UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2020

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	**84-3365066**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
139 Main Street **Cambridge, MA**	**02142**
(Address of principal executive offices)	**(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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

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

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

As of August 27, 2020, the registrant had 35,044,758 shares of common stock, $0.001 par value per share, outstanding.

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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)	June 30, 2020	December 31, 2019
Assets		
Current assets:		
Cash	$ 136,870	$ 19,868
Grants receivable	212	5,196
R&D tax credits receivable	133	133
Prepaid expenses and other current assets	3,180	879
Total current assets	140,395	26,076
Property and equipment, net	1,251	1,336
R&D tax credits receivable	3,172	2,917
Restricted cash	123	122
Other assets	270	293
Total assets	$ 145,211	$ 30,744
Liabilities, redeemable convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 2,656	$ 1,174
Accrued expenses and other current liabilities	3,360	4,262
Preferred stock tranche rights liability	—	5,400
Deferred income	1,500	2,360
Total current liabilities	7,516	13,196
Grants repayable	4,161	1,397
Other noncurrent liabilities	484	482
Total liabilities	12,161	15,075
Commitments and contingencies (Note 9)		
Redeemable convertible preferred stock:		
Series B-2 preferred stock, $0.001 par value: 44,453,477 and 0 shares authorized, issued and outstanding at June 30, 2020 and December 31, 2019, respectively; liquidation value of $127,090	127,090	—
Series B preferred stock, $0.001 par value: 31,989,428 and 20,942,781 shares authorized at June 30, 2020 and December 31, 2019, respectively; 20,942,781 shares issued and outstanding at June 30, 2020 and December 31, 2019; liquidation value of $55,300	48,529	46,404
Series A-1 and A-2 preferred stock, $0.001 par value: 6,167,726 shares authorized, issued and outstanding; liquidation value of $7,114	5,353	5,353
Stockholders' deficit:		
Common stock, $0.001 par value, 90,000,000 and 50,000,000 shares authorized at June 30, 2020 and December 31, 2019, respectively; 388,415 and 256,548 shares issued and outstanding at June 30, 2020 and December 31, 2019, respectively	1	1
Additional paid-in capital	687	—
Accumulated other comprehensive loss	(296)	(224)
Accumulated deficit	(48,314)	(35,865)
Total stockholders' deficit	(47,922)	(36,088)
Total liabilities, redeemable convertible preferred stock and stockholders' deficit	$ 145,211	$ 30,744

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

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

(in thousands, except share and per share amounts)	Three months ended June 30, 2020	Three months ended June 30, 2019	Six months ended June 30, 2020	Six months ended June 30, 2019
Operating expenses:				
Research and development expenses	$ 6,137	$ 3,902	$ 11,962	$ 8,253
General and administrative expenses	2,394	2,093	4,812	3,862
Total operating expenses	8,531	5,995	16,774	12,115
Loss from operations	(8,531)	(5,995)	(16,774)	(12,115)
Other income and expenses:				
Grant income	1,081	678	2,670	1,442
Fair value adjustment for preferred stock tranche rights liability and anti-dilution warrants liability	—	(488)	1,265	296
R&D tax credits	186	155	370	353
Other income (expense), net	12	(47)	(30)	(75)
Loss before income taxes	(7,252)	(5,697)	(12,499)	(10,099)
Income tax benefit (expense)	50	(58)	50	(58)
Net loss	(7,202)	(5,755)	(12,449)	(10,157)
Cumulative dividends on Series A preferred stock	(106)	(106)	(213)	(213)
Accretion of redeemable convertible preferred stock to redemption value	(2,994)	(915)	(4,189)	(1,612)
Net loss attributable to common stockholders	$ (10,302)	$ (6,776)	$ (16,851)	$ (11,982)
Basic and diluted net loss per common share	$ (29.49)	$ (36.49)	$ (55.63)	$ (64.52)
Weighted-average common shares outstanding—basic and diluted	349,290	185,716	302,919	185,716
Net loss	$ (7,202)	$ (5,755)	$ (12,449)	$ (10,157)
Foreign currency translation adjustments	245	529	(72)	262
Comprehensive loss	$ (6,957)	$ (5,226)	$ (12,521)	$ (9,895)

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
(in thousands except share amounts)
(unaudited)

	Series A preferred stock		Series B preferred stock		Common stock		Profit certificates		Additional paid-in capital	Accumulated other comprehensive income (loss)	Retained earnings/ (accumulated deficit)	Total stockholders' equity/ (deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2018	**6,167,726**	**$ 5,353**	**10,900,376**	**$ 20,378**	**185,716**	**$ 87**	**7,022**	**$ 11**	**$ —**	**$ (11)**	**$ (10,765)**	**$ (10,678)**
Accretion of Series B Preferred Stock to redemption value	—	—	—	697	—	—	—	—	(205)	—	(492)	(697)
Stock-based compensation	—	—	—	—	—	—	—	—	205	—	—	205
Currency translation adjustment	—	—	—	—	—	—	—	—	—	(267)	—	(267)
Net loss	—	—	—	—	—	—	—	—	—	—	(4,402)	(4,402)
Balance at March 31, 2019	**6,167,726**	**5,353**	**10,900,376**	**21,075**	**185,716**	**87**	**7,022**	**11**	**-**	**(278)**	**(15,659)**	**(15,839)**
Issuance of Series B Preferred Stock	—	-	10,042,405	22,372								
Accretion of Series B Preferred Stock to redemption value	—	—	—	915	—	—	—	—	(203)	—	(712)	(915)
Exercise of stock options into profit certificates	—	—	—	—	—	—	63,810	102	—	—	—	102
Stock-based compensation	—	—	—	—	—	—	—	—	203	—	—	203
Currency translation adjustment	—	—	—	—	—	—	—	—	—	529	—	529
Net loss	—	—	—	—	—	—	—	—	—	—	(5,755)	(5,755)
Balance at June 30, 2019	**6,167,726**	**$ 5,353**	**20,942,781**	**$ 44,362**	**185,716**	**$ 87**	**70,832**	**$ 113**	**$ —**	**$ 251**	**$ (22,126)**	**$ (21,675)**

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

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)	Six months ended June 30, 2020	2019
Cash flows from operating activities		
Net loss	$ (12,449)	$ (10,157)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	250	307
Stock-based compensation	536	408
Fair value adjustment for preferred stock tranche rights and anti-dilution warrants liabilities	(1,265)	(296)
Deferred rent	(14)	(5)
Changes in operating assets and liabilities:		
Grants receivable	4,962	(1,586)
R&D tax credits receivable	(238)	(282)
Prepaid expenses and other current assets	(580)	(376)
Accounts payable	1,055	508
Accrued expenses and other liabilities	(886)	(234)
Deferred income	(852)	1,055
Net cash used in operating activities	(9,481)	(10,658)
Cash flows from investing activities		
Purchase of property and equipment	(119)	(673)
Purchase of other assets	(19)	(121)
Net cash used in investing activities	(138)	(794)
Cash flows from financing activities		
Proceeds from issuance of Series B-2 Preferred Stock	125,358	—
Payment of issuance costs on Series B-2 Preferred Stock	(332)	—
Proceeds from issuance of Series B Preferred Stock	—	22,372
Proceeds from issuance of common stock and profit certificates upon exercise of options	205	102
Payment of IPO costs	(1,311)	
Proceeds from grants repayable	2,713	
Net cash provided by financing activities	126,633	22,474
Effects of exchange rate changes on cash and restricted cash	(11)	184
Net increase in cash and restricted cash	117,003	11,206
Cash and restricted cash at beginning of period	19,990	22,054
Cash and restricted cash at end of period	$ 136,993	$ 33,260
Non-cash investing and financing activities		
Accretion of Series B and B-2 Preferred Stock to redemption value	$ 4,189	$ 1,612
Settlement of preferred stock tranche right	$ 4,135	$ —
Deferred IPO costs in accounts payable	$ 400	
Supplemental disclosure of cash flows		
Cash paid for taxes	$ 147	$ 2

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

Note 1. Nature of business

Description of business

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 that focuses on developing cancer immunotherapies by targeting key mechanisms of immunosuppression in the tumor microenvironment. The most advanced clinical program is EOS-850, a small molecule antagonist of the $A_{2A}R$, which is currently in an open-label Phase 1/2a clinical trial in adult patients. The second clinical program is EOS-448, an antibody directed to TIGIT, which entered a Phase 1/2a clinical trial in February 2020. The Company also has a preclinical pipeline targeting additional mechanisms.

Corporate reorganization

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.

Going concern

Since inception, the Company's activities have consisted primarily of performing research and development to advance its product candidates. The Company is still in the development phase and has not been marketing any developed products to-date. Through June 30, 2020, the Company has funded its operations with proceeds from sales of redeemable convertible preferred stock, collaboration and licensing agreements, grants and borrowings under various agreements with foreign public funding agencies. Since inception, the Company has incurred recurring losses, including a net loss of $12.4 million for the six months ended June 30, 2020. As of June 30, 2020, the Company had an accumulated deficit of $48.3 million. The Company expects to continue to generate operating losses in the foreseeable future. On July 28, 2020, the Company closed its initial public offering, or IPO, which generated net proceeds of $184.0 million, and on August 5, 2020, the underwriters purchased 1,505,359 additional shares of common stock under their option for net proceeds of $26.6 million after deducting underwriting discounts and commissions (see Note 12). As of September 1, 2020, the issuance date of the condensed consolidated financial statements for the six months ended June 30, 2020, the Company expected that its cash 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 will seek additional funding in order to reach its development and commercialization objectives. The Company will seek funds either through public debt or equity offerings or further private equity financings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. 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 accompanying condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The condensed consolidated financial statements do not reflect any adjustments relating to the recoverability and classification of assets or the amounts and classification of liabilities that might be necessary if the Company is unable to continue as a going concern.

COVID-19

In December 2019, a novel strain of coronavirus (COVID-19) emerged in Wuhan, Hubei Province, China. As of June 30, 2020, COVID-19 has spread to Europe, the United States and many other countries, and has been declared a pandemic by the World Health Organization. Efforts to contain the spread of COVID-19 have intensified. The United States, including the Commonwealth of Massachusetts where our headquarters are located, as well as countries throughout Europe and Asia have implemented severe travel restrictions, social distancing requirements and stay-at-home orders, among other restrictions, which, in some cases, have had the effect of delaying the commencement of non-COVID-19-related clinical trials. As a result, the COVID-19 pandemic has caused significant disruptions to the U.S., regional and global economies and has contributed to significant volatility and negative pressure in financial markets.

The Company has been carefully monitoring the COVID-19 pandemic and its potential impact on the Company's business and has taken important steps to help ensure the safety of employees and their families and to reduce the spread of COVID-19 in the Cambridge and Belgian communities. The Company has established a work-from-home policy for all employees, other than those performing or supporting business-critical operations, such as certain members of our laboratory and facilities staff. For those employees, we have implemented stringent safety measures designed to comply with applicable federal, state and local guidelines instituted in response to the COVID-19 pandemic. The Company has also maintained efficient communication with the Company's partners and clinical sites as the COVID-19 situation has progressed. The Company has taken these precautionary steps while maintaining business continuity so that we can continue to progress our programs.

Risk and uncertainties

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

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.

Note 2. Summary of significant accounting policies

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, 2019 and 2018, and the notes thereto, which are included in the Company's final prospectus related to the Company's IPO filed on July 27, 2020 (File No. 333-239415) with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended. 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.

Principles of consolidation

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

Use of estimates

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

Deferred offering costs

The Company capitalizes incremental legal, professional accounting and other third-party fees that are directly associated with the IPO as other non-current assets until the IPO is consummated. After consummation of the IPO, these costs will be recorded in stockholders' deficit as a reduction of additional paid-in-capital generated as a result of the offering. As of June 30, 2020, there were deferred offering costs of approximately $1.7 million included in prepaid expenses and other current assets.

Collaborative Arrangements

The Company analyzes its collaboration arrangements to assess 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 dependent on the commercial success of such activities and are, therefore within the scope of ASC Topic 808, *Collaborative Arrangements*. This assessment is performed throughout the life of the arrangement and takes into consideration changes in the responsibilities of all parties to the arrangement.

Recently adopted accounting standards updates

In August 2018 the FASB issued ASU No. 2018-13, *Fair Value Measurement* (Topic 820): *Disclosure Framework Changes to the Disclosure Requirements for Fair Value Measurement*. This standard modifies certain disclosure requirements on fair value measurements. We adopted the standard prospectively effective January 1, 2020. The adoption of this standard did not have a material impact on our interim disclosures and is not expected to have a material impact on our annual 2020 disclosures.

In November 2018 the FASB issued ASU No. 2018-18, *Collaborative Arrangements* (Topic 808): *Clarifying the Interaction between Topic 808 and Topic 606*. This standard makes targeted improvements for collaborative arrangements as follows:

- Clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under ASC 606, *Revenue from Contracts with Customers*, when the collaborative arrangement participant is a customer in the context of a unit of account. In those situations, all the guidance in ASC 606 should be applied, including recognition, measurement, presentation and disclosure requirements;
- Adds unit-of-account guidance to ASC 808, *Collaborative Arrangements*, to align with the guidance in ASC 606 (that is, a distinct good or service) when an entity is assessing whether the collaborative arrangement or a part of the arrangement is within the scope of ASC 606; and

- Requires that in a transaction with a collaborative arrangement participant that is not directly related to sales to third parties, presenting that transaction together with revenue recognized under ASC 606 is precluded if the collaborative arrangement participant is not a customer.

The standard was adopted on January 1, 2020 and was applied retrospectively to when ASC 606 was adopted (January 1, 2017). It did not have a material impact on our consolidated financial position and results of operations.

Recently issued accounting standards and updates not yet effective

In February 2016 the FASB issued ASU No. 2016-02, *Leases* (Topic 842). This standard established a right-of-use model that requires all lessees to recognize right-of-use assets and liabilities on their balance sheet that arise from leases with terms longer than 12 months as well as provide disclosures with respect to certain qualitative and quantitative information related to their leasing arrangements. This standard becomes effective for the Company on January 1, 2021. The FASB has subsequently issued some amendments to ASU 2016-02, which have the same effective date and transition date of January 1, 2021.

The Company plans to adopt the new leasing standard on January 1, 2021, using a modified retrospective transition approach to be applied to leases existing as of, or entered into after, January 1, 2021. The Company is reviewing its existing lease contracts and the impact of the new leasing standards on its consolidated results of operations, financial position and disclosures. While the adoption of this standard is expected to result in an increase in reported assets and liabilities, the Company has not yet determined the full impact that the adoption of ASU 2016-02 will have on its consolidated financial statements.

In June 2016 the FASB issued ASU No. 2016-13, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*. This standard requires that credit losses be reported using an expected losses model rather than the incurred losses model that is currently used, and establishes additional disclosures related to credit risks. For available-for-sale debt securities with unrealized losses, this standard now requires allowances to be recorded instead of reducing the amortized cost of the investment. This standard will be effective for the Company on January 1, 2023. The Company is currently evaluating the potential impact that this standard may have on its consolidated financial position and results of operations.

Note 3. Fair value measurements

No financial instruments were measured at fair value on a recurring basis as of June 30, 2020. 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 December 31, 2019 (in thousands):

	December 31, 2019			
(in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Preferred stock tranche rights liability	$ —	$ —	$ 5,400	$ 5,400
Totals	$ —	$ —	$ 5,400	$ 5,400

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):

	Valuation Dates			
	December 31, 2018	**June 30, 2019**	**December 31, 2019**	**March 23, 2020 (Tranche 3 settlement)**
Implied equity value (in millions)	€30.8 ($35.4)	€48.8 ($55.6)	$ 74.4	$ 208.2
Probability of success of reaching necessary milestone:				
Tranche 2 milestone	85% by March 31, 2019	N/A	N/A	N/A
Tranche 3 milestone (by March 31, 2020)	90%	90%	90%	90%
Expected industry return over period during which milestones are expected to be achieved	15.0%	15.5%	15.0%	13.0%
Risk-free interest rate	2.5%	2.3%	2.3%	1.1%

During the periods presented, the Company has not changed the manner in which it values assets and liabilities that are measured at fair value. The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers within the hierarchy during the six month periods ended June 30, 2019 and 2020.

The following table presents changes during the three and six months ended June 30, 2020 and 2019 in Level 3 liabilities measured at fair value on a recurring basis:

(in thousands)	Preferred Stock Tranche Rights Liability	Anti-Dilution Warrants
Balances at January 1, 2019	$ 6,325	$ 401
Change in estimated fair value	(784)	—
Effects of exchange rate changes	(127)	(9)
Balances at March 31, 2019	5,414	392
Change in estimated fair value	488	—
Effects of exchange rate changes	53	6
Balances at June, 2019	$ 5,955	$ 398
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	$ —	$ —

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

The anti-dilution warrants are classified as Level 3 in the fair value hierarchy. Due to the Share Exchange transaction on October 4, 2019 (see Note 7), there was no value to the anti-dilution warrants at December 31, 2019.

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

Note 4. Supplemental balance sheet information

Property and equipment

Property and equipment, net consisted of the following:

(in thousands)	June 30, 2020	December 31, 2019
Scientific equipment	$ 2,326	$ 2,300
Furniture & office equipment	445	346
Leasehold improvements	782	771
Total	3,553	3,417
Accumulated depreciation and amortization	(2,302)	(2,081)
Property & equipment, net	$ 1,251	$ 1,336

Depreciation and amortization expense was $0.1 million and $0.2 million for the three months ended June 30, 2020 and 2019, respectively, and $0.3 million for the six months ended June 30, 2020 and 2019.

Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of the following:

(in thousands)	June 30, 2020	December 31, 2019
Accrued clinical trial costs	$ 1,988	$ 2,683
Accrued personnel costs	1,228	1,409
Accrued professional fees	25	30
Accrued other	119	140
Total accrued expenses and other current liabilities	$ 3,360	$ 4,262

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 addition, on a per target basis, the Company may be required to pay development, regulatory and commercial milestones totaling up to an aggregate of $42.8 million for the first three products and additional milestone payments up to $13.5 million for each additional product. 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.

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

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

The Company has been awarded grants from the Walloon Region, a federal region of Belgium (the Walloon Region) and the European Union (the granting agencies) to fund research and development activities. The grants reimburse a percentage (55-100%) of actual qualifying expenditures. The Company periodically submits proof of qualifying expenditures to the granting agencies for approval and reimbursement. During the six month periods ended June 30, 2020 and 2019, the Company received funding under several grants which included no obligation to repay and two grants that include potential obligations to repay (RCAs).

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

Grants which do not include an obligation to repay

The total amount that the granting agencies have agreed to fund in the future if the Company incurs qualifying research and development expenses under these grants is $3.5 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 $21.2 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 $4.0 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 and RCA-2 ends in December and February 2021, respectively, per the current agreements. The Company must repay 30% of the amount received under the grant by annual installments from 2022 to 2041 (the fixed annual repayments) unless the Company decides not to pursue commercial development or out licensing of the drug candidate, applies for a waiver from the Walloon Region justifying its decision based upon the failure of the program, and returns the intellectual property to the Walloon Region. Because of the requirement to repay 30% of the amounts received under the grant, the Company records the present value of such amounts as grants repayable on the condensed consolidated balance sheets.

In addition, in the event that the Company receives revenue from products or services related to the results of the research, it has to pay to the Walloon Region a 0.33% royalty on revenue resulting from RCA-1 and a 0.12% royalty on revenue resulting from RCA-2. The maximum amount payable to the Walloon Region under each grant, including the fixed annual repayments, the royalty on revenue, and the interest thereon, is twice the amount of funding received. The Company assessed whether there is an obligation to make a royalty payment based on the probability of successful completion of the research and development and future sales and commercial success of the drug candidate, and no grant repayable was recorded as of June 30, 2020 or December 31, 2019.

The Company recorded grant income in the condensed consolidated statements of operations and comprehensive loss for the three and six months ended June 30, 2019 and 2020 for amounts of grants received from the Walloon Region in the period during which the related qualifying expenses were incurred, net of any grants repayable recorded in the condensed consolidated balance sheets.

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

The following table reflects activity for grant programs for the three and six months ended June 30, 2020 and 2019 and end of period balances as of June 30, 2020 and December 31, 2019:

	RCA -1		RCA-2		Other Grants		Total	
(In thousands)	2020	2019	2020	2019	2020	2019	2020	2019
Cash received during the six months ended June 30	$ 7,693	$ —	$ 1,968	N/A	$ 168	$ 900	$ 9,829	$ 900
Grant income recognized during the six months ended June 30	1,857	1,219	508	N/A	305	223	$ 2,670	$ 1,442
Cash received during the three months ended June 30	—	—	30	N/A	168	21	$ 198	$ 21
Grant income recognized during the three months ended June 30	725	550	137	N/A	219	128	$ 1,081	$ 678
Grants receivable at the end of the period	—	4,449	—	676	212	71	$ 212	$ 5,196
Grants repayable at the end of the period	$ 3,583	$ 1,397	$ 578	N/A	$ —	$ —	$ 4,161	$ 1,397

Note 7. Stockholders' equity (deficit)

Series B-2 preferred stock

On March 24, 2020, the Company issued 44,453,477 shares of Series B-2 Convertible Preferred Stock in exchange for gross proceeds of $125.4 million. Issuance costs were $0.3 million. Part of the Series B-2 shares issued served as settlement for the 11,046,657 Series B shares due to be issued under the Third Tranche of the Series B Subscription Agreement.

The Series B and Series B-2 preferred stock are collectively referred to as the "Senior Preferred Stock".

Under the Amended and Restated Certificate of Incorporation dated March 24, 2020, the significant rights and preferences of the outstanding preferred stock of the Company are as follows:

Dividends—The Preferred Stock of the Company accrues dividends at a rate of 6% per annum on the original issue price. Dividends are cumulative and accrue whether declared or not.

Liquidation preference—In the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company or a Deemed Liquidation Event, as defined below, (and after payment of all liabilities and all costs incurred in connection with the Liquidation Event or setting aside of monies sufficient to cover such liabilities and costs), the net assets in cash, shares or other assets (Liquidation Proceeds) shall be distributed in the following order:

1) First, the holders of Senior Preferred Stock (if necessary, on a pro rata basis) shall, in preference to any other outstanding securities, receive an amount equal to the original subscription price paid, plus accrued but unpaid dividends.

2) Second, out of the remaining Liquidation Proceeds (if any), the holders of Series A Preferred stock (if necessary, on a pro rata basis) shall, in preference to other outstanding securities, receive an amount equal to the original subscription price paid plus accrued but unpaid dividends.

3) Third, any remaining Liquidation Proceeds shall be distributed among the holders of the shares of Senior Preferred Stock and common stock, pro rata based on the number of shares held by each such holder, treating for this purpose all such securities as if they had been mandatorily converted to common stock pursuant to the terms of the Amended and Restated Certificate of Incorporation.

Deemed liquidation event—Means (i) a merger or consolidation in which the Company is a constituent party or a subsidiary of the Company is a constituent party and the Company issues shares of its capital stock pursuant to such merger or consolidation, (ii) (a) the sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by the Company or any subsidiary of the Company of all or substantially all the assets of the Company and its subsidiaries taken as a whole, or (b) the sale or disposition of one or more subsidiaries of the Company if substantially all of the assets of the Company and its subsidiaries taken as a whole are held by such subsidiary or subsidiaries, except where such sale, lease, transfer, exclusive license or other disposition is to a wholly owned subsidiary of the Company, or (iii) the transfer of more than a majority of the outstanding capital stock of the Company by way of sale or disposition (whether by merger, consolidation, or otherwise, and whether in a single transaction or a series of related transactions) or otherwise.

Redemption rights—At any time after the fifth anniversary of the original issue date of the Series B-2 Preferred Stock (March 24, 2025), upon a vote of 60% of the holders of Senior Preferred Stock, unless prohibited by Delaware law governing distributions to stockholders, shares of Senior Preferred Stock will be redeemed by the Company at a price equal to the greater of: 1) the applicable original issue price per share, plus any accrued but unpaid dividends and 2) the fair market value of the Senior Preferred Stock as of the date of the redemption request. Fair market value shall be based on the enterprise value without discount for illiquidity or lack of marketability, minority position, or transfer restrictions. Series A Preferred Stock is only redeemable upon a liquidity event.

Voting rights—All outstanding shares are entitled to one vote.

Optional conversion—Each share of Senior Preferred Stock is convertible, at the option of the holder, into shares of common stock at a ratio equal to the original applicable issuance price plus accrued but unpaid dividends divided by the applicable conversion price in effect at the time of conversion (initially equal to the applicable original issue price, adjusted going forward for any dilutive issuances, stock splits or similar events).

Mandatory conversion—Each share preferred stock (Series A and Senior Preferred) shall automatically convert into common shares at the then applicable conversion rate upon (i) vote by 60% of the then-outstanding shares of Senior Preferred Stock or, (ii) an initial public offering of the Company's common stock at a price of at least $9.34 per share and a proposed offering size of at least $50.0 million. See Note 12.

Directors—The Series B-2 Preferred shareholders are entitled to elect 2 directors and the Series B Preferred shareholders are entitled to elect 3 directors out of the 9 directors of the Board.

Note 8. Stock-based compensation

On March 24, 2020, the Board of Directors approved an increase to the total authorized options under the 2019 Stock Option and Grant Plan to 3,464,316.

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

	Three months ended June 30,		Six months ended June 30,	
(in thousands)	2020	2019	2020	2019
Research and development	67	43	$ 117	$ 86
General and administrative	283	160	419	322
Total stock-based compensation expense	$ 350	$ 203	$ 536	$ 408

The following table summarizes stock option activity for the six months ended June 30, 2020:

	Stock Options			
	Shares	Weighted average exercise price	Weighted average remaining contractual life (in years)	Aggregate intrinsic value (in thousands)
Outstanding as of December 31, 2019	1,387,003	$ 4.62		
Granted	2,127,318	4.33		
Forfeited	(59,076)	5.20		
Exercised	(131,867)	1.56		
Outstanding as of June 30, 2020	3,323,378	$ 4.54	8.0	$ 5,938
Exercisable at June 30, 2020	716,304	$ 5.27	4.8	$ 1,203

The weighted-average grant-date fair value of options awarded during the six month periods ended June 30, 2020 and 2019 was approximately $3.21 per share and $1.49 per share, respectively. As of June 30, 2020, there was a total of $7.2 million of unrecognized employee compensation costs related to non-vested stock option awards expected to be recognized over a weighted average period of 3.6 years.

The Company received $0.2 million from the exercise of 131,867 options into common stock in April 2020.

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 June 30,		Six months ended June 30,	
	2020	2019	2020	2019
Risk-free interest rate	0.45%	2.51%	0.45% - 1.35%	2.51%
Expected term (in years)	6	5	6	5
Expected volatility	92%	93%	90% - 92%	93%
Expected dividend yield	—	—	—	—
Estimated fair value of common stock	$4.24 - $6.16	2.38	$2.95 - $6.16	$ 2.38

Note 9. Commitments and contingencies

Purchase commitments

The Company has contractual arrangements with research and development organizations and suppliers; however, these contracts are generally cancelable on 30-60 days' notice and the obligations under these contracts are largely based on services performed. The Company may also enter into contracts in the normal course of business with clinical research organizations for clinical trials, with contract manufacturing organizations for clinical supplies and with other vendors for preclinical studies, supplies and other services and products for operating purposes. These contracts generally provide for termination on notice. As of June 30, 2020 and December 31, 2019, there were no amounts accrued related to termination charges.

Leases

The Company leases primarily office space in Charleroi, Belgium and Cambridge, Massachusetts under non-cancelable operating leases with expiration dates in December 2021 and May 2022, respectively, in addition to some small car leases that typically have four-year terms. Rent expense was $0.1 million for the three months ended June 30, 2020 and 2019, and $0.3 million and $0.2 million for the six month periods ended June 30, 2020 and 2019, respectively.

As of June 30, 2020, the Company had the following future minimum lease payments under non-cancelable operating leases for the remainder of 2020 and the future years thereafter (in thousands):

Year ending December 31:		
2020	$	267
2021		523
2022		122
2023		6
Total	$	918

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, the Company has approximately $66,000 on hand serving as a guarantee for its lease obligation in Belgium. These amounts have been classified as restricted cash in the condensed consolidated balance sheets as of June 30, 2020 and December 31, 2019.

Note 10. Related party transactions

On June 11, 2018, the Company entered into a Royalty Transfer Agreement with the charitable foundations of two of its investors (MPM Oncology Charitable Foundation, Inc. and UBS Optimus Foundation), which requires it to pay a royalty equal to 1% percent of its net product sales each year within 120 days following each year end. Such agreement was entered into as a result of the capital contributions received from the investors. As the Company has no product sales to date, no royalties were owed to these charitable foundations as of June 30, 2020.

Note 11. Net loss per share attributable to common stock

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

	June 30,	
	2020	2019
Series B and B-2 Preferred Stock, as converted	20,597,566	6,563,548
Series A Preferred Stock, as converted	1,862,510	1,862,510
Profit certificates, as converted	—	7,022
Stock options outstanding	3,323,378	1,388,969
Total	25,783,454	9,822,049

Note 12. Subsequent events

The Company evaluated all material subsequent events. The following events occurred subsequent to June 30, 2020:

Reverse Stock Split

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.

Initial Public Offering

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.

Amendment to 2019 Stock Option and Grant Plan

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

2020 Stock Option and Incentive Plan

The 2020 Stock Option and Incentive Plan (the "2020 Plan") was approved by the Company's board of directors on July 15, 2020, and the Company's stockholders on July 20, 2020 and became effective on July 22, 2020, the date immediately prior to the date on which the registration statement for the Company's IPO became effective. The 2020 Plan provides for the grant of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock units, restricted stock awards, unrestricted stock awards, cash-based awards and dividend equivalent rights to the Company's officers, employees, directors and consultants. The number of shares of common stock initially reserved for issuance under the 2020 Plan is 3,809,818 which shall be cumulatively increased on January 1, 2021 and each January 1 thereafter by 5% of the number of shares of the Company's common stock outstanding on the immediately preceding December 31 or such lesser number of shares as determined by the Company's compensation committee of the board of directors. The 2020 Plan will replace 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.

On July 15, 2020, the Board of Directors approved a grant of stock options to purchase 132,864 shares of common stock to directors of the Company. The stock options were granted upon IPO and have an exercise price equal to the price to the public in the Company's IPO ($19 per share). The options have a 10-year contractual term and vest on the earlier of (i) the first anniversary of the grant date or (ii) the Company's next annual meeting of the stockholders, subject to continued service through the applicable vesting date. Upon a Sale Event, as defined in the 2020 Plan, the options may become 100% vested and exercisable immediately.

On July 15, 2020, the Board of Directors approved a grant of stock options to purchase 1,035,424 shares of common stock to the CEO of the Company. The options were granted upon IPO equal to the amount necessary for the CEO to have 5% equity ownership on a fully-diluted basis and have an exercise price equal to the price to the public in the Company's IPO ($19 per share). The options have a 10-year contractual term and vest over a period of four years. Upon a Sale Event, as defined in the 2020 Plan, the options may become 100% vested and exercisable immediately.

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 become effective on July 22, 2020, the date immediately prior to the date on which the registration statement for the Company's IPO was declared effective. The ESPP will initially reserve and authorize the issuance of up to a total 317,484 shares of common stock to participating employees. The ESPP will provide that the number of shares reserved and available for issuance will automatically increase on January 1, 2021 and 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.

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, 2019 included in our final prospectus for our initial public offering of our common stock filed with the Securities and Exchange Commission, or the SEC, pursuant to rule 424(b)4 of the Securities Act on July 27, 2020, which we refer to as the Prospectus. Some of the information contained in this discussion includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk factors" section of this Quarterly Report on Form 10-Q, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biopharmaceutical company pioneering the discovery and development of a new generation of highly differentiated immuno-oncology therapeutics for patients. We leverage our deep understanding of the tumor microenvironment and immunosuppressive pathways to design novel product candidates with an aim to improve the clinical benefit of oncology therapies. Our innovative pipeline includes two clinical-stage programs targeting novel, validated immuno-oncology pathways designed to build on prior learnings in the field to have differentiated pharmacological and clinical profiles. Our most advanced product candidate, EOS-850, is designed as a highly selective small molecule antagonist of the adenosine A2a receptor, in the adenosine triphosphate, or ATP, adenosine pathway, a key driver of immunosuppression in the tumor microenvironment across a broad range of tumors. We are investigating EOS-850 in an open-label Phase 1/2a clinical trial in patients with advanced solid tumors and in the dose escalation portion of the trial it has shown encouraging preliminary single-agent activity. We expect to report additional data from monotherapy and combination therapy expansion cohorts in the first half of 2021. Our lead antibody product candidate, EOS-448, is an antagonist of TIGIT, a checkpoint that has a role in both inhibitory and stimulatory pathways in the immune system. EOS-448 was also designed to engage the Fc gamma receptor, or Fc□R, to promote antibody-dependent cellular cytotoxicity, or ADCC, activity, including the elimination of tumor-infiltrating regulatory T cells. We have recently initiated an open-label Phase 1/2a clinical trial of EOS-448 in patients with advanced solid tumors and expect to report initial data in the first half of 2021. We are using our expertise in tumor immunology to select additional targets for other novel, differentiated programs. To date, we have initiated one preclinical program that we believe has the potential to be complementary to both standard cancer treatments and our own product candidates. We retain worldwide rights to develop and commercialize all of our product candidates.

Since our inception in August 2011, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, conducting discovery and research activities, filing patent applications, identifying potential product candidates, undertaking preclinical studies and clinical trials and establishing arrangements with third parties for the manufacture of initial quantities of our product candidates and component materials. To date, we have not generated any revenue from product sales and have financed our operations primarily through the private placement of our securities, license agreements and grant proceeds. As of June 30, 2020, we had raised an aggregate of $177.1 million from the sale of preferred stock. As of June 30, 2020, our principal source of liquidity was cash, which totaled $136.9 million.

We have incurred recurring losses since inception. Our net losses were $7.2 million and $5.8 million for the three months ended June 30, 2020 and 2019, respectively, and $12.4 million and $10.2 million for the six months ended June 30, 2020 and 2019, respectively. As of June 30, 2020, we had an accumulated deficit of $48.3 million. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product candidates.

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

- continue preclinical studies and clinical trials and initiate new clinical trials for our product candidates;
- pursue regulatory approvals for our product candidates;
- advance the development of our product candidate pipeline;
- continue research activities as we seek to discover and develop additional product candidates;
- obtain, maintain, expand and protect our intellectual property portfolio;

- hire additional research and development, clinical and commercial personnel;
- scale up our clinical and regulatory capabilities; and
- add operational, financial and management information systems and personnel, including personnel to support our research and development programs, any future commercialization efforts and our transition to operating as a public company.

As a result of these anticipated expenditures, we will need substantial additional financing to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt financings, grants, collaborations, strategic alliances and licensing arrangements. We may be unable to raise additional funds or enter into such other agreements when needed on favorable terms or at all. Our inability to raise capital as and when needed would have a negative impact on our financial condition and our ability to pursue our business strategy. We will need to generate significant revenue to achieve profitability, and we may never do so.

As of June 30, 2020, we had cash of $136.9 million. In addition, we closed on our IPO in July 2020, which raised net proceeds of approximately $184.0 million. In August 2020, the underwriters purchased an additional 1,505,359 shares of common stock under their option for net proceeds of $26.6 million. We believe that the net proceeds from our IPO, together with our existing cash will enable us to fund our operating expenses and capital expenditure requirements into the second half of 2023. Our future viability beyond that point is dependent on our ability to raise additional capital to finance our operations. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See “Liquidity and Capital Resources.” Because of the numerous risks and uncertainties associated with our programs, we are unable to estimate the amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates.

We are party to collaboration and license agreements pursuant to which we may be required to make future royalty and milestone payments. In January 2017, we entered into a collaboration agreement with Adimab, LLC, or Adimab, pursuant to which we paid $1.0 million to exercise an option to acquire certain licenses from Adimab. This agreement provides for potential future milestone payments up to an aggregate of $42.8 million for the first three products and additional milestone payments up to $13.5 million for each additional product. 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. 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.

Recent Developments

As of July 23, 2020, the date of our final prospectus for our IPO, further evaluation of the autopsy and etiology of a pericardial effusion that was a reported serious adverse event, or SAE, which occurred in a treated patient in our Phase 1 clinical trial of EOS-850 was pending. In the case of the subject with endometroid adenocarcinoma of the cervix who experienced SAEs that were considered possibly drug-related, the final autopsy results are now available. The subject’s death due to acute right heart failure related to disease progression is not considered drug-related, and the lung findings that had been previously diagnosed as pneumonitis have been determined to be related to disease progression within the lung. There was not clear evidence that the pericardial effusion, which occurred approximately 4 weeks after treatment with EOS-850 was discontinued, was related to the underlying malignancy on autopsy, so a possible relationship to the study drug cannot be ruled out, and this event is considered possibly drug-related.

Impact of COVID-19

In December 2019, a novel strain of coronavirus (COVID-19) emerged in Wuhan, Hubei Province, China. As of June 30, 2020, COVID-19 has spread to Europe, the United States and many other countries, and has been declared a pandemic by the World Health Organization. Efforts to contain the spread of COVID-19 have intensified and the United States, including the Commonwealth of Massachusetts where our headquarters are located, Europe and Asia have implemented severe travel restrictions, social distancing requirements and stay-at-home orders, among other restrictions, which, in some cases, have had the effect of delaying the commencement of non-COVID-19-related clinical trials. As a result, the COVID-19 pandemic has caused significant disruptions to the U.S., regional and global economies and has contributed to significant volatility and negative pressure in financial markets.

We have been carefully monitoring the COVID-19 pandemic and its potential impact on our business and have taken important steps to help ensure the safety of our employees and their families and to reduce the spread of COVID-19 in the Cambridge and Belgian communities. We have established a work-from-home policy for all employees, other than those performing or supporting business-critical operations, such as certain members of our laboratory and facilities staff. For those employees, we have implemented stringent safety measures designed to comply with applicable federal, state and local guidelines instituted in response to the COVID-19 pandemic. We have also maintained efficient communication with our partners and clinical sites as the COVID-19 situation has progressed. We have taken these precautionary steps while maintaining business continuity so that we can continue to progress our programs. The effect of the COVID-19 pandemic on our development timelines for EOS-850 and EOS-448 and its effect on our preclinical research and development is uncertain.

While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our common stock.

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, among others. See “Risk factors” for a discussion of the potential adverse impact of COVID-19 on our business, results of operations and financial condition.

Components of our results of operations

Revenue

To date, we have not generated any revenue from product sales and do not expect to do so in the near future, if at all. All of our revenue to date has been derived from licensing fees in connection with a research collaboration and license agreement with Pfizer, which terminated in 2017.

We expect that our revenue, if any, will be less than our expenses for the foreseeable future and that we will experience increasing losses as we continue our development of, and seek regulatory approvals for, our product candidates and begin to commercialize any approved products. Our ability to generate revenue for each product candidate for which we receive regulatory approval will depend on numerous factors, including competition, commercial manufacturing capability and market acceptance of our products.

Research and development expenses

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

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

We expense research and development costs as incurred. We recognize costs for certain development activities, such as preclinical studies and clinical trials, based on an evaluation of the progress to completion of specific tasks using

information provided to us by our vendors, such as patient enrollment or clinical site activations for services received and efforts expended.

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

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

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

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

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

	Three months ended June 30,		Six months ended June 30,	
(in thousands)	**2020**	**2019**	**2020**	**2019**
Direct research and development expenses by program:				
EOS-850	$ 2,379	$ 1,004	$ 4,781	$ 2,390
EOS-448	1,552	1,293	2,465	2,213
Other non-clinical programs	1,093	139	1,758	240
Indirect research and development expenses(1)	1,113	1,466	2,958	3,410
Total research and development expense	$ 6,137	$ 3,902	$ 11,962	$ 8,253

(1) The substantial majority of these costs relate to the EOS-850 and EOS-448 programs. Approximately half of these costs are payroll and related costs for our employees performing in-house research and development activities and the remainder represents other research and development costs.

General and administrative expenses

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

We anticipate that our general and administrative expenses will increase in the future to support continued research and development activities, potential commercialization of our product candidates and increased costs of operating as a public company. These increases will likely include increased costs related to the hiring of additional personnel and fees to outside consultants, lawyers and accountants, among other expenses. Additionally, we anticipate increased costs associated with being a public company, including services associated with maintaining compliance with exchange listing and SEC requirements, director and officer insurance costs and investor and public relations costs.

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.

Grant funding for research and development received under grant agreements where there is no obligation to repay is recognized as other income in the period during which the related qualifying expenses are incurred, based on the applicable reimbursement percentage, provided that the grants are fully approved by the granting agencies and the conditions under which the grants were provided have been met.

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.

We assess whether there is an obligation to repay under the repayment provision through a royalty payment the probability of successful completion of the research and development and future sales and commercial success of the drug candidate.

When we receive grant funding in advance of incurring qualifying expenses, we record deferred income. When we incur qualifying expenses in advance of receipt of grant funding, we record grants receivable.

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 2020 and 2019) 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 and warrants

We have determined that our obligation to issue and our investors' obligation to purchase additional shares of Series B preferred stock of iTeos Belgium SA represented a freestanding financial instrument. In addition, the investors in Series A and B preferred stock held anti-dilution warrants, which also represented a freestanding financial instrument. The resulting preferred stock tranche right and anti-dilution warrant liabilities were initially recorded at fair value, with gains and

losses arising from changes in fair value recognized in the statement of operations and comprehensive loss during each period while such instruments were outstanding. The anti-dilution warrants were settled in October 2019 in connection with our corporate reorganizations and the tranche rights were settled in the first quarter of 2020. Accordingly, we are no longer required to record liabilities for these obligations or changes in the fair value of those liabilities.

Other income (expense), net

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

Income taxes

Income tax expense results from foreign minimum income tax and profit on a legal entity basis. Income tax benefit results from carryback claims for federal income tax purposes. As of June 30, 2020, we had deferred taxes, primarily resulting from net operating loss carryforwards. We have been considered that it is more likely than not that we will not realize the benefits of the deferred tax asset, and accordingly, have maintained a full valuation allowance as of June 30, 2020.

Results of operations

Comparison of the six months ended June 30, 2020 and 2019

The following table summarizes our results of operations for the six months ended June 30, 2020 and 2019, together with the dollar change in those items:

	Six months ended June 30,		Period to period
(in thousands)	2020	2019	change
Operating expenses:			
Research and development expenses	$ 11,962	$ 8,253	$ 3,709
General and administrative expenses	4,812	3,862	950
Total operating expenses	16,774	12,115	4,659
Loss from operations	(16,774)	(12,115)	(4,659)
Other income and expense:			
Grant income	2,670	1,442	1,228
Fair value adjustment for preferred stock tranche rights liability and anti-dilution warrants liability	1,265	296	969
R&D tax credits	370	353	17
Other income (expense), net	(30)	(75)	45
Loss before income taxes	(12,499)	(10,099)	(2,400)
Income tax benefit (expense)	50	(58)	108
Net loss	$ (12,449)	$ (10,157)	$ (2,292)

Research and development expenses

The increase of $3.7 million in research and development expenses for the six months ended June 30, 2020 compared to the six months ended June 30, 2019 was primarily 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 EOS-850, which had a full period of activity during the six months ended June 30, 2020 and only a partial period during the six months ended June 30, 2019. In addition, there was an increase in spending related to our preclinical programs during the six months ended June 30, 2020.

General and administrative expenses

The increase of $1.0 million in general and administrative expenses for the six months ended June 30, 2020 compared to the six months ended June 30, 2019 was primarily attributable to an increase of $0.5 million of professional fees related to financing and other related activities in preparing to operate as a public company, an increase of $0.2 million in recruiting fees related to the hiring of new executives, a $0.1 million increase in stock-based compensation, an

increase of $0.1 million in facilities, including rent, mostly related to the office in Cambridge, Massachusetts, which we opened in May 2019, and an increase of $0.1 million related to various other expenses.

Grant income

Grant income increased by $1.2 million for the six months ended June 30, 2020 compared to the six months ended June 30, 2019. The overall increase in grant income, driven by spending on qualified research and development activities, was primarily attributable to an increase in grants for the following programs:

- EOS-850: $0.6 million
- EOS-448: $0.5 million
- Other preclinical programs - $0.1 million

EOS-448 was a new program in 2019 and had generated no grant income during the six months ended June 30, 2019.

Fair value adjustment for preferred stock tranche rights liability and anti-dilution warrants liability

As a result of changes in the fair value of preferred stock tranche rights liability and anti-dilution warrants liability, we recognized other income of $1.3 million and $0.3 million for the six months ended June 30, 2020 and 2019, respectively. In October 2019, as part of the Share Exchange transaction, the anti-dilution warrants were settled and the related liability was removed from the consolidated balance sheet. As of June 30, 2020, the tranche rights have been settled and the remaining liability has been reclassified to additional paid-in capital.

Income tax benefit (expense)

We generated income tax expense for our U.S. subsidiary in 2019 due to taxable income generated from intercompany charges between the United States and Belgium. In 2020, the U.S. subsidiary generated a net operating loss, which is expected to be carried back to taxable income generated in 2019. This generated an income tax benefit for 2020.

Comparison of the three months ended June 30, 2020 and 2019

The following table summarizes our results of operations for the three months ended June 30, 2020 and 2019, together with the dollar change in those items:

(in thousands)	Three months ended June 30, 2020	Three months ended June 30, 2019	Period to period change
Operating expenses:			
Research and development expenses	$ 6,137	$ 3,902	$ 2,235
General and administrative expenses	2,394	2,093	301
Total operating expenses	8,531	5,995	2,536
Loss from operations	(8,531)	(5,995)	(2,536)
Other income and expenses:			
Grant income	1,081	678	403
Fair value adjustment for preferred stock tranche rights liability and anti-dilution warrants liability	—	(488)	488
R&D tax credits	186	155	31
Other income (expense), net	12	(47)	59
Loss before income taxes	(7,252)	(5,697)	(1,555)
Income tax benefit (expense)	50	(58)	108
Net loss	$ (7,202)	$ (5,755)	$ (1,447)

Research and development expenses

The increase of $2.2 million in research and development expenses for the three months ended June 30, 2020 compared to the three months ended June 30, 2019 was primarily 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, and an increase in spending on EOS-850. In addition, there was an increase in spending related to our preclinical programs during the three months ended June 30, 2020.

General and administrative expenses

The increase of $0.3 million in general and administrative expenses for the three months ended June 30, 2020 compared to the three months ended June 30, 2019 was primarily due to an increase of $0.6 million of payroll and related costs and recruiting fees due the hiring of additional executives in the second quarter of 2020. In addition, there was a $0.1 million increase related to stock-based compensation. These increases were partially offset by a $0.4 million decrease in professional fees, including legal, consulting, accounting, and audit fees, due in part to a large portion of these costs that were incurred during the three months ended June 30, 2020 being recorded as deferred IPO costs on the condensed consolidated balance sheet as of June 30, 2020.

Grant income

Grant income increased by $0.4 million for the three months ended June 30, 2020 compared to the three months ended June 30, 2019. The overall increase in grant income, driven by spending on qualified research and development activities, was primarily attributable to an increase in grants for the following programs:

- EOS 850: $0.2 million
- EOS-448: $0.1 million
- Other preclinical programs: $0.1 million

Fair value adjustment for preferred stock tranche rights liability and anti-dilution warrants liability

As a result of changes in the fair value of the preferred stock tranche rights and anti-dilution warrants liabilities, we recognized other expense of $0.5 million for the three months ended June 30, 2019. No income or expense was recognized for the three months ended June 30, 2020, as the preferred stock tranche rights were settled on March 24, 2020 and the anti-dilution warrants were settled as a result of the Share Exchange transaction in October 2019.

Income tax benefit (expense)

We generated income tax expense for our U.S. subsidiary in 2019 due to taxable income generated from intercompany charges between the United States and Belgium. In 2020, the U.S. subsidiary generated a net operating loss, which is expected to be carried back to taxable income generated in 2019. This generated an income tax benefit for 2020.

Liquidity and capital resources

Since our inception, we have incurred significant operating losses. We expect to incur significant expenses and operating losses for the foreseeable future as we advance the clinical development of our programs. To date, we have funded our operations primarily with proceeds from the sales of preferred stock, grants and licenses, and going forward through proceeds from our IPO, which closed in July 2020. As of June 30, 2020, we had $136.9 million in cash.

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.

To date, we have not generated any revenue from product sales and do not expect to generate revenue from the sale of products for the foreseeable future. We anticipate the need for additional capital in order to continue to fund our research and development, including our plans for clinical and preclinical trials and new product development, as well as to fund general operations. As and if necessary, we will seek to raise these additional funds through various potential sources, such as equity and debt financings or through corporate collaboration and license agreements. Especially in light of the COVID-19 pandemic, we can give no assurances that we will be able to secure such additional sources of funds to support our operations on acceptable terms, if at all, or, if such funds are available to us, that such additional financing will

be sufficient to meet our needs. For a more detailed discussion of risks related to COVID-19, please see Part II., Item 1A., Risk factors—Risks related to our relationships with third parties, in this Quarterly Report on Form 10-Q.

Cash flows

The following table provides information regarding our cash flows for the six months ended June 30, 2020 and 2019:

	Six months ended June 30,	
(in thousands)	**2020**	**2019**
Net cash (used in) provided by:		
Operating activities	$ (9,481)	$ (10,658)
Investing activities	(138)	(794)
Financing activities	126,633	22,474
Effects of exchange rate changes on cash and restricted cash	(11)	184
Net increase in cash and restricted cash	$ 117,003	$ 11,206

Net cash used in operating activities

The use of cash in both periods resulted primarily from our net losses adjusted for non-cash charges and changes in components of working capital. The net loss was $2.3 million higher for the six months ended June 30, 2020 compared to the six months ended June 30, 2019, which was primarily offset by grant proceeds received.

Net cash used in investing activities

Net cash used in investing activities decreased $0.7 million for the six months ended June 30, 2020 compared to the six months ended June 30, 2019. The decrease in cash used in investing activities was primarily due to higher investments in laboratory and other equipment and software during the six months ended June 30, 2019.

Net cash provided by financing activities

Net cash provided by financing activities was $126.6 million during the six months ended June 30, 2020. We raised cash through the issuance of Series B-2 preferred stock, with net proceeds of $125.0 million. In addition, we received $2.7 million under grant programs with a potential obligation for repayment and $0.2 million from the exercise of stock options. These sources of cash were partially offset by payments of $1.3 million for IPO costs. During the six months ended June 30, 2019, we raised $22.4 million from the issuance of Series B preferred stock under tranche 2 of the Series B subscription agreement and $0.1 million from the exercise of stock options.

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 Phase 1/2a clinical trial of EOS-850, 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 incur additional costs associated with operating as a public company. Accordingly, we will need to obtain additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

We believe that the net proceeds from the IPO, together with our existing cash as of June 30, 2020, will enable us to fund our operating expenses and capital expenditure requirements through the second half of 2023.

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-850 and EOS-448, and the research, development and commercialization of other potential product candidates, we are unable to estimate the exact amount of our operating capital requirements. Our future capital requirements will depend on many factors, including:

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

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

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

If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or grants when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Contractual obligations and commitments

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

During the six months ended June 30, 2020, there were no significant changes to our contractual obligations and commitments as of December 31, 2019, as described in the section entitled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our final prospectus relating to our IPO.

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.

While our significant accounting policies are described in more detail in the notes to our condensed consolidated financial statements, we believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our condensed consolidated financial statements:

Research and development expenses

We expense research and development costs to operations as incurred. Research and development expenses comprise costs incurred in performing research and development activities, including salaries, benefits and other employee-related expenses, share-based compensation expense, laboratory supplies and other direct expenses, facilities cost, overhead costs, third-party contract costs relating to pre-clinical studies and clinical trial activities and related contract manufacturing expenses, and other outside costs.

As part of the process of preparing our financial statements, we are required to estimate our accrued 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. Advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed. 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 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

We account for stock-based compensation arrangements in accordance with ASC 718, *Stock Compensation*. On January 1, 2017, we early-adopted Accounting Standard Update, or ASU, No. 2018-07 (Topic 718), *Compensation—Stock Compensation*, which expanded the scope of Topic 718 to include share-based payment transactions with non-employees.

Stock-based awards granted include stock options with time-based vesting. ASC 718 requires the recognition of compensation expense, using a fair value-based method, for costs related to all stock-based payments. Our determination of the fair value of stock options with time-based vesting on the date of grant utilizes the Black-Scholes option-pricing model, and is impacted by our common stock price as well as other variables including, but not limited to, expected term that options will remain outstanding, expected common stock price volatility over the term of the option awards, risk-free interest rates and expected dividends.

The fair value of a stock-based award is recognized over the period during which an optionee is required to provide services in exchange for the option award, known as the requisite service period (usually the vesting period) on a straight-line basis. Stock-based compensation expense is recognized based on the fair value determined on the date of grant and is reduced for forfeitures as they occur. Estimating the fair value of equity-settled awards as of the grant date using valuation models, such as the Black-Scholes option pricing model, is affected by assumptions regarding a number of complex variables. Changes in the assumptions can materially affect the fair value and ultimately how much stock-based compensation expense is recognized. These inputs are subjective and generally require significant analysis and judgment to develop.

Prior to our IPO in July 2020, there has been no public market for our common stock. The estimated fair value of our common stock has been 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 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 represent management's best estimate, which involve inherent uncertainties and the application of management judgement. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation could be materially different.

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

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 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 repay 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 no obligation to repay is recognized as other income in the period during which the related qualifying expenses are incurred, based on the applicable reimbursement percentage, provided that the grants are fully approved by the granting agencies and the conditions under which the grants were provided have been met.

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.

We assess whether there is an obligation to repay under the repayment provision through a royalty payment the probability of successful completion of the research and development and future sales and commercial success of the drug candidate.

When we receive grant funding in advance of incurring qualifying expenses, we record deferred income. When we incur qualifying expenses in advance of receipt of grant funding, we record grants receivable.

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 condensed consolidated financial statements of this Quarterly Report for a discussion of recent accounting pronouncements.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. As of June 30, 2020 and December 31, 2019, we had cash of $136.9 million and $19.9 million, respectively. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of interest rates in the United States and Belgium. As of June 30, 2020, our cash is held primarily in savings and money market accounts. 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. As of June 30, 2020 we had cash balances held by iTeos Belgium SA in euro. An immediate 5% change in the Euro exchange rate would not have any material effect on our results of operations.

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

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

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

Changes in Internal Control over Financial Reporting

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

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

Risk factors

The following risk factors and other information included in this Quarterly Report on Form 10-Q should be carefully considered. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we presently deem less significant may also impair our business operations. Please see the Section titled "Forward-Looking Statements" of 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 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, EOS-850 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, and our initial public offering, or IPO, in July 2020. 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, EOS-850, and our lead antibody product candidate, EOS-448, are each in ongoing Phase 1/2a clinical trials. We have no products licensed for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. We have financed our operations primarily through private placements of our preferred stock.

We have incurred significant net losses in each period since inception. For the six months ended June 30, 2020 and 2019, our net losses were $12.4 million and $10.2 million, respectively. As of June 30, 2020, we had an accumulated deficit of $48.3 million. We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase substantially if and as we:

- conduct preclinical studies and clinical trials for our current and future product candidates;
- continue our research and development efforts and submit investigational new drug applications, or 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, EOS-850, EOS-448, and any future product candidates;
- obtaining marketing approvals for EOS-850, EOS-448, and any future product candidates for which we complete clinical trials;
- developing a sustainable and scalable manufacturing process for EOS-850, EOS-448, and any future product candidates, including establishing and maintaining commercially viable supply and manufacturing relationships with third parties;
- launching and commercializing EOS-850, 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 EOS-850, 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 EOS-850, EOS-448, or any future product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain marketing approval, the accepted price for the product, the ability to get reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, the labels for our current product candidates and any future product candidates contain significant safety warnings, regulatory authorities impose burdensome or restrictive distribution requirements, or the reasonably accepted patient population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate revenue from the sale of any approved products, we could be prevented from or significantly delayed in achieving profitability.

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

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

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the clinical development of our product candidates, including our ongoing Phase 1/2a clinical trials of EOS-850 and EOS-448 and our ongoing and planned IND-enabling studies for our other product candidates. If approved, we will require significant additional amounts in order to launch and commercialize our product candidates.

As of June 30, 2020, we had $136.9 million of cash. 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 will not be sufficient to fund all of our efforts that we plan to undertake.

We believe the net proceeds from the IPO, together with our existing cash, will enable us to fund our operations into the second half of 2023. 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 EOS-850, 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 EOS-850, EOS-448, and any future product candidates if clinical trials are successful;
- the extent to which we develop, in-license or acquire other product candidates and technologies;
- the number and development requirements of other product candidates we may pursue;
- the success of any collaborations;
- the cost of commercialization activities for any approved product, including marketing, sales and distribution costs;
- the cost of manufacturing EOS-850, EOS-448, and any future product candidates for clinical trials in preparation for marketing approval and commercialization;

- our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the timing, receipt, and amount of sales of, or royalties on, future approved products, if any; and
- the emergence of competing cancer therapies and other adverse market developments.

We have limited committed external source of funds or other support for our development efforts. Until we can generate sufficient product revenue to finance our cash requirements, which we may never do, we expect to finance our future cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic alliances, licensing and grant arrangements and other marketing or distribution arrangements. We cannot be certain that additional funding will be available on acceptable terms, or at all. Further, our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue our research and development initiatives. We could be required to seek collaborators for our product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to our product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves.

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

Risks related to 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.

Our most advanced product candidate, EOS-850, has been administered to 21 adult patients with advanced solid tumors, as of February 28, 2020, in a first-in-human open-label Phase 1/2a clinical trial, and we plan to initiate additional trials of EOS-850 in combination with pembrolizumab and with carboplatin and paclitaxel. In addition, in February 2020, we dosed our first patients with our lead antibody product candidate, EOS-448, in a first-in-human open-label Phase 1/2a clinical trial in adult patients with advanced cancers. We have additional oncology-focused product candidates in preclinical development. Our current product candidates and any future product candidates we may develop will require preclinical and clinical trials before we can submit a marketing application to the applicable regulatory authorities. Our current product candidates and any future product candidates are susceptible to the risks of failure inherent at any stage of product development, including the occurrence of unexpected or unacceptable adverse events or the failure to demonstrate efficacy in clinical trials. Clinical development is expensive and can take many years to complete, and its outcome is inherently uncertain.

The results of preclinical studies, preliminary study results, and early clinical trials of our current product candidates and any future product candidates may not be predictive of the results of later-stage clinical trials. Even if early-stage clinical trials are successful, we may need to conduct additional clinical trials of our product candidates in additional patient populations or under different treatment conditions before we are able to seek approvals from the FDA or comparable foreign regulatory authorities. While we are currently conducting first-in-human Phase 1/2a trials of EOS-850 and EOS-448, we have not yet completed any clinical trials. Our current product candidates and any future product candidates may not perform as we expect, may ultimately have a different or no impact on tumors, may have a different mechanism of action than we expect, and may not ultimately prove to be safe and effective.

Preliminary and final results from preclinical studies and early stage trials, and trials in compounds that we believe are similar to ours, may not be representative of results that are found in larger, controlled, blinded, and longer-term studies. Product candidates may fail at any stage of preclinical or clinical development. Product candidates may fail to show the desired safety and efficacy traits even if they have progressed through preclinical studies or initial clinical trials. Preclinical studies and clinical trials may also reveal unfavorable product candidate characteristics, including safety concerns. A number of companies in the biopharmaceutical industry have suffered significant setbacks in clinical trials, notwithstanding promising results in earlier preclinical studies or clinical trials or promising mechanisms of action. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same

product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the clinical trial protocols and the rate of dropout among clinical trial participants. Moreover, should there be an issue with the design of a clinical trial, our results may be impacted. We may not discover such a flaw until the clinical trial is at an advanced stage.

Additionally, our clinical trials, to date, have been open-label trials, where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug, introducing bias in early interpretation of the results. Most typically, open-label clinical trials test only the investigational product candidate and sometimes do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. Therefore, it is possible that positive results observed in open-label trials will not be replicated in later placebo-controlled trials. We may also experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our current product candidates and any future product candidates, including:

- regulators or institutional review boards, or IRBs, may not authorize us or our investigators to commence a clinical trial, conduct a clinical trial at a prospective trial site, or amend trial protocols, or may require that we modify or amend our clinical trial protocols;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites and/or clinical research organizations, or CROs;
- we may be unable to initiate or complete preclinical studies or clinical trials on time or at all due to the impacts of COVID-19;
- clinical trials of our current product candidates and any future product candidates may produce negative or inconclusive results, or our studies may fail to reach the necessary level of statistical significance, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our current product candidates and any future product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials or be lost to follow-up at a higher rate than we anticipate, or may elect to participate in alternative clinical trials sponsored by our competitors with product candidates that treat the same indications as our current product candidates and any future product candidates;
- our third-party contractors may fail to comply with regulatory requirements or the clinical trial protocol, or meet their contractual obligations to us in a timely manner, or at all, or we may be required to engage in additional clinical trial site monitoring;
- we, regulators, or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks, undesirable side effects, or other unexpected characteristics of the product candidate, including where combination dosing of or with our product candidates results in serious adverse events or undesirable side effects, or due to findings of undesirable effects caused by a chemically or mechanistically similar therapeutic or therapeutic candidate;
- changes could be adopted in marketing approval policies during the development period, rendering our data insufficient to obtain marketing approval;
- statutes or regulations or site policies could be amended or new ones could be adopted;
- changes could be adopted in the regulatory review process for submitted product applications;
- the cost of clinical trials of our current product candidates and any future product candidates may be greater than we anticipate or we may have insufficient funds for a clinical trial or to pay the substantial user fees required by the FDA or comparable foreign regulatory authorities upon the filing of a Biologics License
- Application, or BLA, or a New Drug Application, or NDA, or equivalent authorizations from comparable foreign regulatory authorities;

- the supply or quality of our current product candidates and any future product candidates or other materials necessary to conduct clinical trials of our current product candidates and any future product candidates may be insufficient or inadequate or may be interrupted or impacted by the COVID-19 pandemic;
- we may decide, or regulators may require us, to conduct or gather, as applicable, additional clinical trials, analyses, reports, data, or preclinical trials, or we may abandon product development programs;
- we may fail to reach an agreement with regulators or IRBs regarding the scope, design, or implementation of our clinical trials, and the FDA or comparable foreign regulatory authorities may require changes to our study designs that make further study impractical or not financially prudent;
- regulators may ultimately disagree with the design or our conduct of our preclinical studies or clinical trials, finding that they do not support product candidate approval;
- we may have delays in adding new investigators or clinical trial sites, or we may experience a withdrawal of clinical trial sites;
- patients that enroll in our studies may misrepresent their eligibility or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the patients from the study or clinical trial, increase the needed enrollment size for the clinical trial or extend its duration;
- there may be regulatory questions or disagreements regarding interpretations of data and results, or new information may emerge regarding our current product candidates and any future product candidates;
- the FDA or comparable foreign regulatory authorities may disagree with our study design, including endpoints, or our interpretation of data from preclinical studies and clinical trials or find that a product candidate's benefits do not outweigh its safety risks;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a drug or biologic candidate is safe and effective for its proposed indication or a related companion diagnostic is suitable to identify appropriate patient populations;
- the FDA or comparable foreign regulatory authorities may not accept data from studies with clinical trial sites in foreign countries;
- the FDA or comparable foreign regulatory authorities may disagree with our intended indications;
- the FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or our manufacturing facilities for clinical and future commercial supplies;
- the data collected from clinical trials of our current product candidates and any future product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of an BLA or NDA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may take longer than we anticipate to make a decision on our current product candidates and any future product candidates; and
- we may not be able to demonstrate that a product candidate provides an advantage over current standards of care or current or future competitive therapies in development.

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

We 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 Phase 1/2a clinical trial of EOS-850 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 Phase 1/2a clinical trial of EOS-850, 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 EOS-850 and EOS-448 and may develop other future product candidates for use in combination with checkpoint inhibitor immunotherapies and may develop EOS-850, 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.

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

We expect initially to focus on the development of EOS-850 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 in drug product development. We cannot assure you that we will be able to successfully advance any future product candidates through the development process.

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

Difficulty in enrolling patients could delay or prevent clinical trials of our current product candidates and any future product candidates. We may find it difficult to enroll patients in our ongoing clinical trials or any subsequent trials we may conduct and our receipt of necessary regulatory approvals could be delayed or prevented.

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

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.

We may also engage third parties to develop companion diagnostics for use in our clinical trials, but such third parties may not be successful in developing such companion diagnostics, furthering the difficulty in identifying patients with the targeted genetic mutations for our clinical trials. Further, if we are required to develop companion diagnostics and are unable to include patients with the targeted genetic mutations, this could compromise our ability to seek participation in the FDA's expedited review and development programs, including Breakthrough Therapy Designation and Fast Track Designation, or otherwise to seek to accelerate clinical development and regulatory timelines.

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

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

In addition, our clinical trials will compete with other clinical trials for product candidates that 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 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.

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 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.

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, EOS-850 and EOS-448. We may not be able to file any additional INDs required for our current product candidates and any future product candidates on the timelines we expect. For example, we may experience manufacturing delays or other delays with IND-enabling studies, including due to the impact of the COVID-19 pandemic on suppliers, study sites or third-party contractors and vendors on whom we depend. Moreover, we cannot be sure that submission of an IND will result in the FDA or comparable foreign regulatory authorities allowing further clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate clinical trials. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, we cannot guarantee that such regulatory authorities will not change their requirements in the future. These considerations also apply to new clinical trials we may submit as amendments to existing INDs or to a new IND. Any failure to file INDs on the timelines we expect or to obtain regulatory approvals for our trials may prevent us from completing our clinical trials or commercializing our products on a timely basis, if at all. There are similar risks related to the review and authorization of our protocols and amendments by comparable foreign regulatory authorities.

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

We are conducting 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 U.S. population and U.S. 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.

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.

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 EOS-850, 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 EOS-850, 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.

Risks related to regulatory approval

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 EOS-850, 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, 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, such as the possibly drug-related serious adverse event of pericardial effusion recently observed and pending investigation in our Phase 1/2a clinical trial of EOS-850, 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, decline to approve the product candidate or issue a letter requesting additional data or information prior to making a final decision regarding whether or not to approve the product candidate.

The FDA or comparable foreign regulatory authorities, or IRBs and other reviewing entities, may also require, or we may voluntarily develop, strategies for managing adverse events during clinical development, which could include restrictions on our enrollment criteria, the use of stopping criteria, adjustments to a study's design, reconsent of enrolled patients, or the monitoring of safety data by a data monitoring committee, among other strategies. The FDA or a comparable foreign regulatory authority requests for additional data or information could also result in substantial delays in the approval of our current product candidates and any future product candidates. Additionally, we may evaluate our product candidates in combination with one another, and safety concerns arising during a combination trial could negatively affect the individual development program of each candidate, as the FDA or comparable foreign regulatory authorities may require us to discontinue single-candidate trials until the contribution of each product candidate to any safety issues is better understood.

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

Undesirable side effects caused by our current product candidates or any future product candidates could also result in denial of regulatory approval by the FDA or comparable foreign regulatory authorities for any or all targeted indications or the inclusion of unfavorable information in our product labeling, such as limitations on the indicated uses for which the products may be marketed or distributed, a label with significant safety warnings, including boxed warnings, contraindications, and precautions, a label without statements necessary or desirable for successful commercialization, or may result in requirements for costly post-marketing testing and surveillance, or other requirements, including REMS, to monitor the safety or efficacy of the products, and in turn prevent us from commercializing and generating revenues from the sale of our current product candidates and any future product candidates. Undesirable side effects may limit the potential market for any approved products or could result in the discontinuation of the sales and marketing of the product, or withdrawal of product approvals. 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.

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

As product candidates are developed through preclinical studies to later-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. Any of these changes could cause our current product candidates or any future product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. Such changes may also require additional testing, or notification to, or approval by the FDA or a comparable foreign regulatory authority. This could delay completion of clinical trials, require the conduct of bridging clinical trials or studies, require the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our current product candidates and any future product candidates and/or jeopardize our ability to commence product sales and generate revenue.

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

In the United States, the promotion of biopharmaceutical products 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, 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.

A Breakthrough Therapy designation by the FDA, even if granted for any of our current product candidates and any future product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our current product candidates and any future product candidates will receive marketing approval.

We may seek Breakthrough Therapy designation for our current and future product candidates. A breakthrough therapy is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Drugs designated as breakthrough therapies by the FDA may also be eligible for other expedited approval programs, including accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe our current product candidates and any future product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy designation for a product candidate may not result in a faster development process, review or approval compared to candidate products considered for approval under non-expedited FDA review procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our current product candidates and any future product candidates qualify as breakthrough therapies, the FDA may later decide that the product no longer meets the conditions for qualification. Thus, even though we intend to seek Breakthrough Therapy designation for some or all of our current and future product candidates for the treatment of various cancers, there can be no assurance that we will receive breakthrough therapy designation.

A Fast Track designation by the FDA, even if granted for any of our current or future product candidates, may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that our current product candidates and any future product candidates will receive marketing approval.

If a drug is intended for the treatment of a serious or life-threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA Fast Track designation for a particular indication. We may seek Fast Track designation for our current and future product candidates, but there is no assurance that the FDA will grant this status to any of our proposed product candidates. Marketing applications filed by sponsors of products in Fast Track development may qualify for priority review under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion whether or not to grant Fast Track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive Fast Track designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures, and receiving a Fast Track designation does not provide assurance of ultimate FDA approval. In addition, the FDA may withdraw Fast Track designation if it believes that the designation is no longer supported by data from our clinical development program. In addition, the FDA may withdraw any Fast Track designation at any time.

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

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

We may also submit marketing applications in other countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and/or receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our current product candidates or any future product candidates will be harmed.

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 U.S. 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.

Risks Related to Commercialization

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.

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.

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

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

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

We have no prior experience in the marketing, sale, and distribution of biopharmaceutical products, and there are significant risks involved in building and managing a commercial infrastructure. The establishment and development of commercial capabilities, including compliance plans, to market any products we may develop will be expensive and time consuming and could delay any product launch, and we may not be able to successfully develop this capability. We will have to compete with other biopharmaceutical and biotechnology companies, including oncology-focused companies, to recruit, hire, train, manage, and retain marketing and sales personnel, which is expensive and time consuming and could delay any product launch. Developing our sales capabilities may also divert resources and management attention away from product development.

In the event we are unable to develop a marketing and sales infrastructure, we may not be able to commercialize our current product candidates or any future product candidates in the United States or elsewhere, which could limit our ability to generate product revenues and materially harm our business, financial condition, results of operations, stock price and prospects. Factors that may inhibit our efforts to commercialize our current product candidates or any future product candidates include:

- the inability to recruit, train, manage, and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to physicians and educate adequate numbers of physicians on the benefits of prescribing our current product candidates or any future product candidates;
- our inability to effectively oversee a geographically dispersed sales and marketing team;
- the costs associated with training sales and marketing personnel on legal and regulatory compliance matters and monitoring their actions;
- an inability to secure adequate coverage and reimbursement by government and private health plans;
- the clinical indications for which the products are approved and the claims that we may make for the products;
- limitations or warnings, including distribution or use restrictions, contained in the products' approved labeling;
- any distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities or to which we agree as part of a mandatory REMS or voluntary risk management plan;
- liability for sales or marketing personnel who fail to comply with the applicable legal and regulatory requirements;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization or engaging a contract sales organization.

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

We have never commercialized a product candidate for any indication. Even if our current product candidates and any future product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors, and others in the medical community. If any product candidates for which we obtain regulatory approval do not gain an adequate level of market acceptance, we may not generate significant revenue and may not become profitable, or may be significantly delayed in achieving profitability. Market acceptance of our current product candidates and any future product candidates by the medical community, patients, and third-party payors will depend on a number of factors, some of which are beyond our control. For example, physicians are often reluctant to switch their patients and patients may be reluctant to switch from existing therapies even when new and potentially more effective or safer treatments enter the market. If public perception is influenced by claims that the use of cancer immunotherapies is unsafe, whether related to our immunomedicines or our competitors' products, our products may not be accepted by the general public or the medical community. Future adverse events in 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 products.

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

- the efficacy of our current product candidates and any future product candidates as a single agent and in combination with marketed checkpoint inhibitor immunotherapies;
- the commercial success of the checkpoint blockade drugs and biologics with which our products are co-administered;
- the prevalence and severity of adverse events associated with our current product candidates and any future product candidates or those products with which they are co-administered;

- the clinical indications for which the products are approved and the approved claims that we may make for the products;
- limitations or warnings contained in the product's FDA-approved labeling or those of comparable foreign regulatory authorities, including potential limitations or warnings for our current product candidates and any future product candidates that may be more restrictive than other competitive products;
- changes in the standard of care for the targeted indications for our current product candidates and any future product candidates, which could reduce the marketing impact of any claims that we could make following FDA approval or approval by comparable foreign regulatory authorities, if obtained;
- the relative convenience and ease of administration of our current product candidates and any future product candidates and any products with which they are co-administered;
- the cost of treatment compared with the economic and clinical benefit of alternative treatments or therapies;
- the availability of adequate coverage or reimbursement by third party payors, including government healthcare programs such as Medicare and Medicaid and other healthcare payors;
- the price concessions required by third-party payors to obtain coverage;
- the willingness of patients to pay out-of-pocket in the absence of adequate coverage and reimbursement;
- the extent and strength of our marketing and distribution of our current product candidates and any future product candidates;
- the safety, efficacy, and other potential advantages over, and availability of, alternative treatments already used or that may later be approved;
- distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities with respect to our current product candidates and any future product candidates or to which we agree as part of a REMS or voluntary risk management plan;
- the timing of market introduction of our current product candidates and any future product candidates, as well as competitive products;
- our ability to offer our current product candidates and any future product candidates for sale at competitive prices;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;
- the extent and strength of our third-party manufacturer and supplier support;
- the actions of companies that market any products with which our current product candidates and any future product candidates are co-administered;
- the approval of other new products;
- adverse publicity about our current product candidates and any future product candidates or any products with which they are co-administered, or favorable publicity about competitive products; and
- potential product liability claims.

The size of the potential 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 EOS-850, 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 EOS-850, 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 EOS-850, EOS-448, or any future product candidates.

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

reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product 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. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. 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.

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. 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 U.S. 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.

There remain judicial and Congressional challenges to certain aspects of the ACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. While Congress has not passed repeal legislation to date, the Tax Cuts and Jobs Act of 2017, or TCJA, repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a federal district court in Texas ruled the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the ACA are invalid as well. Additionally, on December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments, which are expected to occur in the fall of 2020. We will continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

Further, on January 20, 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On October 13, 2017, President Trump signed an Executive Order terminating the cost-sharing subsidies that reimburse insurers under the ACA. 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.

In addition, the 2020 federal spending package permanently eliminates, 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 eliminates 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, which was signed into law in March 2020 and is designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended the 2% Medicare sequester from May 1, 2020 through December 31, 2020. 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 U.S. Congressional inquiries and proposed federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump administration's budget for

fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. On March 10, 2020, the Trump administration sent “principles” for drug pricing to Congress, calling for legislation that would, among other things, cap Medicare Part D beneficiary out-of-pocket pharmacy expenses, provide an option to cap Medicare Part D beneficiary monthly out-of-pocket expenses, and place limits on pharmaceutical price increases. Additionally, the Trump administration previously released a “Blueprint” to lower drug prices and reduce out of pocket costs of drugs that contained proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of product candidates paid by consumers. HHS has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS’s policy change that was effective January 1, 2019.

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.

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

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for 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. For example, on April 18, 2020, CMS announced that QHP issuers under the ACA may suspend activities related to the collection and reporting of quality data that would have otherwise been reported between May and June 2020 given the challenges healthcare providers are facing responding to the COVID-19 virus.

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;
- the federal civil and federal false claims laws and civil monetary penalty laws, including the False Claims Act which can be enforced through civil whistleblower or qui tam actions, impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false of fraudulent claim for purposes of the False Claims Act;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal physician payment transparency requirements, sometimes referred to as the "Sunshine Act" under the ACA require certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program to report CMS information related to payments and other transfers of value to physicians, as defined by such law, and teaching hospitals and the ownership and investment interests of such physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and its implementing regulations, which also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws that may be broader in scope and apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug

manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures; state and local laws that require the registration of pharmaceutical sales representatives; and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Ensuring that our future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. We have entered into certain advisory board and consulting agreements with physicians, including some who are compensated in the form of stock or stock options who may influence the ordering or use of our product candidates, if approved, in the future. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations were to be found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, 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 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 U.S. 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 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 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 U.S. 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 U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the U.S. Congress, the U.S. courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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.

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.

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.

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 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.

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.

As a result, 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.

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 employee matters and managing growth

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

Public health pandemics or outbreaks could adversely impact our business. In December 2019, a novel strain of coronavirus (COVID-19) emerged in Wuhan, Hubei Province, China and has since spread to several other countries, including the United States and European countries, with infections and deaths reported globally. The continued spread of COVID-19 could adversely impact our manufacturing and other operations, including our ability to recruit and retain patients, principal investigators, clinical trial sites and their staff, caregivers and healthcare providers as necessary. The COVID-19 outbreak 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. While we do not anticipate any negative effects from remote monitoring, it could potentially affect quality, training and source data verification at clinical trial sites. Additionally, if a clinical trial site does not have remote monitoring capabilities, we may be required to find other distance monitoring solutions. Further, we are currently experiencing challenges with respect to climate-controlled shipping of our product candidates, which may delay our ability to dose patients in our ongoing trials. Any negative impact COVID-19 has to patient enrollment, retention or treatment could delay our clinical trial timelines and adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, particularly on our current projected timelines, increase our operating expenses and have a material adverse effect on our business and financial results. We remain in active dialog with our CROs and clinical sites to minimize the impact of this pandemic to our clinical trials of EOS-850 and EOS-448 without adversely impacting the safety of patients. Despite our best efforts, it may prove difficult to continue to treat patients in a timely manner and activation of new sites could be delayed, particularly for our clinical trial sites in areas with high rates of community spread.

In addition, COVID-19 has resulted in significant governmental measures being implemented to control the spread of the virus, including quarantines, travel restrictions and business shutdowns. As of the date hereof, we have taken temporary precautionary measures intended to help minimize the risk of the virus to our employees and their families, including temporarily requiring all non-laboratory employees and all non-essential employees for laboratory work to work remotely. We have suspended non-essential travel worldwide for our employees and are discouraging employee attendance at other gatherings. Further measures may be taken as the pandemic continues. These measures could negatively affect our business. For instance, temporarily requiring most employees to work remotely has required us to decrease pre-clinical laboratory work, which may delay and otherwise adversely impact our pre-clinical program development. Further, remote work may disrupt our operations or increase the risk of a cybersecurity incident. In addition, although our employees are accustomed to working remotely, changes in internal controls due to remote work arrangements could potentially result in control deficiencies in the preparation of our financial reports, which could be significant. COVID-19 has also caused volatility in the global financial markets and threatened a slowdown in the global economy, which may negatively affect our ability to raise additional capital on attractive terms or at all.

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

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

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

As of June 30, 2020, we had 46 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.

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 will commence enforcement actions against violators beginning July 1, 2020. The CCPA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states. By way of example regarding foreign laws and regulations with respect to data privacy and security, the GDPR went into effect in the 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 U.S. 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 U.S. 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 EOS-850 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 EOS-850 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 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.

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 will be subject to a transition period until December 31, 2020, or the Transition Period, during which European Union rules will continue to apply. Negotiations between the United Kingdom and the European Union are expected to continue in relation to the customs and trading relationship between the United Kingdom and the European Union following the expiry of the Transition Period.

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, as a result of the uncertainty surrounding Brexit, the EMA relocated to Amsterdam from London. Following the Transition Period, the United Kingdom will no longer be covered by the centralized procedures for obtaining European Union-wide marketing and manufacturing authorizations from the EMA and, unless a specific agreement is entered into, a separate process for authorization of drug products will be required in the United Kingdom, the potential process for which is currently unclear. 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.

U.S. federal income tax reform could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. 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 U.S. 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 U.S. net operating loss carryforwards and certain other U.S. 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. U.S. 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 U.S. 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, 2019, we had U.S. federal net operating loss carryforwards of $0.4 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 favourable Belgian tax legislation, our business, results of operations and financial condition may be adversely affected.

At December 31, 2019, we had cumulative carry forward tax losses of €42.5 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-850 and EOS-848. During the six months ended [June 30], 2020, we received €7.0 million under the EOS-850 grant and €1.8 million under the EOS-448 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.

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 U.S. 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.

The audit report relating to our 2019 financial statements is prepared by an auditor who is not inspected by the PCAOB, and, as such, you are deprived of the benefits of such inspection.

Auditors of companies that are registered with the SEC and traded publicly in the United States, including our auditors, must be registered with the United States Public Corporation Accounting Oversight Board, or PCAOB, and are required by the laws of the United States to undergo regular inspections by the PCAOB to assess their compliance with the laws of the United States and professional standards. Although our auditors are registered with the PCAOB, because our auditors are located in Belgium, a jurisdiction where the PCAOB is currently unable to conduct inspections without the approval of the Belgian authorities, our auditors are not currently inspected by the PCAOB. This lack of PCAOB inspections in Belgium currently prevents the PCAOB from regularly evaluating audits and quality control procedures of any auditors operating in Belgium, including our auditors. The inability of the PCAOB to conduct inspections of auditors in Belgium makes it more difficult to evaluate the effectiveness of our auditors' audit procedures or quality control procedures as compared to auditors outside of Belgium that are subject to PCAOB inspections. As a result, investors may be deprived of the benefits of PCAOB inspections.

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.

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 recently closed on July 28, 2020. Prior to our IPO, there was no public market for our common stock. Although we have completed our IPO and 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, including pursuant to our 2020 Plan, 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.

Pursuant to our 2020 Plan, our management is authorized to grant stock options to our employees, directors, and consultants.The aggregate number of shares of our common stock that may be issued pursuant to stock awards under the 2020 Plan is 3,809,818 shares. The number of shares of our common stock reserved for issuance under the 2020 Plan shall be cumulatively increased on January 1, 2021 and each January 1 thereafter by 5% of the total number of shares of our common stock outstanding on December 31 of the preceding calendar year or a lesser number of shares determined by our board of directors. Unless our board of directors elects not to increase the number of shares available for future grant each year, our stockholders may experience additional dilution, which could cause our stock price to fall.

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 45% of our outstanding voting stock as of July 28, 2020. 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 will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we will 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 will require, 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.

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

Our officers, directors and substantially all of our stockholders have agreed to be subject to a contractual lock-up with the underwriters for our IPO, which will expire on January 23, 2021. The lock-up agreements contain important exceptions that govern their applicability. J.P. Morgan Securities LLC, SVB Leerink LLC and Piper Sandler & Co., however, may, in their sole discretion, permit our officers, directors and other stockholders who are subject to these lock-up agreements to sell shares prior to the expiration of the lock-up agreements. If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lockup and other legal restrictions on resale lapse, the trading price of our common stock could decline. As of August 5, 2020, we had a total of 34,940,166 shares of common stock outstanding. Only the 12,091,675 shares of common stock sold in the IPO are freely tradable without restriction in the public market.

In addition, shares of common stock that are either subject to outstanding options or reserved for future issuance under our 2020 Plan will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock-up agreements and Rule 144 and Rule 701 under the Securities Act of 1933, as amended, or the Securities Act. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

The holders of shares of our common stock are entitled to rights with respect to the registration of their shares under the Securities Act, subject to the 180-day lock-up agreements described above. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

We 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 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 or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock may depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

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.

Special note regarding forward-looking statements

This prospectus, including the sections entitled "Prospectus summary," "Risk factors," "Management's discussion and analysis of financial condition and results of operations," and "Business," 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 prospectus include, but are not limited to, statements about:

- the timing, progress and the success of our clinical trials of EOS-850 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 EOS-850 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 EOS-850 and EOS-448 or any other product candidates we may develop;
- the outcomes of our preclinical studies;
- our ability to enroll patients in our clinical trials at the pace that we project;
- our ability to establish clinical programs moving forward in multiple indications by 2020, with a rapidly advancing portfolio and sustainable platform;
- our ability to establish and conduct our clinical programs on our expected timelines;
- the costs of development of any of our product candidates or clinical development programs;
- our expectation about the period of time over which our existing capital resources and the net proceeds from this offering 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 EOS-850 and EOS-448 and any other product candidates we may identify and pursue;
- the potential attributes and clinical benefits of the use of EOS-850 and EOS-448 or any other product candidate, if approved;
- our ability to successfully commercialize EOS-850 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;
- the rate and degree of market acceptance of EOS-850 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 expectations regarding government and third-party payor coverage and reimbursement;
- our ability to manufacture EOS-850 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 successfully build a specialty sales force and commercial infrastructure;
- 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 reliance on third parties to conduct our clinical trials;
- our reliance on third-party CMOs to manufacture and supply our product candidates for us;
- our ability to retain and recruit key personnel;
- our ability to obtain and maintain intellectual property protection for EOS-850 and EOS-448 or any other product candidates we may identify and pursue;
- our estimates of our expenses, ongoing losses, future revenue, capital requirements 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 and future clinical trials;
- 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 prospectus. 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 prospectus and the documents that we reference in this prospectus and have filed with the Securities and Exchange Commission as exhibits to the registration statement, of which this prospectus 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 prospectus represent our views as of the date of this prospectus. 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 prospectus.

This prospectus 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 prospectus, 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 prospectus.

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

During the period between April 1, 2020 and June 30, 2020, we issued to certain employees, directors and advisors, options to purchase an aggregate of 1,249,399 and 414,497 shares of our common stock at an exercise price of $4.24 and $6.16 per share, respectively. On April 27, 2020, we issued and sold to eight employees an aggregate of 131,867 shares of common stock upon the exercise of stock options under our 2019 Stock Option and Grant Plan at an exercise price of $1.56. We deemed the issuance of stock options and the common stock issuable upon exercise of such options to be exempt from registration under the Securities Act of 1933 (the "Securities Act") either in reliance on Rule 701 of the Securities Act as sales and offers under compensatory benefit plans and contracts relating to compensation in compliance with Rule 701, or in reliance on Section 4(a)(2), as transactions by an issuer not involving a public offering. All recipients either received adequate information about our company or had access, through employment or other relationships, to such information. No underwriters were involved in the foregoing issuances of securities.

Use of Proceeds from Initial Public Offering of Common Stock

On July 28, 2019, we closed our initial public offering of 10,586,316 shares of our common stock at a public offering price of $19.00 per share for an aggregate offering of $201.1 million. In addition, on August 5, 2020, we issued and sold an additional 1,505,359 shares of common stock pursuant to the underwriters' option to purchase additional shares for aggregate gross proceeds of $28.6 million.

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

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

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

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

Item 6. Exhibits.

Exhibit Number	Description
3.1	Second Amended and Restated Certificate of Incorporation of the Registrant (Incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-39401) filed with the Securities and Exchange Commission on July 28, 2020)
3.2	Amended and Restated Bylaws of the Registrant (Incorporated by reference to Exhibit 3.3 to the Registrant's Current Report on Form 8-K (File No. 001-39401) filed with the Securities and Exchange Commission on July 28, 2020)
4.1	Specimen Common Stock Certificate (Incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1/A (File No. 333-239415) filed with the Securities and Exchange Commission on July 20, 2020)
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*+	Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase 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: September 1, 2020

By: /s/ Michel Detheux

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

Date: September 1, 2020

By: /s/ Mathew Gall

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

Exhibit 31.1

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

I, Michel Detheux, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 2020 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: September 1, 2020

By: /s/ Michel Detheux
Michel Detheux
President, Chief Executive Officer and Director
(Principal Executive Officer)

Exhibit 31.2

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

I, Matthew Gall, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended June 30, 2020 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: September 1, 2020

By: /s/ Mathew Gall
Matthew Gall
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

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

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

(1) the Quarterly Report on Form 10-Q for the period ended June 30, 2020 (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: September 1, 2020

By: /s/ Michel Detheux
Michel Detheux
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: September 1, 2020

By: /s/ Mathew Gall
Matthew Gall
Chief Financial Officer
(Principal Financial Officer and
Principal Accounting Officer)