

**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 September 30, 2021

OR

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

For the transition period from _____ to _____

Commission File Number: 001-39401

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 No

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

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

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

As of November 2, 2021, the registrant had 35,273,893 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.

- 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

Item 1. Financial Statements.

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

(in thousands, except share amounts)	September 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 899,767	\$ 336,326
Grants receivable	4,891	133
Research and development tax credits receivable	539	192
Prepaid expenses and other current assets	8,940	2,893
Total current assets	914,137	339,544
Property and equipment, net	2,121	1,352
Research and development tax credits receivable	2,852	3,286
Restricted cash	137	128
Right of use assets	2,859	-
Other assets	273	248
Total assets	<u>\$ 922,379</u>	<u>\$ 344,558</u>
Liabilities, redeemable convertible preferred stock and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 4,707	\$ 3,026
Accrued expenses and other current liabilities	12,189	7,486
Income tax payable	2,771	—
Deferred income	522,075	4,486
Lease liabilities	486	—
Total current liabilities	542,228	14,998
Grants repayable, net of current portion	5,548	5,883
Other noncurrent liabilities	181	480
Lease liabilities, net of current portion	2,383	—
Total liabilities	550,340	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 September 30, 2021 and December 31, 2020	—	—
Common stock, \$0.001 par value, 150,000,000 shares authorized; 35,257,464 and 35,044,758 shares issued and outstanding at September 30, 2021 and December 31, 2020, respectively	35	35
Additional paid-in capital	407,499	396,443
Accumulated other comprehensive income	8,754	617
Accumulated deficit	(44,249)	(73,898)
Total stockholders' equity	372,039	323,197
Total liabilities and stockholders' equity	<u>\$ 922,379</u>	<u>\$ 344,558</u>

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 income (loss)
(unaudited)

(in thousands, except share and per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue:				
License Revenue	\$ 104,271	\$ —	\$ 104,271	\$ —
Total Revenue	<u>104,271</u>	<u>—</u>	<u>104,271</u>	<u>—</u>
Operating expenses:				
Research and development expenses	16,102	8,726	41,983	20,688
General and administrative expenses	8,761	4,799	30,907	9,611
Total operating expenses	<u>24,863</u>	<u>13,525</u>	<u>72,890</u>	<u>30,299</u>
Income (loss) from operations	79,408	(13,525)	31,381	(30,299)
Other income and expenses:				
Grant income	1,320	2,299	8,936	4,969
Fair value adjustment for preferred stock tranche rights liability	—	—	—	1,265
Research and development tax credits	169	273	288	643
Other income (expense), net	(8,484)	265	(8,185)	235
Income (loss) before income taxes	72,413	(10,688)	32,420	(23,187)
Income tax (expense) benefit	(2,771)	8	(2,771)	58
Net income (loss)	69,642	(10,680)	29,649	(23,129)
Cumulative dividends on Series A preferred stock	—	(36)	—	(249)
Accretion of redeemable convertible preferred stock to redemption value	—	(931)	—	(5,120)
Net income (loss) attributable to common stockholders	\$ 69,642	\$ (11,647)	\$ 29,649	\$ (28,498)
Basic net income (loss) per common share	\$ 1.98	\$ (0.48)	\$ 0.84	\$ (3.40)
Diluted net income (loss) per common share	\$ 1.86	\$ (0.48)	\$ 0.79	\$ (3.40)
Weighted-average common shares outstanding - basic	35,196,995	24,349,222	35,134,692	8,376,860
Weighted-average common shares outstanding - diluted	37,482,089	24,349,222	37,539,184	8,376,860
Net income (loss)	\$ 69,642	\$ (10,680)	\$ 29,649	\$ (23,129)
Foreign currency translation adjustments	8,516	393	8,137	321
Comprehensive income (loss)	<u>\$ 78,158</u>	<u>\$ (10,287)</u>	<u>\$ 37,786</u>	<u>\$ (22,808)</u>

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

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

In thousands except share amounts	Series A preferred stock		Series B preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity (deficit)
	Shares	Amount	Shares	Amount	Shares	Amount				
	Balance at December 31, 2019	6,167,726	\$ 5,353	20,942,781	\$ 46,404	256,548				
Issuance of Series B-2 Preferred Stock, net of 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)
Accretion of Series B and B-2 preferred stock to redemption value	—	—	—	931	—	—	(931)	—	—	(931)
Conversion of redeemable convertible preferred stock to common stock upon closing of initial public offering	(6,167,726)	(5,353)	(65,396,258)	(176,550)	22,460,076	22	181,881	—	—	181,903
Issuance of common stock from initial public offering, net of issuance costs of \$19.0 million	—	—	—	—	12,091,675	12	210,687	—	—	210,699
Exercise of stock options into common stock	—	—	—	—	104,592	—	450	—	—	450
Stock-based compensation	—	—	—	—	—	—	1,714	—	—	1,714
Currency translation adjustment	—	—	—	—	—	—	—	393	—	393
Net loss	—	—	—	—	—	—	—	—	(10,680)	(10,680)
Balance at September 30, 2020	—	\$ —	—	\$ —	35,044,758	\$ 35	\$ 394,488	\$ 97	\$ (58,994)	\$ 335,626

In thousands except share amounts	Series A preferred stock		Series B preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive income	Accumulated deficit	Total stockholders' equity
	Shares	Amount	Shares	Amount	Shares	Amount				
	Balance at December 31, 2020	—	\$ —	—	\$ —	35,044,758				
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
Stock-based compensation	—	—	—	—	—	—	3,942	—	—	3,942
Common stock issued upon exercises of options	—	—	—	—	109,354	—	441	—	—	441
Currency translation adjustment	—	—	—	—	—	—	—	8,516	—	8,516
Net income	—	—	—	—	—	—	—	—	69,642	69,642
Balance at September 30, 2021	—	\$ —	—	\$ —	35,257,464	\$ 35	\$ 407,499	\$ 8,754	\$ (44,249)	\$ 372,039

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)

(in thousands)	Nine Months Ended September 30,	
	2021	2020
Cash flows from operating activities		
Net income (loss)	\$ 29,649	\$ (23,129)
Adjustments to reconcile net income (loss) to net cash provided by (used in) operating activities:		
Depreciation and amortization	452	392
Stock-based compensation	9,753	2,250
Change in operating lease right-of-use assets	10	
Fair value adjustment for preferred stock tranche rights liability	—	(1,265)
Deferred rent	—	(11)
Changes in operating assets and liabilities:		
Grants receivable	(4,927)	3,007
Research and development tax credits receivable	(98)	(505)
Prepaid expenses and other current assets	(6,304)	(2,346)
Accounts payable	1,763	901
Accrued expenses and other liabilities	4,732	1,579
Income tax payable	2,771	—
Deferred income	534,155	(585)
Net cash provided by (used in) operating activities	571,956	(19,712)
Cash flows from investing activities		
Purchase of property and equipment	(1,019)	(222)
Purchase of other assets	(62)	(21)
Net cash used in investing activities	(1,081)	(243)
Cash flows from financing activities		
Proceeds from initial public offering, net of underwriting discount	—	213,660
Payment of initial public offering costs	—	(2,691)
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	1,303	655
Proceeds from grants repayable	—	2,856
Net cash provided by financing activities	1,303	339,506
Effects of exchange rate changes on cash, cash equivalents and restricted cash	(8,728)	566
Net increase in cash, cash equivalents and restricted cash	563,450	320,117
Cash, cash equivalents and restricted cash at beginning of period	336,454	19,990
Cash, cash equivalents and restricted cash at end of period	\$ 899,904	\$ 340,107
Non-cash investing and financing activities		
Conversion of redeemable convertible preferred stock to common stock upon closing of the initial public offering	\$ —	\$ 181,903
Capital expenditure included in accounts payable	\$ 224	\$ —
Accretion of Series B and B-2 Preferred Stock to redemption value	\$ —	\$ 5,120
Settlement of preferred stock tranche right	\$ —	\$ 4,135
Deferred IPO costs in accounts payable	\$ —	\$ 270
Operating lease liabilities arising from obtaining right-of-use assets	\$ 3,322	\$ —
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 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. EOS-448 is being evaluated in two Phase 1/2 clinical trials in adult cancer patients with advanced solid tumors, the first evaluating monotherapy and the second evaluating EOS-448 in combinations with pembrolizumab and with inupadenant. The Company is also advancing inupadenant, a next-generation adenosine A2A receptor antagonist tailored to overcome cancer immunosuppression. Inupadenant is being evaluated in two early phase trials in adult cancer patients with advanced solid tumors of inupadenant monotherapy and inupadenant combinations with pembrolizumab and with chemotherapy, and we are evaluating a salt form of inupadenant. 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 Therapeutics U.S. Inc. (iTeos U.S.) included the Company's U.S. operations and was located in Cambridge, Massachusetts. iTeos U.S., which was a wholly owned subsidiary of iTeos Belgium prior to the Share Exchange, continued to be 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.

On December 2, 2020, iTeos Securities Corporation (iTeos SC) was incorporated as a Massachusetts Security Corporation. It is a wholly-owned subsidiary of iTeos Inc. On July 27, 2021, iTeos BE, LLC (iTeos LLC) was incorporated as a Delaware Limited Liability Company. It is a wholly-owned subsidiary of iTeos Belgium.

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. For the first time since inception, the Company has earned income during the current period, which equaled net income of \$29.6 million for the nine months ended September 30, 2021. As of September 30, 2021, the Company had an accumulated deficit of \$44.2 million. As of November 10, 2021, the issuance date of the condensed consolidated financial statements for the nine months ended September 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 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 sustained 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 nine 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 ongoing 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, the identification of additional variants of COVID-19, the availability and utilization of vaccines and treatments for COVID-19, or the effectiveness of actions taken globally to contain and address COVID-19, such as travel restrictions, quarantines, social distancing and business closure requirements, but particularly in the geographies where the Company, its 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, revenue, and expenses, as well as the related disclosures of contingent assets and liabilities. The Company bases its estimates and assumptions on historical experiences, when available, and on various factors that it believes to be reasonable under the circumstances. The Company evaluates its estimates and assumptions on an ongoing basis. Actual results could differ materially from these 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.

Revenue Recognition

As of September 30, 2021, all of the Company's revenue to date had been collaboration revenue generated from its Collaboration and License Agreement with GlaxoSmithKline (GSK), or the GSK Collaboration Agreement.

The Company analyzes its collaboration arrangements to assess whether they are within the scope of Accounting Standards Codification ASC Topic 808, *Collaborative Arrangements* (ASC 808), to determine whether such arrangements involve joint operating activities performed by parties that are both active participants in the activities and exposed to significant risks and rewards that are dependent on the commercial success of such activities. If the Company concludes that some or all aspects of the arrangement are within the scope of ASC 808 and do not represent a transaction with a customer, the Company recognizes its allocation of the shared costs incurred with respect to the jointly conducted activities pursuant to ASC 730, *Research and Development*. As such, the Company will expense costs as incurred, including any reimbursements made, and recognize reimbursements received as a reduction of research and development expense. If the Company concludes that some or all aspects of the arrangement represent a transaction with a customer, the Company accounts for those aspects of the arrangement within the scope of ASC 606, *Revenue from Contracts with Customers* (ASC 606).

At inception, the Company determines whether contracts are within the scope of ASC 606 or other topics. For contracts that are determined to be within the scope of ASC 606, revenue is recognized when a customer obtains control of promised goods or services. The amount of revenue recognized reflects the consideration to which the Company expects to be entitled to receive in exchange for these goods and services. To achieve this core principle, the Company applies the following five steps (i) identify the contract with the customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when performance obligation is satisfied. The Company only applies the five-step model to contracts when it determines that collection of substantially all consideration for goods and services that are transferred is probable based on the customer's intent and ability to pay the promised consideration.

Performance obligations promised in a contract are identified based on the goods and services that will be transferred to the customer that are both capable of being distinct and are distinct in the context of the contract. To the extent a contract includes multiple promised goods and services, the Company applies judgment to determine whether promised goods and services are both capable of being distinct and distinct in the context of the contract. If these criteria are not met, the promised goods and services are accounted for as a combined performance obligation.

The transaction price is determined based on the consideration to which the Company will be entitled in exchange for transferring goods and services to the customer. To the extent the transaction price includes variable consideration, the Company estimates the amount of variable consideration that should be included in the transaction price utilizing either the expected value method or the most likely amount method, depending on the nature of the variable consideration. Variable consideration is included in the transaction price if, in management's judgment, it is probable that a significant future reversal of cumulative revenue under the contract will not occur. Any estimates, including the effect of the constraint on variable consideration, are evaluated at each reporting period for any changes. Determining the transaction price requires significant judgment.

If the contract contains a single performance obligation, the entire transaction price is allocated to the single performance obligation. Contracts that contain multiple performance obligations require an allocation of the transaction price to each performance obligation on a relative standalone selling price basis unless the transaction price is variable and meets the criteria to be allocated entirely to a performance obligation or to a distinct service that forms part of a single performance obligation. The consideration to be received is allocated among the separate performance obligations based on relative standalone selling prices. The Company typically determines standalone selling prices using an adjusted market assessment approach model.

The Company satisfies performance obligations either over time or at a point in time. Revenue is recognized over time if either (i) the customer simultaneously receives and consumes the benefits provided by the entity's performance, (ii) the entity's performance creates or enhances an asset that the customer controls as the asset is created or enhanced, or (iii) the entity's performance does not create an asset with an alternative use to the entity and the entity has an enforceable right to payment for performance completed to date. If the entity does not satisfy a performance obligation over time, the related performance obligation is satisfied at a point in time by transferring the control of a promised good or service to a customer

For licenses of intellectual property (IP), if the license to the Company's IP is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from consideration allocated to the license when the license is transferred to the customer and the customer can use and benefit from the licenses. For licenses that are combined with other promises, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time and, if over time, the appropriate method of measuring progress for purposes of recognizing revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

At the inception of each arrangement that includes development or regulatory milestone payments, the Company evaluates the probability of reaching the milestones and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur in the future, the associated milestone value is included in the transaction price. Milestone payments that are not within the Company's control or the licensee's, such as regulatory approvals, are not considered probable of being achieved until those approvals are received and therefore revenue recognized is constrained as management is unable to assert that a reversal of revenue would not be possible. The transaction price is then allocated to each performance obligation on a relative standalone selling price basis, for which the Company recognizes revenue as or when the performance obligations under the contract are satisfied. At the end of each subsequent reporting period, the Company re-evaluates the probability of achievement of such development milestones and any related constraint, and if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment. To date, the Company has not recognized any milestone revenue resulting from any of its agreements.

For arrangements that include sales-based royalties, including milestone payments based on levels of sales, if the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). To date, the Company has not recognized any royalty revenue resulting from any of its agreements.

Deferred revenue arises from amounts received in advance of the culmination of the earnings process and is recognized as revenue in future periods as performance obligations are satisfied. Deferred revenue expected to be recognized within the next twelve months is classified as a current liability. Upfront payment contract liabilities resulting from the Company's license agreements do not represent a financing component as the payment is not financing the transfer of goods or services, and the technology underlying the licenses granted reflects research and development expenses already incurred by the Company.

Contract costs

The Company recognizes as an asset the incremental costs of obtaining a contract with a customer if the costs are expected to be recovered. The Company has elected the practical expedient in ASC 340, *Other Assets and Deferred Costs*, wherein it recognizes the incremental costs of obtaining a contract as an expense when incurred if, at inception, the expected amortization period of the asset that the Company otherwise would have recognized is one year or less. In connection with the GSK Collaboration Agreement, the Company incurred an incremental cost of \$6.8 million, which was included in general and administrative costs in the accompanying statement of operations and comprehensive income (loss) for the nine months ended September 30, 2021.

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.

In December 2019, the FASB issued ASU No. 2019-12, *Simplifying the Accounting for Income Taxes*, as part of its initiative to reduce complexity in accounting standards. The amendments in the ASU include removing exceptions to incremental intraperiod tax allocation of losses and gains from different financial statement components, exceptions to the method of recognizing income taxes on interim period losses, and exceptions to deferred tax liability recognition related to foreign subsidiary investments. In addition, the ASU requires that entities recognize franchise tax based on an incremental method and requires an entity to evaluate the accounting for step-ups in the tax basis of goodwill as inside or outside of a business combination. We adopted ASU 2019-12 starting January 1, 2021, which did not have a material impact on our consolidated financial statements.

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 September 30, 2021 and December 31, 2020:

(in thousands)	September 30, 2021			
	Level 1	Level 2	Level 3	Total
Cash equivalents (money market funds)	\$ 229,035	\$ —	\$ —	\$ 229,035
Totals	\$ 229,035	\$ —	\$ —	\$ 229,035

(in thousands)	December 31, 2020			
	Level 1	Level 2	Level 3	Total
Cash equivalents (money market funds)	\$ 314,636	\$ —	\$ —	\$ 314,636
Totals	\$ 314,636	\$ —	\$ —	\$ 314,636

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):

	<u>Valuation Dates</u>
	<u>March 23, 2020</u>
	<u>(Tranche 3 settlement)</u>
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	<u>1.1%</u>

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 nine month periods ended September 30, 2021 and 2020.

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

<u>(in thousands)</u>	<u>Preferred Stock Tranche Rights Liability</u>
Balances at January 1, 2020	\$ 5,400
Change in estimated fair value	(1,265)
Settlement of tranche right	(4,135)
Balances at March 31, 2020	<u>\$ —</u>

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 nine months ended September 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:

<u>(in thousands)</u>	<u>September 30, 2021</u>	<u>December 31, 2020</u>
Scientific equipment	\$ 3,008	\$ 2,617
Furniture & office equipment	1,015	542
Leasehold improvements	1,002	855
Total	5,025	4,014
Accumulated depreciation and amortization	(2,904)	(2,662)
Property & equipment, net	<u>\$ 2,121</u>	<u>\$ 1,352</u>

Depreciation and amortization expense was \$0.2 and \$0.1 million for the three months ended September 30, 2021 and 2020, respectively, and \$0.5 and \$0.4 million for the nine months ended September 30, 2021 and 2020, respectively.

Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of the following:

<u>(in thousands)</u>	<u>September 30, 2021</u>	<u>December 31, 2020</u>
Accrued clinical trial costs	\$ 9,038	\$ 4,012
Accrued personnel costs	3,085	3,208
Accrued professional fees	25	37
Accrued other	41	229
Total accrued expenses and other current liabilities	<u>\$ 12,189</u>	<u>\$ 7,486</u>

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 one-year 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-by-product 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.

GlaxoSmithKline (GSK)

Summary of Agreement

On June 11, 2021, the Company and GSK executed the GSK Collaboration Agreement, pursuant to which the Company agreed 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 agreed to make an upfront payment of \$625.0 million to the Company within 10 business days of the date on which the GSK Collaboration Agreement became 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.

The Company concluded that the GSK Collaboration Agreement is under the scope of ASC 808 as both parties will actively participate in a joint operating activity and are exposed to significant risks and rewards that depend on the activity's commercial success. ASC 808 provides that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606 when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all of the guidance in ASC 606 should be applied, including recognition, measurement, presentation, and disclosure requirements related to such unit of account. The unit-of-account guidance in ASC 808, which aligns with the guidance in ASC 606 (that is, a distinct good or service) is used when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of ASC 606.

The Company determined that the co-development in Phases 2 and 3 and the co-commercialization efforts of the GSK Collaboration Agreement represent joint operating activities in which both parties are active participants and of which both parties are exposed to significant risks and rewards that are dependent on the success of the activities. Accordingly, the Company is accounting for these activities in accordance with ASC No. 808, *Collaborative Arrangements* (ASC 808). Additionally, the Company has determined that in the context of these activities, GSK does not represent a customer as contemplated by ASC 606-10-15, *Revenue from Contracts with Customers – Scope and Scope Exceptions*. As a result, these activities will be accounted for as a component of the related expense in the period incurred.

The Company also evaluated the elements of the GSK Collaboration Agreement in accordance with the provisions of ASC 606 and concluded that the contract counterparty, GSK, is a customer. The Company's arrangement with GSK contains the following material promises under the contract at inception: (i) transfer of the license under certain of the Company's intellectual property related to EOS-448, (ii) completion of the Phase 1 clinical study related to EOS-448, (iii) transfer of "Know How" under the EOS-448 intellectual property, and (iv) manufacturing until the "Know How" transfer is complete. The Company evaluated the above material promises under ASC 606 and determined that it has one combined performance obligation.

No development or commercial milestones were included in the transaction price at inception, as all milestone amounts were fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon success in future clinical trials and the licensee's efforts. Any consideration related to sales-based milestones will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to GSK and therefore have also been excluded from the transaction price. The Company is applying the royalty exception for sales-based royalties and will not recognize revenue until the subsequent sale of product occurs.

As of September 30, 2021, the transaction price totaling \$625.0 million was comprised of the up-front license payment. As of September 30, 2021, no development or regulatory milestones have been assessed as probable of being reached and thus have been fully constrained.

During the three months ended September 30, 2021, the Company recognized revenue totaling approximately \$104.3 million with respect to the GSK Collaboration Agreement. The revenue is classified as license revenue in the accompanying unaudited condensed consolidated statements of operations. As of September 30, 2021, there was approximately \$520.7 million of deferred revenue related to the GSK Collaboration Agreement of which all was classified as current deferred revenue in the accompanying unaudited condensed consolidated balance sheet based on the performance period of the underlying obligations.

During the three and nine months ended September 30, 2021, the Company expensed approximately \$1.6 million of costs related to the cost-sharing provisions of the GSK Collaboration Agreement, of which approximately \$0.3 million are reimbursable by GSK and recorded as a reduction to research and development expense during the three and nine months ended September 30, 2021.

The Company incurred approximately \$6.8 million of capitalizable costs to obtain the contract. The Company utilized the practical expedient in ASC 340 and recognize such costs immediately as the Company expected to complete its performance obligations under the GSK Collaboration Agreement in less than 12 months.

The following table presents changes in the Company's GSK contract assets and liabilities during the nine months ended September 30, 2021:

Nine Months Ended September 30, 2021

(in thousands)	—	Balance at Beginning of Period	Additions	Deductions	Balance at End of Period
Contract Assets:					
Account Receivable	\$	—	\$ 304	\$ —	\$ 304
Contract Liabilities:					
Deferred Revenue	\$	—	\$ 625,000	\$ (104,271)	\$ 520,729

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 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 income (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 income (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 \$1.2 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 \$21.8 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 \$4.1 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. For the RCA-1, no grant repayable related to royalties was recorded as of September 30, 2021 or December 31, 2020. For the RCA-2, the Company recorded a royalty accruals, equaling \$0.7 million, as of September 30, 2021, due to the revenue recognized from the GSK Collaboration Agreement. No grant repayable related to royalties was recorded as of December 31, 2020 for the RCA-2.

The Company recorded grant income in the condensed consolidated statements of operations and comprehensive income (loss) for the three and nine months ended September 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 nine months ended September 30, 2021 and 2020 and end of period balances as of September 30, 2021 and December 31, 2020:

(In thousands)	RCA -1		RCA-2		Other Grants		Total	
	2021	2020	2021	2020	2021	2020	2021	2020
Cash received during the three months ended September 30	\$ —	\$ —	\$ —	\$ 511	\$ —	\$ 148	\$ —	\$ 659
Grant income recognized during the three months ended September 30	\$ 1,115	\$ 1,810	\$ —	\$ 428	\$ 205	\$ 61	\$ 1,320	\$ 2,299
Cash received during the nine months ended September 30	\$ —	\$ 7,693	\$ —	\$ 2,479	\$ —	\$ 316	\$ —	\$ 10,488
Grant income recognized during the nine months ended September 30	\$ 4,110	\$ 3,667	\$ 725	\$ 936	\$ 4,101	\$ 366	\$ 8,936	\$ 4,969
Grants receivable at the end of the period	\$ 2,944	\$ —	\$ 921	\$ —	\$ 1,026	\$ 133	\$ 4,891	\$ 133
Grants repayable at the end of the period	\$ 4,836	\$ 5,102	\$ 736	\$ 781	N/A	\$ —	\$ 5,572	\$ 5,883

As of September 30, 2021, \$24,000 of the grants repayable was included as a current liability and the remaining balance was included in the grants repayable, net of current portion.

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 stock-based awards to employees and non-employees to purchase the Company's common stock. Total authorized options under the 2019 Stock Option and Grant Plan is 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 to 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 reserved for issuance as of September 30, 2021 under the 2020 Plan was 5,562,055 and will be increased each January 1 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. 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 number of shares of common stock reserved for issuance as of September 30, 2021 under the 2020 ESPP was 667,931. The ESPP provides that the number of shares reserved and available for issuance 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. As of September 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 income (loss) as follows:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Research and development	\$ 553	\$ 81	\$ 1,324	\$ 198
General and administrative	3,389	1,633	8,429	2,052
Total stock-based compensation expense	\$ 3,942	\$ 1,714	\$ 9,753	\$ 2,250

The following table summarizes stock option activity for the nine months ended September 30, 2021:

	Stock Options			
	Shares	Weighted average exercise price	Weighted average remaining contractual life (in years)	Aggregate intrinsic value (in thousands)
Outstanding as of December 31, 2020	4,552,396	\$ 9.13	8.2	
Granted	1,077,150	33.37		
Forfeited	(28,031)	27.02		
Exercised	(212,706)	6.13		
Outstanding as of September 30, 2021	5,388,809	\$ 14.00	7.9	\$ 78,236
Exercisable at September 30, 2021	1,854,930	\$ 7.60	6.3	\$ 35,949

The weighted-average grant-date fair value of options awarded during the nine month periods ended September 30, 2021 and 2020 was approximately \$25.80 per share and \$7.00 per share, respectively. As of September 30, 2021, there was a total of \$41.3 million of unrecognized employee compensation costs related to non-vested stock option awards expected to be recognized over a weighted average period of 3.0 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 Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Risk-free interest rate	0.66% - 0.89%	0.36%	0.42% - 0.90%	0.36% - 1.35%
Expected term (in years)	6.0	5.5 - 6.0	6.0	5.5 - 6.0
Expected volatility	92% - 94%	92%	92% - 100%	90% - 92%
Expected dividend yield	—	—	—	—
Estimated fair value of common stock	\$20.54 - \$25.65	\$19.00	\$20.54 - \$41.58	\$2.95 - \$19.00

Note 9. Income taxes

The following table presents the income (loss) before income taxes, income tax (expense) benefit and effective income tax rates for all periods presented:

Loss before income tax expense (in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Domestic	(5,466)	(12,001)	(35,671)	(15,258)
Foreign	77,879	1,313	68,091	(7,929)
Loss before income tax expense	72,413	(10,688)	32,420	(23,187)
Income tax (expense) benefit	(2,771)	8	(2,771)	58
Effective tax rate	3.8%	-0.1%	8.5%	-0.3%

Our effective tax rates were 3.8% and (0.1%) for the three months ended September 30, 2021 and 2020, respectively. Our effective tax rates were 8.5% and (0.3%) for the nine months ended September 30, 2021 and 2020, respectively. The change in effective tax rates was primarily due to the generation of taxable income from the GSK Collaboration Agreement and the utilization of net operating loss carryforwards in the U.S. and Belgium during the three and nine months ended September 30, 2021.

In the nine months ended September 30, 2020, we recorded a \$0.1 million one-time tax benefit from the change in tax law resulting from the enactment of the CARES Act in the first half of 2020.

Note 10. 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 September 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 space 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 \$0.2 million and \$0.1 million for the three months ended September 30, 2021 and 2020, respectively, and \$0.5 and \$0.4 million for the nine months ended September 30, 2021 and 2020.

The following table summarizes lease terms and discount rate:

	September 30, 2021	December 31, 2020
Weighted-average remaining lease term (years)	7.0	—
Weighted-average discount rate	4.86%	—

The following table summarizes the cash flow and other information:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating lease liabilities arising from obtaining right-of-use assets (non-cash)	\$ 6	\$ —	\$ 3,322	\$ —
Operating cash flows used in operating leases	\$ 191	\$ —	\$ 558	\$ —

As of September 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	\$ 226
2022	579
2023	468
2024	447
2025	402
Thereafter	1,292
Total Lease Payments	3,414
Less: Interest	(545)
Total Lease Liability	\$ 2,869
Lease liabilities	\$ 486
Lease liabilities, net of current portion	\$ 2,383

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 September 30, 2021 and December 31, 2020, the Company had approximately \$80,000 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 September 30, 2021 and December 31, 2020.

Note 11. 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 September 30, 2021.

Note 12. Net income (loss) per share attributable to common stock

The Company grants certain stock options under the 2019 and 2020 Stock Option Plan and these are considered common stock equivalents. For the period ending September 30, 2020, the common stock equivalents were excluded from the calculation of net income (loss) per share due to their anti-dilutive effect. For the period ending September 30, 2021, the common stock equivalents were included to calculate weighted-average diluted shares outstanding. The Company used the treasury stock method.

The following table summarizes the impact of the treasury stock method:

Net income (loss) per shares (in thousands, except per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Numerator				
Net income (loss) attributable to common stockholders	\$ 69,642	\$ (11,647)	\$ 29,649	\$ (28,498)
Denominator				
Weighted-average shares used in compute net income (loss) per share, basic	35,196,995	24,349,222	35,134,692	8,376,860
Effect of dilutive securities (a)	2,285,093	—	2,404,492	—
Weighted-average shares used to compute net income (loss) per share, diluted	37,482,089	24,349,222	37,539,184	8,376,860
Net income (loss) per share:				
Basic	\$ 1.98	\$ (0.48)	\$ 0.84	\$ (3.40)
Diluted	\$ 1.86	\$ (0.48)	\$ 0.79	\$ (3.40)

(a) The common stock equivalents were excluded for the period ending September 30, 2020, due to their anti-dilutive effect.

Note 13. Subsequent events

In November 2021, the Company entered into a new lease for 9,068 square feet of office space in Watertown, Massachusetts, which terminates in February 2027. In October 2021, the Company entered into an agreement to increase the Belgium office space by 453 square meters.

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

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 GSK Collaboration Agreement, which became effective on July 26, 2021. Pursuant to the GSK Collaboration Agreement, 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 GSK Collaboration Agreement, GSK made an upfront payment of \$625 million to us, or the Upfront Payment. 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 GSK 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 GSK Collaboration Agreement.

In September 2021, we dosed the first patients in a Phase 1/2 clinical trial of EOS-448 in combination with pembrolizumab and with inupadenant in patients with solid tumors.

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 June 2021, we reported additional data from monotherapy expansion cohorts at the American Society of Clinical Oncology, or 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 have completed enrollment in the safety evaluation portion of the clinical trial of inupadenant in combination with chemotherapy and with pembrolizumab, as well as the monotherapy expansion cohort in prostate cancer. We have also initiated an expansion arm evaluating inupadenant in combination with pembrolizumab in patients with PD-1-resistant melanoma. In addition, we are evaluating a salt form of inupadenant in a Phase 1 study. We plan to advance inupadenant into randomized controlled clinical trials in combination.

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 immunosuppression. In September 2021, we nominated an additional product candidate in the adenosine pathway for Investigational New Drug, or IND, enabling studies.

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 financed our operations through license revenue generated through the GSK Collaboration Agreement and through our Initial Public Offering, or IPO. Through September 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. For the three and nine months ended September 30, 2021, we have earned \$104.3 from license revenue. As of September 30, 2021, our principal source of liquidity was cash and cash equivalents, which totaled \$899.7 million.

For the first time since inception, we recognized revenue in the current period. All license revenue was all earned through the GSK Collaboration Agreement. Our net income was \$69.6 million for the three months ended September 30, 2021 and our net losses were \$10.7 million for the three months ended September 30, 2020, respectively. Our net income was \$29.6 million for the nine months ended September 30, 2021 and our net losses were \$23.1 million for the nine months ended September 30, 2020, respectively. As of September 30, 2021, we had an accumulated deficit of \$44.2 million. Our ability to generate product revenue sufficient to achieve sustained 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 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.

The expenses will be offset by the license revenue earned and future collaboration revenue. For the three and nine months ended September 30, 2021 we have earned \$104.3 million in license revenue and expect to earn additional deferred revenue in the upcoming year, which equaled \$520.7 million for the period ended September 30, 2021. We are also eligible to receive up to \$1.45 billion in milestone payments, contingent upon the EOS-448 program achieving certain development and commercial milestones.

As of September 30, 2021, we had cash and cash equivalents of \$899.7 million. The significant increase in cash and cash equivalents is due to the GSK Upfront Payment received on August 5, 2021. 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 and earn milestone payments, contingent upon the EOS-448 program achieving certain development and commercial milestones. 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 also party to other collaboration and license agreements in addition to the GSK Collaboration Agreement with GSK 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 nine months of 2021, we have maintained and expanded our business continuity plans to address and mitigate the impact of the COVID-19 pandemic on our business. In March 2020, to protect the health of our employees, and their families and communities, we restricted access to our 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 our employees work remotely. In May 2020, as certain states eased restrictions, we established new protocols to better allow its full laboratory staff access to our facilities. These protocols included several shifts working over a seven-day-week protocol. We expect to continue incurring additional costs to ensure we adhere to the guidelines instituted by the Centers for Disease Control and Prevention, or CDC, and to provide a safe working environment to our onsite employees.

The extent to which the ongoing COVID-19 pandemic impacts our business, our corporate development objectives, results of operations and financial condition, and the value of and market for our 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, the identification of additional variants of COVID-19, the availability and utilization of vaccines and treatments for COVID-19, or the effectiveness of actions taken globally to contain and address 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 our business, financial condition, results of operations and growth prospects.

While the ongoing COVID-19 pandemic did not significantly impact the our business or results of operations during the nine months ended September 30, 2021, the length and extent of the pandemic, its consequences, and containment efforts will determine the future impact on our 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, our revenues have been derived from license revenues generated through collaboration and license agreements with GSK to further the development and commercialization of EOS-448.

For all collaboration agreements, no development or commercial milestones were included in the transaction price at inception, as all milestone amounts were fully constrained. As part of our evaluation of the constraint, we considered numerous factors, including that receipt of the milestones is outside our control and contingent upon success in future clinical trials and the licensee's efforts. Any consideration related to sales-based milestones will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to GSK and therefore have also been excluded from the transaction price. We are applying the royalty exception for sales-based royalties and will not recognize revenue until the subsequent sale of product occurs.

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 ongoing COVID-19 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:

(in thousands)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Direct research and development expenses by program:				
EOS-448	\$ 4,566	\$ 1,196	\$ 10,757	\$ 3,661
Inupadenant	4,632	4,554	13,803	9,335
Other non-clinical programs	2,368	553	5,178	2,311
Indirect research and development expenses(1)	4,536	2,423	12,245	5,381
Total research and development expense	<u>\$ 16,102</u>	<u>\$ 8,726</u>	<u>\$ 41,983</u>	<u>\$ 20,688</u>

(1) The substantial majority of these costs relate to the EOS-448 and inupadenant programs. The majority 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 income (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 income (loss). Items included are interest income, bank fees and gain or loss on foreign currency transactions.

Income taxes

We are subject to income taxes in the U.S. and Belgium. Belgium has a statutory tax rate different from the U.S. Accordingly, our effective tax rates will vary depending on the relative proportion of foreign to U.S. income, the utilization of foreign tax credits and changes in tax laws. Deferred tax assets are reduced through the establishment of a valuation allowance, if, based upon available evidence, it is determined that it is more likely than not that the deferred tax assets will not be realized.

Results of operations

Comparison of the nine months ended September 30, 2021 and 2020

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

(in thousands)	Nine Months Ended September 30,		Period to period change
	2021	2020	
Revenue:			
License Revenue	\$ 104,271	\$ —	\$ 104,271
Total Revenue	104,271	—	104,271
Operating expenses:			
Research and development expenses	41,983	20,688	21,295
General and administrative expenses	30,907	9,611	21,296
Total operating expenses	72,890	30,299	42,591
Income (loss) from operations	31,381	(30,299)	61,680
Other income and expenses:			
Grant income	8,936	4,969	3,967
Fair value adjustment for preferred stock tranche rights liability	—	1,265	(1,265)
Research and development tax credits	288	643	(355)
Other income (expense), net	(8,185)	235	(8,420)
Income (loss) before income taxes	32,420	(23,187)	55,607
Income tax benefit (expense)	(2,771)	58	(2,829)
Net income (loss)	\$ 29,649	\$ (23,129)	\$ 52,778

License revenue

License revenue equaled \$104.3 million for the nine months ended September 30, 2021, and was the first period we recognized operating revenue. The license revenue was due to the portion of the GSK Upfront Payment that was recognized in the third quarter of 2021.

Research and development expenses

Research and development expenses increased by \$21.3 million to \$42.0 million for the nine months ended September 30, 2021, from \$20.7 million for the nine months ended September 30, 2020. This increase was primarily related to an increase of \$5.0 million of payroll and related costs, a \$14.6 million increase CRO and CMO fees and internal laboratory expenses, a \$1.1 million increase in stock-based compensation, an increase of \$0.6 million in professional fees and an increase of \$0.4 million related to facilities. The increases were offset by a \$0.4 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 nine months ended September 30, 2021.

General and administrative expenses

General and administrative expenses increased by \$21.3 million to \$30.9 million for the nine months ended September 30, 2021 from \$9.6 million for the nine months ended September 30, 2020.

The increase was primarily attributable to an increase of \$1.8 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 \$6.4 million increase in stock-based compensation, an increase of \$9.8 million in professional fees and an increase of \$1.6 million for directors and officers insurance as a result of becoming a public company in July 2020. In addition, there was also a \$1.7 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 nine months ended September 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 \$4.0 million to \$9.0 million for the nine months ended September 30, 2021 from \$5.0 million for the nine months ended September 30, 2020. The overall increase in grant income, driven by spending on qualified research and development activities, was primarily attributable to preclinical activities, which were approved in March 2021, and the inupadenant program. For the nine months ended September 30, 2021, we recognized \$3.9 million in grant income related to preclinical activities and the grant income relating to the inupadenant program increased by \$0.4 million. The remaining \$0.3 million net decrease 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 nine months ended September 30, 2020. As of September 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 nine months ended September 30, 2021 primarily relates to foreign exchange losses recorded as a result of the change in euro to U.S. dollar exchange rate that occurred in the first nine months of 2021.

Income tax benefit (expense)

On a consolidated basis, we recognized income tax expense of \$2.8 million for the nine months ended September 30, 2021, due to the generation of taxable income from the GSK Collaboration Agreement, partially offset by the utilization of net operating loss carryforwards in the U.S. and Belgium.

In the nine months ended September 30, 2020, we recorded a \$0.1 million one-time tax benefit from the change in the tax law resulting from the enactment of the CARES Act in the first half of 2020.

Results of operations

Comparison of the three months ended September 30, 2021 and 2020

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

(in thousands)	Three Months Ended September 30,		Period to period change
	2021	2020	
Revenue:			
License Revenue	\$ 104,271	\$ —	\$ 104,271
Total Revenue	104,271	—	104,271
Operating expenses:			
Research and development expenses	16,102	8,726	7,376
General and administrative expenses	8,761	4,799	3,962
Total operating expenses	24,863	13,525	11,338
Income (loss) from operations	79,408	(13,525)	92,933
Other income and expenses:			
Grant income	1,320	2,299	(979)
Research and development tax credits	169	273	(104)
Other income, net	(8,484)	265	(8,749)
Income (loss) before income taxes	72,413	(10,688)	83,101
Income tax benefit (expense)	(2,771)	8	(2,779)
Net income (loss)	\$ 69,642	\$ (10,680)	\$ 80,322

License revenue

License revenue equaled \$104.3 million for the three months ended September 30, 2021, and was the first period we recognized operating revenue. The license revenue was due to the portion of the GSK Upfront Payment that was recognized in the third quarter of 2021.

Research and development expenses

Research and development expenses increased by \$7.4 million to \$16.1 million for the three months ended September 30, 2021, from \$8.7 million for the three months ended September 30, 2020. This increase was primarily related to an increase of \$0.9 million of payroll and related costs, a \$4.7 million increase CRO and CMO fees and internal laboratory expenses, a \$0.5 million increase in stock-based compensation, an increase of \$0.7 million in professional fees and an increase of \$0.1 million related to facilities. In addition, there was also a \$0.5 million increase 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 September 30, 2021.

General and administrative expenses

General and administrative expenses increased by \$4.0 million to \$8.8 million for the three months ended September 30, 2021 from \$4.8 million for the three months ended September 30, 2020.

The increase was primarily attributable to an increase of \$0.2 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 \$1.8 million increase in stock-based compensation, an increase of \$1.5 million in professional fees and an increase of \$0.3 million for directors and officers insurance as a result of becoming a public company in July 2020. In addition, there was also a \$0.2 million increase related to various other general and administrative expenses. The increase in professional fees was related to SEC reporting, SOX compliance and consulting related to our corporate structure in Belgium.

Grant income

Grant income decreased by \$1.0 million to \$1.3 million for the three months ended September 30, 2021 from \$2.3 million for the three months ended September 30, 2020. The overall decrease in grant income was driven by a reduction in spending on qualified research and development activities. The grant income relating to the inupadenant program decreased by \$0.7 million. The remaining \$0.3 million net decrease 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 September 30, 2021 primarily relates to foreign exchange losses recorded as a result of the change in euro to U.S. dollar exchange rate that occurred in the third quarter of 2021.

Income tax benefit (expense)

On a consolidated basis, we recognized income tax expense of \$2.8 million for the three months ended September 30, 2021, due to the generation of taxable income from the GSK Collaboration Agreement, partially offset by the utilization of net operating loss carryforwards in the U.S. and Belgium.

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.

In June, 2021, the Company and GSK executed the GSK Collaboration Agreement, pursuant to which we agreed to grant GSK a license under certain of our intellectual property rights to develop, manufacture, and commercialize products comprised of or containing our antibody product, EOS-448. Under the GSK Collaboration Agreement, GSK made an upfront payment of \$625 million, which occurred on August 5, 2021.

To date, we have funded our operations primarily with proceeds from the IPO, the sales of preferred stock, grants and licenses and upfront payment from the GSK Collaboration Agreement. As of September 30, 2021, we had \$899.7 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 sales of products for the foreseeable future.

Cash flows

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

(in thousands)	Nine Months Ended	
	September 30,	
	2021	2020
Net cash provided by (used in):		
Operating activities	\$ 571,956	\$ (19,712)
Investing activities	(1,081)	(243)
Financing activities	1,303	339,506
Effects of exchange rate changes on cash, cash equivalents and restricted cash	(8,728)	566
Net increase in cash, cash equivalents and restricted cash	<u>\$ 563,450</u>	<u>\$ 320,117</u>

Net cash used in operating activities

Net cash provided by operating activities was \$572.0 million during the nine months ended September 30, 2021. The increase was due to the GSK Upfront Fee received in August 2021, which equaled \$625.0 million. The net increase in operating activities were partially offset by operating expenses, excluding stock based compensation, equaling \$63.1 million and various prepayments made in 2021. Net cash used in operating activities was \$19.7million during the nine months ended September 30, 2020, was primarily due to our net losses of \$23.1 million, offset primarily by the decrease of \$3.0 million in grants receivable.

Net cash used in investing activities

Net cash used in investing activities increased \$0.8 million for the nine months ended September 30, 2021 compared to the nine months ended September 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 nine months ended September 30, 2021.

Net cash provided by financing activities

Net cash provided by financing activities was \$1.3 million during the nine months ended September 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 \$339.5 million during the nine months ended September 30, 2020. We raised cash through the issuance of Series B-2 preferred stock, with net proceeds of \$125.0 million and proceeds received from our IPO, with net proceeds of \$210.6 million. In addition, we received \$2.9 million under grant programs with a potential obligation for repayment and \$0.6 million in proceeds received from the exercise of stock options during the period.

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

The \$8.7 million reduction of cash, cash equivalents and restricted cash for the nine months ended September 30, 2021 was primarily caused by the reduction of the euro to dollar exchange rate between December 31, 2020 and September 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.

In June, 2021, we and GSK executed the GSK Collaboration Agreement, pursuant to which we agreed to grant GSK a license under certain of our intellectual property rights to develop, manufacture, and commercialize products comprised of or containing our antibody product, EOS-448. Under the GSK Collaboration Agreement, GSK made an upfront payment of \$625 million, which occurred on August 5, 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.

We believe that our cash and cash equivalents as of September 30, 2021, will enable us to fund our operating expenses and capital expenditure requirements through the second half of 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.

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 nine months ended September 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. In November 2021, we entered into a new lease for 9,068 square feet of office space in Watertown, Massachusetts, which terminates in February 2027. In October 2021, we entered into an agreement to increase the Belgium office space by 453 square meters. There were no other significant changes to our contractual obligations and commitments as of September 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:

Revenue Recognition

We generate revenue from our GSK Collaboration Agreement (see Note 5 to our unaudited consolidated financial statements in Part I, Item I). Financial Information. We recognize revenue in accordance with ASC 606, which applies to all contracts with customers, except for contracts that are within the scope of other standards. Under ASC 606, we recognize revenue when our customer obtains control of promised goods or services, in an amount that reflects the consideration which the entity expects to receive in exchange for those goods or services. To determine revenue recognition for arrangements that we determine are within the scope of ASC 606, we perform the following five steps:

- (i) identify the contract(s) with a customer;
- (ii) identify the performance obligations in the contract;

- (iii) determine the transaction price;
- (iv) allocate the transaction price to the performance obligations in the contract; and
- (v) recognize revenue when (or as) the entity satisfies a performance obligation.

We only apply the five-step model to contracts when it is probable that the entity will collect the consideration we are entitled to in exchange for the goods or services we transfer to the customer. At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within each contract and determine those that are performance obligations, and assess whether each promised good or service is distinct. We then recognize as revenue the amount of the transaction price that is allocated to the respective performance obligation when (or as) the performance obligation is satisfied. We do not include a financing component in our estimated transaction price at contract inception unless we estimate that certain performance obligations will not be satisfied within one year. Additionally, we recognize the incremental costs of obtaining a contract as an expense when incurred if the amortization period of the asset that we otherwise would have recognized is one year or less.

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 September 30, 2021 and December 31, 2020, we had cash and cash equivalents of \$899.7 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 September 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 income (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 income (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.

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 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 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 ongoing impacts of the COVID-19 pandemic;
- 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 ongoing 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 ongoing 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 preliminary results of any of our clinical trials, and/or reporting of results of clinical trials of our competitors; 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 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 ongoing 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 requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar 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 inpatient, 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 inpatient, 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 immuno-oncology 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 in the United States or in other jurisdictions. If significant delays 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, re-consent 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 alone do not guarantee qualification 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 May 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.

may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. Additionally, we or our collaborators may develop companion diagnostic tests for use with our 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 inseparable 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 high-cost 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 biologics 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 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 or 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 sites 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 process.

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 to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or 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 and rigorous testing 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.

For the first time since inception, we recognized revenue in the current period. All license revenue was earned through the GSK Collaboration Agreement. Our net income was \$69.6 million for the three months ended September 30, 2021 and our net losses were \$10.7 million for the three months ended September 30, 2020, respectively. Our net income was \$29.6 million for the nine months ended September 30, 2021 and our net losses were \$23.1 million for the nine months ended September 30, 2020, respectively. As of September 30, 2021, we had an accumulated deficit of \$44.2 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 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 inupadenant, 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 having achieved 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 may require 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 September 30, 2021, we had \$899.8 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 the GSK collaboration and any future collaborations;
- the cost of commercialization activities for any approved product, including marketing, sales and distribution costs;
- the cost of manufacturing inupadenant, 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.

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 additional 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 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 business operations, which could materially harm our business.

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 at issue on the grounds that our patent claims do not cover 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 competitors, and may curtail or preclude our ability to exclude third 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 whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such 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

The current public health pandemic related to COVID-19 may adversely impact our operations, business and financial results.

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 ongoing COVID-19 pandemic has presented a substantial public health and economic challenge around the world. 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 clinical trials, manufacturing and other operations. The ongoing 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. 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 quarantined 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 or to delay monitoring visits. While we do not anticipate significant negative effects from remote or delayed 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 or to delay monitoring. 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 have experienced 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 on 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

Since the beginning of the COVID-19 pandemic, three vaccines for COVID-19 have received Emergency Use Authorization by the FDA and one of these later received marketing approval. Additional vaccines may be authorized or approved 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. In response to these measures, in March 2020 we required all non-laboratory employees and all non-essential employees for laboratory work to work remotely, suspended non-essential travel for our employees and discouraged employee attendance at other gatherings. With increased availability of vaccines and public health guidelines evolving to reflect their availability, we have reopened our offices. We will continue, however, to monitor and make adjustments in response to the public health environment, together with local, state and federal guidance regarding workplace protective measures, including travel restrictions, quarantines, and office access restrictions. If there is an increase in COVID-19 infection rates or new outbreaks, our business may be adversely impacted. For instance, remote work may delay our pre-clinical programs development, disrupt our operations and increase the risk of a cybersecurity incident.

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 September 30, 2021, we had 74 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 yet 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 limit our ability to generate revenue 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 and, should the Belgian tax authorities 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 September 30, 2021, we received less than one thousand dollars in 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, 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 59.0% of our outstanding voting stock as of September 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 loses 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 ceases 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 and conduct our clinical programs on our expected timelines, including our plans to advance inupadenant into randomized controlled trials in combination;
- 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 forward-looking 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.***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 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	<u>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)</u>
3.2	<u>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)</u>
4.1	<u>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)</u>
31.1*	<u>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.</u>
31.2*	<u>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.</u>
32.1*+	<u>Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
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 herewith.

+ 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: November 10, 2021

By: /s/ Michel Detheux

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

Date: November 10, 2021

By: /s/ Matthew Gall

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

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

By: /s/ Michel Detheux

Michel Detheux

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

Date: November 10, 2021

By: /s/ Matthew Gall

Matthew Gall

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