each other in good faith to identify a root cause and remediate the Data Security Breach.
- 10.6 Press Releases and Other Public Statements. Both Parties shall keep the terms of this Agreement confidential and such terms shall be treated as Confidential Information of both Parties in accordance with this Article 10 (Confidentiality; Publications and Presentations) (and for clarity subject to Section 10.3 (Authorized Disclosure)), except that each Party may make the publications and presentations described in Sections 10.8 (Scientific Publications) on the terms set forth therein, and each Party may (a) issue a public announcement of the execution of this Agreement in a form attached hereto as Schedule 10.6; (b) disclose the content of the Agreement to existing or prospective attorneys, auditors, advisors, consultants, contractors, existing or prospective collaboration partners, licensees, sublicensees, existing or prospective shareholders, investors, prospective acquirers, or prospective lenders for limited purposes under obligations of confidentiality and non-use no less restrictive than those in this Agreement; (c) disclose the content as necessary to subcontractors, sublicensees and other bona fide collaboration partners under obligations of confidentiality and non-use similar to those in this Agreement; or (d) as necessary as required by securities regulators, the rules of any stock exchange or as part of any listing of the securities of ITEOS or GSK on any stock exchange. Any public announcement to be made in accordance with this Section 10.6 (Press Releases and Other Public Statements) will be provided by the publishing Party to the other Party at least [\*\*\*] days prior to its scheduled release; provided that, if the Party proposing such public announcement cannot provide the reviewing Party with [\*\*\*] days' notice due to extraordinary circumstances, such Party will provide the reviewing Party with the proposed public statement for comment at least [\*\*\*] before release. Notwithstanding the foregoing in this Section 10.6 (Press Releases and Other Public Statements), a Party may make subsequent public announcements or press releases solely of information previously publicly disclosed in accordance with this Article 10 (Confidentiality; Publications and



Presentations) without the advance written consent of the other Party, so long as (i) such subsequent public announcements or press releases are released without changes to the substantive information provided therein, (ii) are released within [\*\*\*] months of the original release, and (iii) the information provided therein is still considered accurate and has not been superseded by other subsequent information known by such Party.

**10.7 Use of Name**. Notwithstanding any provision to the contrary set forth in this Agreement, neither Party will use the other's name or logo in any press release or product advertising, or for any other promotional purpose, without first obtaining the other's written consent and entering into appropriate trademark or housemark licenses, as applicable.

## **10.8** Scientific Publications.

- **Publication Strategy**. Within [\*\*\*] of the Effective Date, the JDC will prepare a global publication strategy 10.8.1 for the Development activities related to the Licensed Antibodies and Licensed Products Developed under the Development Program (the "Publication Strategy") that is consistent with the Global Development Plan and any Additional Development Proposal; provided that unless otherwise agreed by the Parties, the Publication Strategy will contemplate that, as between the Parties, GSK will be primarily responsible for scientific publications related to Clinical Trials sponsored by GSK and ITEOS will be primarily responsible for scientific publications related to the Clinical Trials sponsored by ITEOS. The JDC (with consultation from the Patent Liaisons, where applicable) will review and approve such Publication Strategy, and may amend it from time to time upon agreement of the Parties. The Parties shall have no right to publish in relation to any Development activities conducted hereunder other than as specified in the Publication Strategy or otherwise in this Section 10.8.1 (Publication Strategy); provided that either Party shall have the right to re-publish (in accordance with 10.8.4 (Re-Publication) below) or reference any publication (or information therein) previously published in accordance with the Publication Strategy and any publication (or information therein) published prior to the Execution Date. If a Party or its employees or consultants (such as clinical investigators) desires to make a publication relating to a Clinical Trial for a Licensed Product that is being conducted under the Global Development Plan or that otherwise relates to the Licensed Antibodies or Licensed Products or the activities conducted hereunder, then it shall make such request to the other Party through the JDC, and such publication shall be subject to review under Section 10.8.2 (Review by the Parties), and the consent of such other Party, which shall not be unreasonably withheld.
- **10.8.2 Review by the Parties.** Except as required by Applicable Law or court order, any proposed scientific or medical publications or public scientific or medical presentations covered by Section 10.8.1 (Publication Strategy) will be subject to the provisions of this Section 10.8.2 (Review by the Parties). For any such publication or presentation, the publishing Party shall submit a copy of the proposed publication or presentation (including manuscripts, abstracts, posters, slides, scheduled interviews or the like) to the representative of the other Party designated to receive such proposed publications at least [\*\*\*] days [\*\*\*] days in the case of

abstracts) prior to any submission or disclosure to any Third Party to allow the other Party to review such proposed publication or presentation. The reviewing Party shall provide the publishing Party with its comments, if any, in writing within [\*\*\*] days [\*\*\*] days in the case of abstracts) after receipt of such proposed publication. The publishing Party shall consider in good faith any comments thereto provided by the reviewing Party and shall comply with the reviewing Party's request to remove any and all of the reviewing Party's Confidential Information from the proposed publication. In addition, upon the reviewing Party's reasonable request, the publishing Party shall delay the submission for a period up to [\*\*\*] days to permit the preparation and filing of a patent application. Upon expiration of such [\*\*\*] days, the publishing Party will be free to proceed with the publication or presentation. If the reviewing Party fails to provide its comments to the publishing Party within such [\*\*\*] day-period [\*\*\*] day-period in the case of abstracts), the reviewing Party shall be deemed to not have any comments.

- **10.8.3 Authorship; Acknowledgement**. Each Party will ascribe authorship of any proposed publication using accepted standards used in peer-reviewed, academic journals at the time of the proposed publication. Any publication or disclosure made by either Party pursuant to this Section 10.8 (Scientific Publications) shall contain appropriate acknowledgements of the contribution of the other Party or any Third Party to the Development activities that are the subject of such publication, in accordance with generally accepted academic practice.
- **10.8.4 Re-Publication**. Once a publication or presentation has been reviewed and approved by the non-publishing Party in accordance with this Section 10.8 (Scientific Publications), the publishing Party may use the information contained in the publication or presentation without seeking further approval so long as (a) such subsequent publications or presentations are released without changes to the substantive information provided therein, (b) are released within [\*\*\*] months of the original publication, and (c) the information provided therein is still considered accurate and has not been superseded by other subsequent information known by such Party.
- **10.8.5 Publications Permitted**. Each publication made in accordance with this Section 10.8 (Scientific Publications) shall not be a breach of the confidentiality provisions contained in Section 10.2 (Confidentiality).
- **10.8.6 Publication of Clinical Information**. Notwithstanding the provisions of this Article 10 (Confidentiality), and [\*\*\*], each Party shall have the right at any time during and after the Term to (a) publish the results or summaries of results of all Clinical Trials conducted by such Party with respect to any and all Licensed Products in any clinical trial register maintained by such Party or its Affiliates and the protocols of such clinical studies on www.clinicaltrials.gov or in each case publish the results, summaries or protocols of such Clinical Trials on such other websites or repositories or at scientific congresses and in peer-reviewed journals within such timescales as required by Applicable Law or such Party's or its Affiliate's Internal Policies, irrespective of the outcome of such clinical studies;

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and (b) make any other public disclosures of clinical Data that become required of such Party due to its Internal Policies and procedures or Applicable Laws. GSK shall have the right to make information from Clinical Trials conducted by or on behalf of GSK with respect to a Licensed Product available under its Data Sharing Initiative; provided that the Parties will agree on [\*\*\*].

## ARTICLE 11 INTELLECTUAL PROPERTY

## **11.1** Ownership of Intellectual Property.

- **11.1.1 Background Patents and Know-How**. Subject to the licenses granted by each Party to the other Party under this Agreement, ITEOS shall retain all of its rights, title and interests in, to and under the ITEOS Background Technology, and GSK shall retain all of its rights, title and interests in, to and under the GSK Background Technology.
- **11.1.2 Inventorship**. For purposes of this Agreement, the determination of inventorship of any Know-How, whether or not patentable, and Patents claiming such Know-How first invented, discovered, created or developed in the course of performing activities under this Agreement, shall be made in accordance with United States patent law. Such principles of inventorship shall be used to determine whether a Party solely, or the Parties jointly, invented, discovered, created or developed Know-How arising as a result of the performance of its or their obligations or exercise of its or their rights under this Agreement.
- **Ownership by GSK.** Subject to Section 11.1.5(b) (Joint Ownership), GSK shall be the sole owner of all 11.1.3 rights, title and interests in and to any Know-How (whether or not patentable) and Patents claiming such Know-How first invented, discovered, created or developed (a) solely by GSK, or by its Affiliates or a Third Party, in each case acting on behalf of GSK, in the performance of activities under this Agreement, (it being understood that any activities carried out by or on behalf of ITEOS under this Agreement shall not be construed or interpreted to be carried out by or on behalf of GSK for purposes hereof), excluding all Joint Arising Technology, and (b) regardless of inventorship, in the performance of activities by or on behalf of either Party, or the Parties jointly, under this Agreement at any time during the Term that, with respect to Know-How, solely relate to, and with respect to Patents, solely claim Know-How solely related to, any Other Component Controlled by GSK or any of its Affiliates, in each case ((a) and (b)), (such Know-How the "GSK Arising Know-How", and such Patents that Cover such GSK Arising Know-How, the "GSK Arising Patents"), and GSK shall retain all of its rights, title and interests thereto, except to the extent that any rights or licenses are expressly granted hereunder by GSK to ITEOS under this Agreement. ITEOS hereby assigns, and agrees to assign, to GSK all of its rights, title and interests in and to the GSK Arising Know-How and GSK Arising Patents.



- **11.1.4 Ownership by ITEOS**. Subject to Section 11.1.5(b) (Joint Ownership), ITEOS shall be the sole owner of all rights, title and interests in and to any Know-How (whether or not patentable) and Patents claiming such Know-How first invented, discovered, created or developed solely by ITEOS, or by its Affiliates or a Third Party, in each case acting on behalf of ITEOS, in the performance of activities under this Agreement, (it being understood that any activities carried out by or on behalf of GSK under this Agreement shall not be construed or interpreted to be carried out by or on behalf of ITEOS for purposes hereof), excluding all Joint Arising Technology (such Know-How, the "ITEOS Arising Know-How", and such Patents that Cover such ITEOS Arising Know-How, the "ITEOS Arising Patents"), and ITEOS shall retain all of its rights, title and interests thereto, except to the extent that any rights or licenses are expressly granted hereunder by ITEOS to GSK under this Agreement.
- 11.1.5 **Joint Ownership.** The Parties shall be the joint owners of all rights, title and interests in and to any Know-How (whether or not patentable) and Patents Covering such Know-How first invented, discovered, created or developed either (a) at any time during the Term by or on behalf of ITEOS or any of its Affiliates or Third Parties acting on behalf of ITEOS on the one hand and by or on behalf of GSK or any of its Affiliates or Third Parties acting on behalf of GSK on the other hand and (b) regardless of inventorship, in the performance of activities by or on behalf of either Party, or the Parties jointly, under this Agreement at any time during the Term that relates to a Combination Product (including Co-Formulated Products) or a Co-Administration Therapy, except for Know-How and Patents described in clause (b) of Section 11.1.3 (Ownership by GSK), which shall be solely owned by GSK as GSK Arising Technology as provided under Section 11.1.3 (Ownership by GSK) (such Know-How, "Joint Arising Know-How," such Patents, "Joint Arising Patents," and collectively, the "Joint Arising Technology"), subject to any rights or licenses that are expressly granted by one Party to the other Party under this Agreement. Each Party will and hereby does assign to the other Party, without additional consideration, an equal, undivided interest in and to all of its rights, title and interests in and to such Joint Arising Technology, and such other Party hereby accepts such assignment. Except to the extent either Party is restricted by the licenses granted by one Party to the other Party pursuant to this Agreement, or the covenants contained herein, each Party shall be entitled to practice and license the Joint Arising Technology without restriction and without consent of, or (subject to the financial provisions of this Agreement) an obligation to account to the other Party (and to the extent necessary by way of Applicable Laws of any jurisdiction regarding joint ownership of intellectual property rights, each Party grants the other Party the right and license to do the same), and each Party hereby waives any right it may have under Applicable Laws to require any such consent or accounting.
- **11.1.6 Assignment Obligation**. Each Party shall cause all employees, independent contractors, consultants and others who perform activities for such Party or its Affiliates under this Agreement to be under an obligation to assign (or, if such Party is unable to cause such person or entity to agree to such assignment obligation

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despite such Party using reasonable efforts to negotiate such assignment obligation, provide an exclusive, perpetual, irrevocable, worldwide license under) their rights in and to any Know-How and all intellectual property rights therein to such Party (or to an entity that is obligated to assign such rights to such Party), except where Applicable Law requires otherwise and except in the case of governmental, not-for-profit and public institutions that have standard policies against such an assignment (in which case a Party shall obtain a suitable license, or right to obtain such a license). Further, each Party acknowledges and agrees that it will not intentionally take any action or make any statement that contradicts or negates any such assignment of Know-How or intellectual property rights by its employees, independent contractors, consultants or others who perform activities for such Party under this Agreement.

## **11.2 Prosecution, Maintenance and Defense.**

Subject Patents. As of the Effective Date and throughout the Term, GSK shall have the first right, but not 11.2.1 the obligation, to prepare, file, prosecute and maintain each of the Patents within the ITEOS Technology and Joint Arising Technology ("Subject Patents"). The Patent Liaison for the Party responsible for preparation, filing, prosecution and maintenance (the "Controlling Party") shall keep the other Party's Patent Liaison reasonably informed on a regular basis regarding such activities, including by providing copies of any material communications or correspondence received from relevant patent authorities to such Patent Liaison, and without limiting the generality of the foregoing, provide the other Party's Patent Liaison with a copy of any proposed filing or correspondence with any patent authority at least [\*\*\*] days prior to the anticipated filing or submission date thereof to allow such other Party to have a reasonable opportunity to comment and consult on, all such filings or correspondence, and the Controlling Party shall implement all such reasonable comments of the other Party with respect thereto. The Controlling Party will give reasonable notice to the other Party, but in any event at least [\*\*\*] days advance written notice, before determining to abandon the prosecution, maintenance or defense of any Subject Patent, and the other Party shall, upon receipt of such notice, be entitled to assume and thereafter direct such prosecution, maintenance or defense activities. Upon provision of written notice by the other Party to the Controlling Party of its desire to assume control of such activities, the Controlling Party shall, and shall cause any patent counsel engaged by such Controlling Party to promptly transfer all relevant documents and records, and provide all such other necessary support to such other Party in order to promptly and fully transfer such activities to the other Party. In such circumstances, the Patent Liaison for the Controlling Party relinquishing direction of the prosecution, maintenance or defense activities will still be kept reasonably informed on a regular basis by the assuming Party's Patent Liaison regarding, and provided with reasonable opportunity to comment and consult on, all such activities in compliance with the preceding principles in this Section 11.2.1 (Subject Patents) applied mutatis mutandis.

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- **11.2.2 Subject Patent Costs.** Subject to Section 6.7.3 (Effects of Opt-Out), the Parties shall share all Patent Costs in the U.S. and the European Union as Development Costs with respect to Subject Patents during the Term until the Regulatory Approval of the first Licensed Product. Following Regulatory Approval of the first Licensed Product, GSK shall pay all such Patent Costs in the Net Sales Territory and, subject to Section 6.7.3 (Effects of Opt-Out), the Parties shall share such Patent Costs with respect to Profit-Sharing Territory as set forth in the Pre-Tax Profit or Loss Schedule.
- **11.2.3 GSK Patent Prosecution and Costs.** GSK shall have the sole right to pursue and direct, at its own cost and discretion, the preparation, filing, prosecution and maintenance of GSK Background Patents, GSK Arising Patents and any other Patents Controlled by GSK or its Affiliates and used in the performance of this Agreement excluding Subject Patents (the "GSK Patents") and shall have no obligation to keep ITEOS informed with respect to such activities. During the Term, GSK shall pay all Patent Costs with respect to GSK Patents.
- **11.2.4 Cooperation**. The Party that is not the Controlling Party will cooperate with the other Party, including furnishing a power of attorney, inventor declaration or assignment documentation, to allow such preparation, prosecution, maintenance or defense activities to be carried out effectively and expeditiously.

## **11.3** Enforcement Rights.

**11.3.1 Notification of Infringement**. If either Party learns of any infringement or threatened or suspected infringement, or misappropriation or threatened or suspected misappropriation, of any (a) ITEOS Technology or GSK Technology by the Manufacture, use, Development or Commercialization by a Third Party of a product that competes with a Licensed Product (a "Competing Product") or (b) Joint Arising Technology, whether or not such Third Party infringement is by a Competing Product (each of (a) and (b), an "Infringement"), such Party shall promptly, but in any event within [\*\*\*] days of becoming aware of such Infringement, provide notice to the Patent Liaisons describing such Infringement (each, an "Infringement Notice"), including any notification of the submission of an Abbreviated Biologic License Application wherein a Licensed Product is the "Reference Product" under the Biologics Price Competition and Innovation Act of 2009 (the "BPCIA") or receipt of manufacturing process from a subsection (k) applicant or other similar procedure where a response is required under Applicable Law (in order to avoid waiving rights), such Party shall provide notice as quickly as possible and in no event later than [\*\*\*] days prior to the applicable deadline for filing a response.

## **11.3.2** Enforcement of Subject Patents.

(a) **Enforcement Right; Step-In Right**. The Controlling Party shall have the initial right, but not the obligation, to pursue and direct enforcement of the applicable Subject Patent against such Infringement. If the Controlling

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Party decides not to abate such Infringement by way of enforcing one or more applicable Subject Patents against the relevant Third Parties, then the Controlling Party shall inform the other Party of such decision in writing no later than [\*\*\*] days after such Controlling Party first becomes aware of such Infringement. Upon receiving such notice from the Controlling Party, or if no such action to abate such Infringement is taken by the Controlling Party within such [\*\*\*] day time period, the other Party shall thereafter immediately become deemed the Controlling Party for the purposes of this Section 11.3.2 (Enforcement and Recoveries). The Controlling Party will keep the other Party reasonably informed through the Patent Liaisons on a regular basis regarding, and provide such other Party with reasonable opportunity to consult and comment on, all enforcement activities and materials in respect of the Subject Patents. The non-Controlling Party shall have the right, to the extent permitted by Applicable Laws and procedural rules to join, using its own counsel, as a party to the enforcement actions included in such enforcement activities.

- (b) **Subject Patent Recoveries**. Any damages or other monetary awards recovered from the settlement of or judgment from such enforcement actions shall be allocated first to reimburse the Parties for the costs and expenses incurred by it in connection with such enforcement actions. Any amounts remaining will be allocated between the Parties as follows: (i) with respect to Infringement in the Profit-Sharing Territory by a Competing Product in relation to Licensed Products prior to the Cost Share End Date, such amounts will be shared by the Parties (50:50) as Other Income in accordance with the Pre-Tax Profit or Loss; and (ii) with respect to Infringement in the Net Sales Territory by a Competing Product in relation to Licensed as Net Sales on which royalties shall be paid to ITEOS in accordance with the terms of this Agreement.
- **11.3.3 Enforcement of GSK Patents**. GSK shall have the right to pursue and direct, at its own cost, enforcement of all GSK Patents. Any damages or other monetary awards recovered from the settlement of or judgment from such enforcement actions shall be allocated as follows: (a) with respect to Infringement of a GSK Arising Patent in the Profit-Sharing Territory by a Competing Product in relation to Licensed Products prior to the Cost Share End Date, such amounts will be shared by the Parties (50:50) as Other Income in accordance with the Pre-Tax Profit or Loss, and (b) with respect to all other recoveries, retained by GSK.
- **11.3.4 Cooperation.** If the Controlling Party brings an enforcement action or proceeding in accordance with Section 11.3.2 (Enforcement of Subject Patents), then the other Party shall cooperate as reasonably requested in the pursuit of such enforcement action, including if necessary by joining as a party to any such enforcement action for which it is a necessary or indispensable party or taking such other actions as are necessary for standing, furnishing a power of attorney, or for the Controlling Party

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to otherwise maintain or pursue such enforcement action effectively and expeditiously.

**11.3.5 Settlement with a Third Party**. The Controlling Party that is controlling an enforcement action shall also have the right to control the settlement of such enforcement action; *provided* that the Controlling Party shall not admit the unenforceability or invalidity of Patents Controlled by the other Party or its Affiliates, or of Patents within the Joint Arising Technology, or that otherwise materially adversely affects the other Party's interest in the ITEOS Technology or the Joint Arising Technology, in all cases, without such other Party's prior written consent.

## **11.4** Infringement Claims by Third Parties.

- **11.4.1 Notice; Control.** Each Party shall promptly notify the other Party in writing of any allegation by a Third Party that any Development, Manufacture or Commercialization or other activities with respect to any Licensed Product infringes or misappropriates or may infringe or misappropriate the intellectual property rights of such Third Party (a "**Third Party Infringement Claim**"). Each Party shall have the right to control the defense of the Third Party Infringement Claim brought against such Party.
- 11.4.2 **Cooperation**; Settlement. Each Party shall keep the other Party reasonably informed of all material developments in connection with any Third Party Infringement Claim through the Patent Liaisons. Such Party shall provide the other Party with copies of all filings by or correspondence from the counterparty(ies) in any suit or proceeding relating to such Third Party Infringement Claim, and with copies of proposed filings to be filed or material correspondence to be delivered to such counterparty(ies) by the Party defending such Third Party Infringement Claim in such proceedings at least [\*\*\*] days prior to the anticipated filing or delivery date thereof for the other Party to comment on, and the Party defending such Third Party Infringement Claim shall take all such comments received under good faith consideration. The Party defending such Third Party Infringement Claim may enter into a settlement or compromise of any Third Party Infringement Claim, provided that, if such settlement or compromise would admit liability on the part of the other Party or any of its Affiliates or would otherwise have a material adverse effect on the rights or interests of the other Party or its Affiliates (including by imposing any monetary obligation upon the other Party or its Affiliates or by limiting the scope of or admitting the unenforceability or invalidity of Patents owned or exclusively licensed by the other Party or its Affiliates), then such Party shall not enter into such settlement or compromise without the prior written consent of the other Party. Any counterclaims of Infringement shall be handled as set forth in Section 11.3 (Enforcement Rights).
- **11.4.3 Costs; Recoveries.** All out-of-pocket expenses incurred by a Party in defending a Third Party Infringement Claim (including outside counsel fees) and all amounts payable by either Party as a judgment based on a Third Party Infringement Claim



or in settlement of such Third Party Infringement Claim, shall be allocated as follows: (a) with respect to Third Party Infringement Claims directed to the activities conducted hereunder for the Licensed Products in the Profit-Sharing Territory prior to the Cost Share End Date, then such out-of-pocket expenses will [\*\*\*], and (b) with respect to Third Party Infringement Claims directed to the activities conducted hereunder for the Licensed Products in the Net Sales Territory, then [\*\*\*].

**11.5 Patent Lists Under the BPCIA**. GSK will have sole decision-making authority with respect to the determination of whether or not to submit Subject Patents or any GSK Patent, in each case, that Cover a Licensed Product, to the applicable regulatory authorities for listing as required under the BPCIA. The Patent Liaisons for each Party will discuss the selection of any such Patents for listing as required under the BPCIA, and GSK will consider the comments and concerns of ITEOS's Patent Liaisons in good faith prior to making its selection.

## ARTICLE 12 TERM AND TERMINATION

- **12.1 Term.** This Agreement shall become effective on the Effective Date and, unless earlier terminated pursuant to this Article 12 (Term and Termination), will continue, on a Licensed Product-by-Licensed Product and country-by-country basis, until (a) in the event that the Cost Share End Date has not occurred, GSK or its Affiliates, Sublicensees, or assignees and ITEOS or its Affiliates, Sublicensees, or assignees, are no longer Commercializing the Licensed Products in the Territory or (b) in the event that the Cost Share End Date has occurred, the expiration of the Royalty Term for all Licensed Products in all countries in the Territory (the "**Term**").
- **12.2 Termination by GSK for Convenience**. GSK will have the right, at its sole discretion, to terminate this Agreement in its entirety or as to one or more Licensed Products (a) upon not less than [\*\*\*]' prior written notice to ITEOS if such notice is provided prior to receipt of the first Regulatory Approval for a Licensed Product, and (b) upon not less than [\*\*\*]' prior written notice to ITEOS if such notice is provided following receipt of the first Regulatory Approval for a Licensed Product.

## **12.3** Termination for Material Breach.

12.3.1 Termination for Material Breach. Subject to Section 12.3.2 (Approved Co-Formulated Product Exception), upon (a) any material breach of this Agreement by ITEOS or (b) any material breach of this Agreement by GSK (the Party so allegedly breaching being the "Breaching Party"), the other Party (the "Non-Breaching Party") will have the right, but not the obligation, to terminate this Agreement with respect to the Licensed Product to which the alleged breach relates, or this Agreement in its entirety if all Licensed Products are adversely affected by such breach, by providing [\*\*\*] days' written notice to the Breaching Party with respect to any such breach of any payment obligation under this Agreement and [\*\*\*] days' written notice to the Breaching Party with respect to any other such breach, which

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notice will, in each case, (i) expressly reference this Section 12.3 (Termination for Material Breach), and (ii) reasonably describe the alleged breach which is the basis of such termination, including the Licensed Products to which the alleged breach relates; *provided*, that other than in the case of a breach of any payment obligation under this Agreement, if such breach is capable of being cured but is not cured within such [\*\*\*]day period and the Breaching Party initiates actions within such period to cure such breach in accordance with a plan to cure such breach that is reasonably acceptable to the other Party and thereafter diligently and in good faith pursues such actions, then the Breaching Party shall have an additional [\*\*\*]-day period to cure such breach. The termination will become effective at the end of the notice period unless the Breaching Party cures such breach during such notice period, as such period may be extended as described in the foregoing sentence, *provided*, that if there is a good faith dispute with respect to the existence of a material breach or whether or not such material breach has been cured, and if the Breaching Party elects to dispute such alleged breach in good faith in writing within [\*\*\*] days for any alleged payment breach or [\*\*\*] days for any other alleged breach of the delivery of the breach notice, or alleged cure or failure to cure is contested within [\*\*\*] days following expiration of the cure period, then the dispute resolution procedure set forth in Article 16 (Dispute Resolution) may be initiated by either Party to determine whether a material breach or a failure to cure has actually occurred. If either Party so initiates such dispute resolution procedure, then the applicable cure period (and the corresponding termination of this Agreement, in its entirety or with respect to one or more Licensed Products to which the material breach relates), will be tolled until such time as the dispute is finally resolved pursuant to Article 16 (Dispute Resolution). [\*\*\*] as used herein will include any material breach (following the applicable cure period without cure and following resolution of any dispute regarding the occurrence of the breach or failure to cure such breach) [\*\*\*].

- **12.3.2 Approved Co-Formulated Product Exception**. Notwithstanding any provision to the contrary set forth in this Agreement, if a Co-Formulated Product has received Regulatory Approval in at least one (1) country anywhere in the Territory, then [\*\*\*].
- 12.4 [\*\*\*]
- **12.5 Termination for Cessation of Development and Commercialization**. Without prejudice to any other remedies available to it at law or in equity (including for any breach of the terms hereof), if GSK does not conduct, or cause to be conducted, any or otherwise ceases or abandons, all Development and Commercialization activities with respect to Licensed Antibodies and Licensed Products for a period [\*\*\*] ("Cessation"), then, ITEOS will have the right to terminate this Agreement [\*\*\*]; *provided*, that if there is a good faith dispute with respect to the existence of [\*\*\*], then the dispute resolution procedure set forth in Article 16 (Dispute Resolution), may be initiated by either Party to determine whether [\*\*\*]. If either Party so initiates such dispute resolution procedure, then the [\*\*\*]-day period (and the corresponding termination of this Agreement), will be tolled until such time

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as the dispute is resolved pursuant to Article 16 (Dispute Resolution). Notwithstanding the foregoing, the [\*\*\*] is the result of [\*\*\*].

**12.6 Termination for Failure to Meet Development Deadlines**. ITEOS will have the right to terminate this Agreement if GSK does not achieve each of the Development milestone events set forth in Table 12.6 by the applicable deadline for achievement set forth in Table 12.6, in each case, by providing [\*\*\*] days' prior written notice to GSK, unless GSK cures such failure during such notice period. Notwithstanding the foregoing, the deadlines for achievement of such Development milestones (and any corresponding determination that GSK has failed to achieve such Development milestone by the applicable deadlines) shall be tolled (and once resolved still subject to such [\*\*\*] day notice (and cure) period) to the extent that the delay in achieving the applicable Development milestone by the applicable deadline is the result of: [\*\*\*].

<u>Table 12.6</u> – Development Deadlines	
Development Milestone Event	Deadline for Achievement
[***]	[***]
[***]	[***]
[***]	[***]

## ARTICLE 13 EFFECTS OF EXPIRATION OR TERMINATION

- **13.1** Accrued Obligations. Expiration or termination of this Agreement for any reason shall not release either Party from any liability that, at the time of such expiration or termination, has already accrued to the other Party or that is attributable to a period prior to such expiration or termination, nor will any early termination of this Agreement preclude either Party from pursuing any and all rights and remedies it may have under this Agreement, or at law or in equity, with respect to breach of this Agreement.
- **13.2** Effects of Termination. If either Party terminates this Agreement prior to expiration of the Term pursuant to Article 12 (Term and Termination), then the provisions of this Section 13.2 (Effects of Termination) will apply. If this Agreement is terminated solely with respect to one or more Licensed Products, but not in its entirety, then the following effects of termination will apply only with respect to such terminated Licensed Products. As referred to throughout this Article 13 (Effects of Expiration or Termination), the phrase "terminated Licensed Products" means, and is limited to, those Licensed Products with respect to which this Agreement has terminated. All of the effects of termination (but not expiration) set forth in this Article 13 (Effects of Expiration or Termination) are in addition to the other rights and remedies that may be available to either of the Parties under this Agreement and will not be construed to limit any such rights or remedies.
  - **13.2.1 General Effects of Termination**. Upon termination of this Agreement in its entirety pursuant to Article 12 (Term and Termination), the Parties' rights and obligations under this Agreement will terminate and neither Party will have any

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further rights or obligations under this Agreement from and after the effective date of termination, except as set forth in this Section 13.2 (Effects of Termination) or Section 13.3 (Survival). Upon termination of this Agreement with respect to one or more terminated Licensed Products, neither Party will have any further rights or obligations under this Agreement with respect to such terminated Licensed Products from and after the effective date of termination for such terminated Licensed Product, except as set forth in this Section 13.2 (Effects of Termination) or Section 13.3 (Survival).

- **13.2.2** [\*\*\*] **Terminated Licensed Products**. In the event of termination of this Agreement with respect to a terminated Licensed Product that is [\*\*\*], unless otherwise agreed by the Parties, the Parties shall file an amendment to the Marketing Approval with the applicable Regulatory Authorities for a change in the label for such terminated Licensed Product such that it shall no longer [\*\*\*].
- **13.2.3 License Termination; Joint Arising Technology**. (i) All licenses granted to each Party under this Agreement, and any Sublicenses thereunder, shall be terminated and of no further force or effect with respect to such terminated Licensed Products; and (ii) each Party will maintain its ownership of its respective one-half undivided interest in and to any and all Joint Arising Technology with the right practice and license the Joint Arising Technology without restriction and without consent of, or an obligation to account to, the other Party; *provided* that in each case doing so does not practice or otherwise Exploit any Background Technology owned or Controlled by the other Party other than in the case of ITEOS practicing or otherwise Exploiting the rights licensed to it under Section 13.2.8 (License of Certain IP); *provided further* that neither Party will practice or license any Joint Arising Technology in connection with any terminated [\*\*\*].
- 13.2.4 **Return of Confidential Information**. At the written request of the Disclosing Party promptly following the termination of this Agreement, the Receiving Party shall (and shall cause its Affiliates and their respective representatives to) return to the Disclosing Party or destroy all originals of documents (in paper or electronic form) and physical materials then in its possession, and copies thereof, to the extent containing Confidential Information received from the Disclosing Party (which is not also considered to be the Receiving Party's Confidential Information) with respect to such terminated Licensed Products, and destroy all documents and other materials that it created to the extent including any such Confidential Information; provided that the Receiving Party may retain in confidence (a) one (1) archival copy of the Confidential Information in its legal files solely to permit the Receiving Party to determine compliance with its obligations hereunder; (b) any portion of the Confidential Information of the other Party which is contained in the Receiving Party's laboratory notebooks or automatic computer backups; (c) any portion of the Confidential Information of the other Party which a Receiving Party is required by Applicable Law to retain; and (d) any Confidential Information that the Receiving Party has the right to continue to use (including in satisfying its obligations under this Article 13 (Effects of Expiration or Termination) or in connection with Exploitation of Licensed Products for which this Agreement has not terminated)



after the date of the Disclosing Party's request after termination or expiration of this Agreement, as applicable. Notwithstanding the return or destruction of the documents and tangible items described above, the Parties will continue to be bound by their obligations under Article 10 (Confidentiality; Publications and Presentations).

- **13.2.5 Termination Covenants.** Except with respect to GSK fulfilling its obligations under this Section 13.2 (Effects of Termination), GSK will not Develop, Manufacture, or Commercialize (i) the Licensed Antibodies anywhere in the world following termination of this Agreement in its entirety or (ii) the terminated Licensed Products anywhere in the world following termination of this Agreement with respect to such Licensed Product, in each case ((i) and (ii)), unless and until the Parties agree otherwise in a written termination agreement pursuant to Section 13.2.16 (Terminated Co-Formulated Products). For clarity, where as a result of the Development of a terminated Licensed Product under this Agreement, a product (other than a Licensed Product) incorporating one or more Other Components Controlled by GSK or its Affiliates has a label that provides for its use in a Co-Administration Therapy together with the EOS-448 Sole Active Product, GSK and its Affiliates Exploiting such product incorporating such Other Components is not a breach of this Section 13.2.5 (Termination Covenants).
- **13.2.6 Transitioning Activities.** If there are any on-going Clinical Trials at termination or expiration of this Agreement involving the terminated Licensed Products, then unless there is a material safety or efficacy issue involving such terminated Licensed Products requiring a pause or cessation of Clinical Trials, the Parties will both complete such Clinical Trials that they are conducting as of the effective date of termination. In addition, the Parties will negotiate in good faith to establish an appropriate course of action, which may include transitioning activities from GSK to ITEOS or its designee, with due regard for patient safety and the rights of any subjects that are participants in any Clinical Trials of the Licensed Products, and take any actions it deems reasonably necessary or appropriate to avoid any human health or safety problems and in compliance with all Applicable Laws. The cost sharing with respect to all such Clinical Trials shall remain the same as it had been prior to such termination.
- **13.2.7 Regulatory Filings**. To the extent there are Regulatory Filings that solely pertain to the terminated Licensed Products [\*\*\*], GSK will and hereby does, and will cause its Affiliates and its and their Sublicensees to, effective as of the effective date of termination, assign to ITEOS all such Regulatory Filings, including filings for Reimbursement Approval, Regulatory Approvals, Data and other material documentation, to the extent allowed under Applicable Law, that are then held by or owned or controlled by GSK or any of its Affiliates or Sublicensees. To the extent assignment pursuant to the foregoing sentence is not permitted by Applicable Law or such materials that are then held by or owned or controlled by GSK or any of its Affiliates or Sublicensees do not solely pertain to such terminated Licensed Products, GSK will and hereby does grant to ITEOS an exclusive right of reference to such Regulatory Filings, including filings for Reimbursement Approval,

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Regulatory Approvals, Data and other material documentation, to the extent allowed under Applicable Laws, solely for such terminated Licensed Products for the continued Development and Commercialization thereof by ITEOS. Further, ITEOS will grant back to GSK a non-exclusive right of reference to such Regulatory Filings in order for GSK to continue Develop and Commercialize products owned or controlled by GSK or its Affiliates that incorporate an Other Component in a Co-Administration Therapy with such terminated Licensed Products.

License of Certain IP. GSK or its Affiliates will and hereby does grant to ITEOS, effective as of the 13.2.8 effective date of termination of this Agreement in its entirety (without any further action required on the part of GSK), an exclusive license, with the right to sublicense (through multiple tiers) under the Patents and Know-How Controlled by GSK or its Affiliates Covering, with respect to Patents, or relating to, with respect to Know-How claiming or relating to the Exploitation of the Licensed Antibody (in the form the Licensed Antibody exists as of the effective date of termination) that are necessary or were actually used by GSK or its Affiliates in the Exploitation of the Licensed Antibody (in the form the Licensed Antibody exists as of the effective date of termination) on or before the effective date of the termination, for ITEOS to Exploit the Licensed Antibody in the Field in the Territory. GSK or its Affiliates will and hereby does grant to ITEOS, effective as of the effective date of termination of this Agreement with respect to one or more terminated Licensed Products that are EOS-448 Sole Active Products (without any further action required on the part of GSK) and subject to GSK's retained rights to Exploit any Licensed Products for which this Agreement has not terminated, an exclusive license, with the right to sublicense (through multiple tiers) under the Patents and Know-How Controlled by GSK or its Affiliates claiming or relating to the Exploitation of the terminated EOS-448 Sole Active Products (in the form such EOS-448 Sole Active Products exist as of the effective date of termination, but after giving effect to Section 13.2.2 ([\*\*\*] Terminated Licensed Products) (if applicable)) that are necessary or were actually used by GSK or its Affiliates in the Exploitation of the terminated EOS-448 Sole Active Products (in the form such EOS-448 Sole Active Products exist as of the effective date of termination) on or before the effective date of the termination, for ITEOS to Exploit the terminated EOS-448 Sole Active Products in the Field in the Territory. Notwithstanding the foregoing, neither this Section 13.2.8 (License of Certain IP) nor anything else in this Article 13 (Effects of Expiration or Termination) provides ITEOS any rights in or to (a) any Other Component Controlled by GSK, including where any Other Component has been used in any Combination Product or Co-Administration Therapy Developed under this Agreement, (b) any Patents or Know-How Controlled by GSK or its Affiliates Covering any Other Component Controlled by GSK or any Exploitation thereof, or (c) any other Third Party assets or rights licensed to GSK, whether or not utilized in connection with the Exploitation of any Licensed Product under the Agreement, in each case, unless the Parties agree otherwise in a written termination agreement entered into by the Parties pursuant to Section 13.2.16 (Terminated Co-Formulated Products). Further, if any exercise of any of the rights licensed to ITEOS under this Section 13.2.8 (License of Certain

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IP) would give rise to any license fee or any other financial obligation or liability owed to any Third Party, then (i) GSK will notify ITEOS of such financial obligations, (ii) ITEOS will confirm in writing whether ITEOS would like the license granted to ITEOS under this Section 13.2.8 (License of Certain IP) to include the rights giving rise to such financial obligations, and (iii) (A) if ITEOS confirms that it would like the license granted to ITEOS under this Section 13.2.8 (License of Certain IP) to include shall be solely responsible for and shall timely pay, and shall hold GSK harmless with respect to, any and all such license fees and financial obligations and liabilities, or (B) if ITEOS confirms that it would like the license granted to ITEOS under this Section 13.2.8 (License of Certain IP) not to include such rights, then the license granted under this Section 13.2.8 (License of Certain IP) not to include such rights, then the license granted under this Section 13.2.8 (License of Certain IP) will not include such rights and ITEOS will not be responsible for such license fees or other financial obligations.

- **13.2.9 Release from Exclusivity**. Notwithstanding any provision to the contrary set forth in this Agreement, if this Agreement is terminated for one or more, but not all, Licensed Products, then Section 9.12 (Exclusivity) will not apply to ITEOS's Development, Manufacture, or Commercialization of such terminated Licensed Products following the effective date of termination.
- **Inventory; Supply**. Upon termination of this Agreement, and for a period of up to [\*\*\*] after the effective 13.2.10 date of such termination, ITEOS will have the right to purchase all of GSK and its Affiliates' then-current remaining inventory of non-GMP drug substance, and master or working cell banks in each case solely for one or more terminated Licensed Products that are EOS-448 Sole Active Products (for clarity, not including any terminated [\*\*\*]. If ITEOS makes such purchase, GSK will provide the relevant primary drug substance reference standard, record of analysis, and a summary report describing its characterization. ITEOS will have the right to purchase such remaining non-GMP inventory of such terminated EOS-448 Sole Active Products at a price equal to GSK's Manufacturing Costs for such inventory, less any amounts previously included in the calculation of Net Profit or Loss prior to termination of this Agreement. In addition, during this period of up to [\*\*\*], (a) in the case that GSK is itself Manufacturing such terminated EOS-448 Sole Active Products, ITEOS will have the right to order additional (to be newly manufactured) supply of such terminated EOS-448 Sole Active Products at a price equal to GSK's Manufacturing Costs for such inventory, and (b) in the case that a Third Party is Manufacturing such terminated EOS-448 Sole Active Products under contracts that only relate to such terminated EOS-448 Sole Active Products and that permit the assignment of such contracts to ITEOS, upon ITEOS's request, GSK will assign to ITEOS (and upon such assignment ITEOS will assume), such contracts.
- **13.2.11 Trademarks**. Unless and until the Parties agree otherwise in a written termination agreement pursuant to Section 13.2.16 (Terminated Co-Formulated Products), effective as of the date of termination, GSK will assign (or, if applicable, will cause its Affiliates or its or their Sublicensees to assign) to ITEOS all of GSK's (and such Affiliates' or its or their Sublicensees') worldwide rights, title and



interests in and to any Product Marks that are specific to and solely used for any such terminated Licensed Products (it being understood that the foregoing will not include any trademarks that (a) contain the corporate or business name(s) of GSK or any of its Affiliates or its or their Sublicensees or (b) refer to any Other Component Controlled by GSK or its Affiliates or products incorporating any such Other Component as a sole active ingredient).

- **13.2.12 Transition Plan**. (i) The Parties shall negotiate in good faith to agree to a plan acceptable to both Parties for the transition of Development and Manufacture of the terminated EOS-448 Sole Active Products to ITEOS, including, if necessary, a Manufacturing technology transfer to ITEOS, to be completed within [\*\*\*] after such termination, of all Know-How Controlled by GSK that is necessary for ITEOS to Manufacture the terminated EOS-448 Sole Active Products (as such Licensed Product exists as of the effective date of termination), and (ii) GSK will, for the duration of the plan, provide any other reasonable assistance or take any other actions, in each case reasonably requested by ITEOS, as necessary to transfer to ITEOS the Development, Manufacture, and Commercialization of the Licensed Antibodies and terminated EOS-448 Sole Active Products as may be reasonably requested by ITEOS in order to give effect to this Section 13.2 (Effects of Termination).
- **13.2.13 Patent Information**. GSK, if requested in writing by ITEOS, will provide any (i) material correspondence with the relevant patent offices pertaining to GSK's prosecution of the Subject Patents to the extent not previously provided to ITEOS during the Term and (ii) a report detailing the status of all Subject Patents at the time of termination, in each case ((i) and (ii)), relating to the terminated Licensed Products.
- **13.2.14 Joint Arising Technology**. The Parties will negotiate in good faith the terms under which the Parties will prosecute, maintain, defend and enforce the Joint Arising Technology Covering (with respect to Patents) or relating to (with respect to Know-How) such terminated Licensed Products following termination of this Agreement in whole or in part, and neither Party may prosecute, maintain, defend, or enforce such Joint Arising Technology with respect to such terminated Licensed Products except as set forth in such agreed terms.
- **13.2.15 Cooperation**. Each Party will use reasonable efforts to cause its Affiliates, its and their sublicensees and subcontractors to comply with the obligations in this Section 13.2 (Effects of Termination).

## 13.2.16 Terminated Co-Formulated Products. [\*\*\*].

**13.3 Survival**. In addition to any other terms or conditions that are otherwise expressly stated to survive elsewhere in Section 13.2 (Effects of Termination), the following provisions shall survive termination or expiration of this Agreement: Section 3.7 (Performance of Development Activities; Development Records) (for the period of time provided therein), Section 3.11.2 (for the period of time provided therein), Sections 10.1-10.4 (for the period

of time provided for in Section 10.2 (Confidentiality)), Section 11.1 (Ownership of Intellectual Property), Section 8.7.7 (Expiration of Royalty Term), and Section 14.4 (Disclaimer of Warranty) and Article 1 (Definitions), Article 13 (Effects of Expiration or Termination), Article 15 (Indemnification), Article 16 (Dispute Resolution), and Article 17 (Miscellaneous).

#### **ARTICLE 14**

## **REPRESENTATIONS AND WARRANTIES AND COVENANTS**

- **14.1 Mutual Representations, Warranties and Covenants**. Each Party represents and warrants to the other Party as of the Execution Date, and covenants (as applicable) that:
  - **14.1.1** such Party is duly organized, validly existing and in good standing under the Applicable Laws of the jurisdiction of its incorporation and has full corporate power and authority and legal right to enter into this Agreement and to carry out the provisions hereof;
  - **14.1.2** such Party has the right to grant the licenses to the other Party purported to be granted pursuant to this Agreement;
  - **14.1.3** such Party has taken all necessary action on its part required to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder, and this Agreement constitutes a legal, valid and binding obligation of such Party that is enforceable against it in accordance with the terms and conditions hereof;
  - **14.1.4** such Party has received all necessary licenses and certificates with respect to facilities within such Party's ownership or control sufficient to allow such Party to conduct the activities assigned to such Party under the Global Development Plan, and such Party is in compliance with the requirements of such licenses and certificates;
  - **14.1.5** entering into this Agreement by such Party (a) will not constitute a default under, or conflict with, any agreement, instrument or understanding, oral or written, to which it is a party or by which it is bound, (b) violate any Applicable Law or regulation of any court, governmental body or administrative or other agency having jurisdiction over such Party; and (c) is not prohibited or limited by, and shall not result in the breach of or a default under, any provision of the certificate or articles of incorporation or bylaws of such Party;
  - **14.1.6** except for any HSR Filings that may be required to comply with the HSR Act, it is not and will not be required to give any notice to any governmental authority or obtain any approval in connection with the execution and delivery of this Agreement;
  - **14.1.7** such Party and its Affiliates have not employed and during the Term, will not employ any Person debarred by the FDA (or subject to a similar sanction of EMA



or foreign equivalent), or any Person who is the subject of an FDA debarment investigation or proceeding (or similar proceeding of EMA or foreign equivalent);

- **14.1.8** such Party and its Affiliates performing activities under this Agreement has in place or will have in place prior to its conduct of its activities under the Agreement a written agreement with its employees and other personnel it appoints to perform such activities hereunder to ensure that such Party has sufficient ownership or license rights to any Arising Technology invented, discovered, created or developed by such Party to grant the rights to the other Party as required to be granted under this Agreement;
- **14.1.9** as relevant to this Agreement: (a) such Party did not employ child labor, forced labor, or cruel or abusive disciplinary practices in the workplace; (b) such Party did not discriminate against any workers on any ground in violation of Applicable Law (including race, religion, disability, gender, sexual orientation or gender identity); and (c) such Party paid each employee at least the minimum wage, provided each employee with all legally mandated benefits, and complies with all Applicable Laws on working hours and employment rights in the countries in which it operates;
- **14.1.10** such Party has complied with Applicable Laws relating to anti-corruption and anti-bribery. It has not prior to the Effective Date as relevant to this Agreement, and will not, in connection with the performance of this Agreement, directly or indirectly, make, promise, authorize, ratify or offer to make, or take any act in furtherance of any payment or transfer of anything of value for the purpose of influencing, inducing or rewarding any act, omission or decision to secure an improper advantage, or improperly assisting such Party in obtaining or retaining business, or in any way with the purpose or effect of public or commercial bribery. Each Party will use commercially reasonable efforts to prevent subcontractors, agents or any other Third Parties, subject to its control or determining influence, from doing any of the foregoing activities. For the avoidance of doubt, the foregoing activities include facilitating payments, which are unofficial, improper, small payments or gifts offered or made to Government Officials to secure or expedite a routine or necessary action to which such Party is legally entitled; and
- **14.1.11** such Party shall, and shall cause its Affiliates and its and their respective subcontractors and Sublicensees to, conduct all activities undertaken pursuant to this Agreement in accordance with Applicable Law, including entering into any data protection agreements required under Data Protection Laws.
- **14.2 Representations, Warranties and Covenants of ITEOS.** ITEOS represents and warrants to GSK, as of the Execution Date, and covenants (as applicable) as follows, except to the extent otherwise disclosed by ITEOS to GSK prior to such date:
  - **14.2.1** ITEOS owns or otherwise Controls the ITEOS Background Patents and ITEOS Background Know-How included in the ITEOS Technology, and that the ITEOS Background Patents on <u>Schedule 14.2.1</u> are solely owned by ITEOS except as otherwise noted on <u>Schedule 14.2.1</u>;

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- **14.2.2** ITEOS has not entered into any agreement, and shall not enter into any agreement, granting any right, interest or claim in or to, any Licensed Antibodies or Licensed Products or the ITEOS Technology, in each case, that would conflict or contravene with the rights and licenses granted to GSK in this Agreement and has not granted, and will not grant, any right to any Third Party that would conflict or contravene with the rights granted to GSK hereunder;
- **14.2.3** all ITEOS Background Patents included in the ITEOS Technology are existing and, to ITEOS's Knowledge, are not invalid or unenforceable;
- **14.2.4** to ITEOS's Knowledge no Person is infringing or threatening to infringe or misappropriating or threatening to misappropriate any ITEOS Background Patents or ITEOS Background Know-How, in each case, included in the ITEOS Technology;
- 14.2.5 no claim or litigation has been brought or threatened in writing by any Person against ITEOS alleging that (a) any ITEOS Background Patents included in the ITEOS Technology are invalid or unenforceable, or (b) except to the extent otherwise disclosed by ITEOS to GSK prior to such date, the use or practice of any ITEOS Background Patents or ITEOS Background Know-How, or the disclosing, copying, making, assigning or licensing of any ITEOS Background Patents or ITEOS Background Know-How, in each case, included in the ITEOS Technology;
- **14.2.6** to ITEOS's Knowledge, there are not any scientific or technical facts or circumstances that have not been disclosed by ITEOS to GSK, and that would, in ITEOS's reasonable estimation, have a material adverse effect on the scientific, therapeutic or commercial potential of Licensed Antibodies and Licensed Product;
- **14.2.7** all information and data provided by or on behalf of ITEOS to GSK on or before the Effective Date in contemplation of this Agreement was and is true and accurate in all material respects at the time of disclosure thereof;
- **14.2.8** to ITEOS's Knowledge, the conception and reduction to practice of any inventions and the use or development of any other information within the ITEOS Background Know-How owned by ITEOS have not constituted or involved the misappropriation of trade secrets of any Third Party;
- **14.2.9** ITEOS is in material compliance with (a) all Data Protection Laws; (b) all privacy policies and other related policies, programs and other notices of ITEOS relating to the privacy, protection and security of PII; and (c) all contractual and other legal requirements to which ITEOS is subject with respect to the privacy, protection, and security of PII; and has in place reasonable safeguards to protect the confidentiality and security of PII, including from unauthorized access or misuse, based on Applicable Law, in each case of (a) through (c), as applicable to the ITEOS's operations and activities directly related to this Agreement; and

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- **14.2.10** ITEOS has provided complete and accurate copies to GSK of ITEOS Background Agreements (which may be redacted as necessary to comply with obligations to such Third Party) and to ITEOS's Knowledge, that are not any material breaches of any ITEOS Background Agreement that would give any Third Party the right to terminate the same.
- **14.3 Representations, Warranties and Covenants of GSK.** GSK represents and warrants to ITEOS, as of the Execution Date, as follows, except to the extent otherwise disclosed by GSK to ITEOS prior to such date:
  - **14.3.1** GSK is in material compliance with (a) all Data Protection Laws; (b) all privacy policies and other related policies, programs and other notices of GSK relating to the privacy, protection and security of PII; and (c) all contractual and other legal requirements to which GSK is subject with respect to the privacy, protection, and security of PII; and has in place reasonable safeguards to protect the confidentiality and security of PII, including from unauthorized access or misuse, based on Applicable Law, in each case of (a) through (c), as applicable to GSK's operations and activities directly related to this Agreement;
  - **14.3.2** [\*\*\*]; and
  - **14.3.3** [\*\*\*].
- 14.4 Disclaimer of Warranty. EXCEPT AS OTHERWISE EXPRESSLY STATED IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR WARRANTY OF ANY KIND, AND BOTH PARTIES EXPRESSLY DISCLAIM ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND NONINFRINGEMENT.
- **14.5 Time For Claims**. Except in the case of any fraud or intentional misrepresentation by a Party: (a) no claim may be made or suit instituted alleging breach or seeking indemnification pursuant to Article 15 (Indemnification) for any breach of, or inaccuracy in, any representation or warranty contained in Section 14.1 (Mutual Representations, Warranties and Covenants), Section 14.2 (Representations, Warranties and Covenants of ITEOS), and Section 14.3 (Representations, Warranties and Covenants of GSK) unless a written notice is provided to the Indemnifying Party at any time prior to the date that is [\*\*\*] following the Effective Date, and (b) after such [\*\*\*] period, no Party may bring any claim against the other Party arising from or relating to such other Party's breach of such representations and warranties.

## ARTICLE 15 INDEMNIFICATION

## 15.1 Indemnification.

**15.1.1 Indemnification by ITEOS.** ITEOS hereby agrees to indemnify, defend and hold harmless GSK and its Affiliates and their respective directors, officers, employees

and agents, and the respective successors and assigns any of the foregoing ("**GSK Indemnitees**"), from and against any and all suits, claims, actions, demands, losses, damages, liabilities, settlements, penalties, fines, costs and expenses (including reasonable attorneys' fees and other expenses of litigation) (collectively, "**Losses**") asserted by a Third Party to the extent arising from (a) any inaccuracy as of the date when made of any of ITEOS's representations and warranties hereunder, (b) an ITEOS Indemnitee's breach of this Agreement, gross negligence or willful misconduct, or (c) the Development and Commercialization by or on behalf of ITEOS or its Affiliates pursuant to this Agreement, except to the extent such Losses arise out of (i) Product Claims relating to or asserted in the Profit-Sharing Territory, other than to the extent attributable to gross negligence or willful misconduct of GSK or its Affiliates, Sublicensees or Third Party contractors, or (ii) the conduct described in Section 15.1.2(a)-(d) (Indemnification by GSK) below.

- **15.1.2 Indemnification by GSK**. GSK hereby agrees to indemnify, defend and hold harmless ITEOS and its Affiliates and their respective directors, officers, employees and agents, and the respective successors and assigns of any of the foregoing ("**ITEOS Indemnitees**"), from and against any and all Losses asserted by a Third Party to the extent arising from (a) any inaccuracy as of the date when made of any of GSK's representations and warranties hereunder, (b) a GSK Indemnitee's breach of this Agreement, gross negligence or willful misconduct, or (c) the Development, Commercialization or other Exploitation of the Licensed Antibodies and Licensed Products by or on behalf of GSK or its Affiliates pursuant to this Agreement, except to the extent attributable to gross negligence or willful misconduct of ITEOS or its Affiliates, Sublicensees or Third Party contractors, or (ii) the conduct described in Section 15.1.1(a)–(b) (Indemnification by ITEOS) above.
- **15.1.3 Indemnification Procedures.** Upon becoming aware or receipt of notice of any Third Party claim that may be subject to indemnification by the other Party (the "**Indemnifying Party**") under this Section 15.1 (Indemnification), any GSK Indemnitee or any ITEOS Indemnitee (each, an "**Indemnitee**"), as the case may be, shall promptly notify the Indemnifying Party in writing. The Indemnifying Party shall have the right, but not the obligation, to conduct and control, through counsel of its choosing, any action for which indemnifying Party shall not be liable to the Indemnifying Party elects to assume the defense thereof, the Indemnifying Party shall not be liable to the Indemnitee in connection with the defense thereof. The Indemnifying Party may settle any action, claim or suit for which the Indemnifee is seeking indemnification; *provided* that the Indemnifying Party shall first give the Indemnitee advance notice of any proposed compromise or settlement and obtains such Indemnitee's prior written approval, such approval not to be unreasonably withheld. The Parties and their employees shall cooperate fully with each other and their legal representatives in the investigation, defense, prosecution, negotiation, or settlement of any such claim or suit. Each Party's indemnification obligations under this Article 15



(Indemnification) shall not apply to amounts paid by an Indemnitee in settlement of any action with respect to a Third Party claim, if such settlement is effected without the prior written consent of the Indemnifying Party, which consent shall not be withheld unreasonably. In no event shall the Indemnifying Party settle or abate any Third Party claim in a manner that would diminish the rights or interests of the Indemnitee, admit any liability on the part of the Indemnitee, or obligate the Indemnitee to make any payment, take any action, or refrain from taking any action, without the prior written approval of the Indemnitee.

### 15.2 Insurance.

- **15.2.1 ITEOS's Insurance Obligations.** ITEOS shall maintain, at its cost, reasonable insurance against liability and other risks associated with its activities contemplated by this Agreement, including its indemnification obligations herein, in such amounts and on such terms as are determined to be advisable by ITEOS, based on advice from insurance professionals, for companies of similar size and with similar resources for the activities to be conducted by it under this Agreement taking into account the scope of the activities for which ITEOS is responsible hereunder. ITEOS shall furnish to GSK evidence of such insurance, upon request.
- **15.2.2 GSK's Insurance Obligations**. GSK shall maintain, at its cost, insurance or self-insurance with respect to liabilities and other risks associated with its activities and obligations under this Agreement, including its indemnification obligations herein, in such amounts and on such terms as are customary for prudent practices for large companies in the pharmaceutical industry for the activities to be conducted by GSK under this Agreement. GSK shall furnish to ITEOS evidence of such insurance or self-insurance, upon reasonable request.
- **15.3 LIMITATION OF CONSEQUENTIAL DAMAGES.** EXCEPT FOR A PARTY'S INDEMNIFICATION OBLIGATIONS UNDER SECTION 15.1 (INDEMNIFICATION), A BREACH OF A PARTY'S OBLIGATIONS UNDER SECTION 9.12 (EXCLUSIVITY) OR A BREACH OF A PARTY'S CONFIDENTIALITY OBLIGATIONS IN Article 10 (CONFIDENTIALITY; PUBLICATIONS AND PRESENTATIONS), NEITHER ITEOS NOR GSK, NOR ANY OF THEIR AFFILIATES OR SUBLICENSEES WILL BE LIABLE TO THE OTHER PARTY TO THIS AGREEMENT, ITS AFFILIATES OR ANY OF THEIR SUBLICENSEES, FOR ANY INCIDENTAL, CONSEQUENTIAL, SPECIAL, PUNITIVE OR OTHER INDIRECT DAMAGES, INCLUDING LOST PROFITS, LOST DATA OR COST OF PROCUREMENT OF SUBSTITUTE GOODS OR SERVICES, WHETHER LIABILITY IS ASSERTED IN CONTRACT, TORT (INCLUDING NEGLIGENCE AND STRICT PRODUCT LIABILITY) OR CONTRIBUTION, AND IRRESPECTIVE OF WHETHER THAT PARTY OR ANY REPRESENTATIVE OF THAT PARTY HAS BEEN ADVISED OF, OR OTHERWISE MIGHT HAVE ANTICIPATED THE POSSIBILITY OF, ANY SUCH LOSS OR DAMAGE.

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### ARTICLE 16 DISPUTE RESOLUTION

- **16.1 Dispute Resolution**. Except as otherwise pursuant to Sections 7.7 (Decision-Making), 8.17 (Resolution of Financial Disputes) or 8.18 (Specific Finance Disputes), any dispute arising out of or relating to the Agreement, or the breach, termination or validity thereof (a "**Dispute**"), shall be finally resolved pursuant to the following provisions:
  - **16.1.1** In the event a Dispute arises, the Parties agree that they shall attempt in good faith to resolve the Dispute by negotiation between an appropriate representative of GSK that is a direct report to GSK's Chief Executive Officer and ITEOS's Chief Executive Officer (or their respective designee with power and authority to resolve such dispute) (each, a "Senior Executive"). Either Party may refer a Dispute to the applicable Senior Executive of the other Party by serving notice that such Dispute has arisen and demand that negotiations commence ("Notice of Dispute").
  - **16.1.2** If the Parties' Senior Executives are unable for any reason to resolve a Dispute by no later than [\*\*\*] days after service of the Notice of Dispute, then the Parties agree that they shall try in good faith to resolve the Dispute by referring it for confidential mediation under the CPR Mediation Procedure in effect at the start of mediation, before resorting to arbitration. If the Parties cannot agree on a mediator within [\*\*\*] days after the Dispute was referred to mediation, the mediator shall, upon request by either Party, be appointed by CPR pursuant to CPR Mediation Procedure. The cost of mediator shall be borne equally by the Parties.
- **16.2 Arbitration**. Any Dispute not resolved within [\*\*\*] days (or within such other time period as may be agreed to by Parties in writing) after appointment of the mediator shall be finally settled by binding arbitration under the Rules of Arbitration of the American Arbitration Association (the "AAA Rules").
  - **16.2.1** Any disputes concerning the propriety of the commencement of the arbitration or the scope or applicability of this agreement to arbitrate shall be finally settled by the arbitrator(s).
  - **16.2.2** There shall be one or more arbitrators appointed in accordance with the AAA Rules.
  - **16.2.3** The governing law in Section 17.1 (Governing Law) shall govern such proceedings. The place of arbitration shall be New York, New York, unless otherwise agreed to by the Parties, and the language of the arbitration shall be English.
  - **16.2.4** The arbitrator(s) shall use their best efforts to rule on the Dispute within [\*\*\*] days after appointment of the arbitrator(s). The determination of the arbitrator(s) as to the resolution of any Dispute shall be binding and conclusive upon the Parties, absent manifest error. All rulings of the arbitrator(s) shall be in writing and shall be delivered to the Parties as soon as is reasonably possible. Nothing contained herein shall be construed to permit the arbitrator(s) to award punitive, exemplary or any similar damages. Any arbitration award may be entered in and enforced by

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a court in accordance with Sections 16.2.5 (Award), 16.2.7 (Injunctive Relief) and 16.2.10 (Patent Disputes).

- **16.2.5** Award. Subject to Section 8.10 (Tax Matters), any award to be paid by one Party to the other Party as determined by the arbitrator(s) as set forth above under Section 16.2.4 (Arbitration) shall be promptly paid in Dollars free of any tax, deduction or offset; and any costs, fees or taxes incident to enforcing the award shall, to the maximum extent permitted by Applicable Law, be charged against the Party resisting enforcement. Each Party agrees to abide by the award rendered in any arbitration conducted pursuant to this Article 16 (Dispute Resolution), and agrees that judgment may be entered upon the final award in a court of competent jurisdiction and that other courts may award full faith and credit to such judgment in order to enforce such award.
- **16.2.6 Costs**. The arbitrator(s) shall award to the prevailing Party, if any, as determined by the arbitrator(s), the prevailing Party's cost, fees and expenses incurred in connection with such arbitration.
- **16.2.7 Injunctive Relief**. Nothing in this Article 16 (Dispute Resolution) will preclude either Party from seeking equitable relief or interim or provisional relief from a court of competent jurisdiction, including a temporary restraining order, preliminary injunction or other interim equitable relief, concerning a Dispute either prior to or during any arbitration if necessary to protect the interests of such Party or to preserve the *status quo* pending the arbitration proceeding. For the avoidance of doubt, nothing in this Section 16.2.7 (Injunctive Relief) shall otherwise limit a breaching Party's opportunity to cure a material breach as permitted in accordance with Section 12.3 (Termination for Material Breach).
- **16.2.8 Confidentiality**. The arbitration proceeding shall be confidential and the arbitrator(s) shall issue appropriate protective orders to safeguard each Party's Confidential Information. Except as required by Applicable Law, no Party shall make (or instruct the arbitrator(s) to make) any public announcement with respect to the proceedings or decision of the arbitrator(s) without prior written consent of the other Party. The existence of any Dispute submitted to arbitration, and any award shall be kept in confidence by the Parties and the arbitrator(s), except as required in connection with the enforcement of such award or as otherwise required by Applicable Law. Notwithstanding the foregoing, each Party shall have the right to disclose information regarding the arbitration proceeding to the same extent as it may disclose Confidential Information of the other Party under Article 10 (Confidentiality; Publications and Presentations) above.
- **16.2.9 Survivability**. Any duty to arbitrate under this Agreement shall remain in effect and be enforceable after termination of this Agreement for any reason.
- **16.2.10 Patent Disputes.** Notwithstanding this Section 16.2 (Arbitration), any dispute, controversy or claim to the extent regarding the validity, scope, enforceability, or inventorship of intellectual property rights shall be submitted to

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a court of competent jurisdiction or patent office in the country in which such intellectual property rights were granted or arose.

## ARTICLE 17 MISCELLANEOUS

- **17.1 Governing Law**. This Agreement and any dispute arising from the performance or breach hereof shall be governed by and construed in accordance with the laws of the State of New York, without reference to conflicts of laws principles. The Parties acknowledge that this Agreement evidences a transaction involving interstate commerce and a foreign (non-U.S.) Party. Notwithstanding the provision in the preceding sentence with respect to the applicable substantive law, any arbitration, decision or award rendered hereunder and the validity, effect and interpretation of the arbitration provision shall be governed by the Federal Arbitration Act.
- 17.2 Assignment. Neither Party may assign this agreement nor the licenses granted hereunder in whole or in part to any Third Party without the prior written consent of the other Party hereto. Notwithstanding the foregoing, either Party may assign its rights and delegate its obligations under this Agreement, in whole or in part, without the consent of the other Party, to (a) an Affiliate or (b) to a Third Party that acquires all or substantially all of the business or assets of such Party to which the subject matter of this Agreement pertains (whether by merger, reorganization, acquisition, sale of assets or otherwise); provided that, if any withholding taxes are imposed with respect to any payment contemplated under this Agreement as a result of or following an assignment or other transfer by a Party of its rights or obligations hereunder to another entity (or as a result of a subsequent transfer following such assignment or transfer), and such withholding taxes would not have been imposed with respect to such payment under then-applicable Tax laws if such Party had not assigned or transferred its rights or obligations hereunder (or had such subsequent transfer not occurred), then clause (b) of Section 8.10.2 shall apply, such that the amount payable under this Agreement shall be increased to take into account the Increased Withholding Taxes so that the recipient of such payment receives an amount equal to the sum it would have received had no such Increased Withholding Taxes been withheld. The assigning Party remains fully liable for the performance of its obligations hereunder by any such assignee. In addition, and notwithstanding the foregoing, ITEOS may assign its right to receive payments under this Agreement as part of a royalty factoring transaction undertaken for *bona fide* financing purposes. Any assignment of this Agreement in violation of this Section 17.2 (Assignment) will be null, void, and of no legal effect. This Agreement will be binding on and will inure to the benefit of the permitted successors and assigns of the Parties.
- **17.3 Non-Solicitation of Employees.** [\*\*\*] thereafter, each Party agrees that neither it nor any of its Affiliates will recruit, solicit, or induce any employee of the other Party that such Party knew was directly and substantially involved in the Exploitation of Licensed Antibodies or Licensed Products under this Agreement to terminate his or her employment with such other Party and become employed by or consult for such Party, whether or not such employee is a full-time employee of such other Party, and whether or not such employment is pursuant to a written agreement or is at-will. For purposes of the foregoing,

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"recruit," "solicit," or "induce" will not be deemed to mean (a) circumstances where an employee of a Party (i) initiates contact with the other Party or any of its Affiliates with regard to possible employment; or (ii) responds to general solicitations of employment not specifically targeted at employees of a Party or any of its Affiliates, including responses to general advertisements or postings, and (b) discussions, interviews, negotiations, offers, or acceptances of employment or similar activities that arise as a result of circumstances described in (a).

- **17.4 Force Majeure**. Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by a Force Majeure and the nonperforming Party promptly provides notice to the other Party. Such excuse shall be continued so long as the condition constituting Force Majeure continues and the non-performing Party takes commercially reasonable efforts to remove the condition, for up to a maximum of [\*\*\*], after which time the Parties will negotiate in good faith any modifications of the terms and conditions of this Agreement that may be necessary to arrive at an equitable solution. To the extent possible, each Party shall use commercially reasonable efforts to minimize the duration of any Force Majeure.
- **17.5 Notices.** Any notice required or permitted to be given by either Party under this Agreement shall be in writing and shall be personally delivered or sent by a nationally recognized private express courier, or by first class mail (registered or certified) to the respective Parties as set forth below. Notices will be deemed effective (a) the next day if sent by courier; or (b) five (5) Business Days after deposit, postage prepaid, if mailed. Either Party may change its address for purposes hereof by written notice to the other in accordance with the provisions of this Section 17.5 (Notices).

If to GSK:

GlaxoSmithKline 259 E Grand Ave Fifth Floor, Suite 1 San Francisco, CA 94080 Attn.: SVP & Head R&D Business Development

With a copy (which shall not constitute notice to):

GlaxoSmithKline 980 Great West Road Brentford, Middlesex TW8 9GS United Kingdom Attn.: VP & Head of Legal Business Development & Corporate

If to ITEOS:

iTeos Therapeutics 139 Main Street Cambridge, MA 02142 Attn.: Chief Operating Officer

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With a copy (which shall not constitute notice to):

Ropes & Gray LLP 800 Boylston St.; Prudential Tower Boston, MA 02199 Attn.: Hannah H. Freeman

- **17.6 Export Clause**. Each Party acknowledges that the Applicable Laws of the United States and other Applicable Laws restrict the export and re-export of certain commodities and technical data. Each Party agrees that it will not export or re-export restricted commodities or technical data of the other Party in any form without the appropriate United States or foreign government licenses.
- **17.7 Waiver**. The terms and conditions of this Agreement may be waived or released only by a written instrument executed by the Party or Parties waiving or releasing compliance. The failure of either Party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition. No waiver by either Party of any condition or term in any one or more instances shall be construed as a continuing waiver or subsequent waiver of such condition or term or of another condition or term.
- **17.8 Severability**. If any provision hereof should be held invalid, illegal or unenforceable in any jurisdiction, then the Parties shall negotiate in good faith a valid, legal and enforceable substitute provision that most nearly reflects the original intent of the Parties and all other provisions hereof shall remain in full force and effect in such jurisdiction and shall be liberally construed in order to carry out the intentions of the Parties hereto as nearly as may be possible. Such invalidity, illegality or unenforceability shall not affect the validity, legality or enforceability of any other provision of this Agreement or of such provision in any other jurisdiction, unless the invalid, illegal or unenforceable provisions are of such essential importance to this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without such invalid provisions.
- **17.9 Performance by Affiliates**. Either Party may exercise its rights and perform its obligations under this Agreement directly or through one or more of its Affiliates. Each Party's Affiliates will have the benefit of all rights (including all licenses) of such Party under this Agreement. Accordingly, in this Agreement "ITEOS" will be interpreted to mean "ITEOS or its Affiliates" and "GSK" will be interpreted to mean "GSK or its Affiliates" where necessary to give each Party's Affiliates the benefit of the rights provided to the applicable Party in this Agreement; *provided, however*, that in any event each Party will remain responsible hereunder for the acts and omissions of its respective Affiliates.
- **17.10 Entire Agreement.** This Agreement, together with the Schedules attached hereto, constitutes the entire agreement between the Parties with respect to the subject matter hereof and thereof. There are no restrictions, promises, warranties or undertakings, other than those set forth or referred to herein or therein. This Agreement supersedes all prior or contemporaneous agreements and understandings between the Parties with respect to the

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subject matter hereof, including the CDA, and all information exchanged between the Parties under the CDA shall be considered Confidential Information exchanged hereunder upon the Effective Date. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties hereto unless reduced to writing and signed by the respective authorized officers of both Parties.

- **17.11 Cumulative Remedies**. No remedy referred to in this Agreement is intended to be exclusive, but each will be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under Applicable Law.
- **17.12 Independent Contractors**. Nothing herein shall be construed to create a partnership, or any relationship of employer and employee, agent and principal, or joint venture between the Parties. Each Party is an independent contractor. Neither Party shall assume, either directly or indirectly, any liability of or for the other Party. Neither Party shall have the authority to bind or obligate the other Party, and neither Party shall represent that it has such authority. Neither Party shall report the transactions and undertakings contemplated by this Agreement as a partnership for United States federal income tax purposes unless the arrangement between the Parties as contemplated by this Agreement is determined to constitute an Entity under Applicable Law (as determined based on the opinion (on a "should" basis) of a nationally recognized law or accounting firm) or by a tax authority on audit or other examination.
- **17.13 Headings**. Headings used herein are for convenience only and shall not in any way affect the construction of or be taken into consideration in interpreting this Agreement.
- **17.14 Further Actions**. Each Party shall execute, acknowledge and deliver such further instruments, and do all such other acts, as may be reasonably necessary or appropriate in order to carry out the expressly stated purposes and the clear intent of this Agreement.
- **17.15 Supremacy**. To the extent of any express conflict or inconsistency between this Agreement and any Schedule hereto, the terms and conditions of this Agreement shall control.
- **17.16 Counterparts.** This Agreement may be executed and delivered (including by PDF or any other electronically transmitted signatures) in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.
- **17.17 Binding Effect; No Third Party Beneficiaries.** As of the Effective Date, this Agreement will be binding upon and inure to the benefit of the Parties and their respective permitted successors and assigns. This Agreement is intended for the benefit of the Parties, their respective permitted successors and assigns, and is not for the benefit of, nor many any provision hereof be enforced by, any other Person other than with respect to the indemnification provisions in Article 15 (Indemnification) and as otherwise expressly set forth herein.
- **17.18 Interpretation.** The definitions of the terms herein will apply equally to the singular and plural forms of the terms defined. Whenever the context may require, any pronoun will include the corresponding masculine, feminine, and neuter forms. The word "any" will

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mean "any and all" unless otherwise clearly indicated by context. Unless the context requires otherwise, (a) any definition of or reference to any agreement, instrument, or other document herein will be construed as referring to such agreement, instrument, or other document as from time to time amended, supplemented, or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (b) any reference to any Applicable Laws herein will be construed as referring to such Applicable Laws as from time to time enacted, repealed, or amended, (c) any reference herein to any Person will be construed to mean the Person's successors and assigns (after any such succession or assignment), (d) the words "herein", "hereof" and "hereunder", and words of similar import, will be construed to refer to this Agreement in its entirety and not to any particular provision hereof, (e) the word "or" will be interpreted to mean "and/or", (f) all references herein to Articles, Sections, or Exhibits, unless otherwise specifically provided, will be construed to refer to Articles, Sections, and Exhibits of this Agreement, (g) the words "include" and "including" will be interpreted to mean "include without limitation" and "including without limitation," respectively, (h) wherever used, the word "shall" and the word "will" are each understood to be imperative or mandatory in nature and are interchangeable with one another, (i) the word "notice" means notice in writing (whether or not specifically stated) and will include notices, consents, approvals and other written communications contemplated under this Agreement, and (j) provisions that require that a Party, the Parties or any committee hereunder "agree," "consent," or "approve" or the like will require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes, or otherwise (but excluding e-mail and instant messaging).

#### [Signature page follows]

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IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the Execution Date by their respective duly authorized representatives as set forth below.

## GLAXOSMITHKLINE INTELLECTUAL PROPERTY (NO. 4) LIMITED

/s/ John Sadler

- By: John Sadler
- Its: Corporate Director

# **ITEOS BELGIUM S.A.**

- /s/ Michel Detheux
- By: Michel Detheux
- Its: Board Member
- /s/ Gregory Driessens
- By: Gregory Driessens
- Its: Board Member

#### CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

#### I, Michel Detheux, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 2021 of iTeos Therapeutics, 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;
- Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. (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 11, 2021

By: /s/ Michel Detheux

Michel Detheux President, Chief Executive Officer and Director (Principal Executive Officer)

#### CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER PURSUANT TO RULE 13a-14(a) OR 15d-14(a) OF THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

#### I, Matthew Gall, certify that:

- 1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 2021 of iTeos Therapeutics, 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;
- Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
- 4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:
  - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b. (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 11, 2021

By: /s/ Matthew Gall

Matthew Gall Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)

#### CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Michel Detheux, the Chief Executive Officer, and Matthew Gall, the Chief Financial Officer, of iTeos Therapeutics, Inc. (the "Company"), hereby certify, that, to their knowledge:

- (1) the Quarterly Report on Form 10-Q for the period ended June 30, 2021 (the "Report") of the Company 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 and results of operations of the Company.

Date: August 11, 2021

By: /s/ Michel Detheux

Michel Detheux President, Chief Executive Officer and Director (Principal Executive Officer)

Date: August 11, 2021

By: /s/ Matthew Gall

Matthew Gall Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)