

**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 March 31, 2023

OR

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

For the transition period from _____ to _____

Commission File Number: 001-39401

iTeos Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

321 Arsenal St

Watertown, MA

(Address of principal executive offices)

84-3365066

(I.R.S. Employer
Identification No.)

02472

(Zip Code)

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, \$0.001 par value per share	ITOS	Nasdaq Global Market

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

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

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

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

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

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

As of May 5, 2023, the registrant had 35,763,742 shares of common stock, \$0.001 par value per share, outstanding.

Summary of the material risks associated with our business

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

- We must complete successful preclinical studies and clinical trials that demonstrate the safety and efficacy of the product candidates before we can begin the commercialization process.
- Challenges enrolling patients in our clinical trials delay and may prevent completion of clinical trials of our product candidates. Patient enrollment requires initiation of clinical trial sites; accordingly, delays in initiation of sites exacerbate enrollment challenges.
- We anticipate that our 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.
- 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 audit and verification procedures could result in material changes in the final data.
- We may not be able to file investigational new drug (IND) applications or IND amendments to commence additional clinical trials on the timelines indicated, and, even if we are able to file, the Federal Drug Administration, or FDA, or a comparable foreign regulatory authority may not permit us to proceed.
- We face significant competition from other biopharmaceutical and biotechnology companies, academic institutions, government agencies, and other research organizations, which may result in others discovering, developing, or commercializing products more quickly or marketing them more successfully than us. If their product candidates are shown to be safer or more effective than ours, our commercial opportunity may be reduced or eliminated.
- Negative developments in the field of immuno-oncology or in the field of TIGIT (as defined herein) or adenosine pathway therapeutics could damage public perception of our product candidates or negatively affect our business.
- 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.
- The regulatory approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time consuming and inherently unpredictable. If we experience delays in obtaining, required regulatory approvals, our ability to generate revenue may be materially impaired.
- We rely on third parties to conduct our clinical trials and perform some of our research and preclinical studies. Failure by these third parties to satisfactorily carry out their contractual duties or to meet expected deadlines may adversely impact our development programs, business and prospects.
- We may not realize the benefits of our collaborations, alliances or licensing arrangements, including our collaboration with GSK (as defined herein) for the global development of belrestotug (formerly EOS-448).
- 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.
- Our limited operating history may make it difficult for you to evaluate our business and assess our future viability.
- We will require additional financing to achieve our goals, and 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.
- 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 commercialize successfully our products may be adversely affected.

- 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 implement successfully our business strategy.
- The trading price of our common stock has been and may continue to be volatile.

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

Special note regarding forward-looking statements

This Quarterly Report on Form 10-Q, including the section entitled "Management's discussion and analysis of financial condition and results of operations" contains express or implied forward-looking statements. These statements relate to future events or 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 differ materially from any future results, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements in this Quarterly Report on Form 10-Q include, but are not limited to, statements about:

- the timing, progress and success of our clinical trials, 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 filings or approvals;
- 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 our product candidates;
- the outcomes of our preclinical studies;
- our ability to enroll patients in our clinical trials at the pace that we project;
- the costs of development of our product candidates or clinical development programs;
- the period of time over which our existing capital resources will be sufficient to fund our operating expenses and capital expenditures, and the degree to which such resources will enable us to fund our planned development of our product candidates;
- the potential attributes and clinical benefits of our product candidates;
- our ability to successfully establish or maintain collaborations or strategic relationships for our product candidates;
- the expected benefits of collaborations, including potential milestones and royalty payments from GSK pursuant to the GSK Collaboration Agreement (as defined herein);
- the rate and degree of market acceptance of our product candidates;
- our ability to obtain orphan drug or Breakthrough Therapy designation or other accelerated approval for any of our product candidates or any other product candidates that we may identify and pursue;
- our ability to manufacture our product candidates in conformity with the Food and Drug Administration's requirements and to scale up manufacturing of our product candidates to commercial scale, if approved;
- our ability to compete with companies currently producing or engaged in the clinical development of treatments for the disease indications that we pursue or treatment modalities that we develop;
- our reliance on third parties to conduct our clinical trials;

- our reliance on third-party contract manufacture organizations ("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 our product candidates;
- our estimates of our expenses, ongoing losses, future revenue, cash runway, capital requirements and our need for or ability to obtain additional financing;
- our expectations regarding the time during which we will be an emerging growth company under the Jumpstart Our Business Startups Act, or JOBS Act;
- our future 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 preclinical and clinical trials;
- the impact of laws and regulations applicable to our industry; 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 negatives of these terms or other comparable terminology, although not all forward-looking statements contain such identifying terminology. 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 our results and financial condition. Factors that may cause actual results to differ materially include, among other things, those listed under the section titled "Risk factors" in this Quarterly Report on Form 10-Q and in our Annual Report on Form 10-K for the year ended December 31, 2022, and in any subsequent filings with the SEC. These risks and uncertainties may result in actual events or results varying significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance. You should read this Quarterly Report on Form 10-Q and the documents that we reference in this Quarterly Report on Form 10-Q and have filed with the SEC and exhibits to this Quarterly Report on Form 10-Q, 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. Statements regarding our cash runway do not indicate when we may access the capital markets.

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. These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q.

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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)	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 225,361	\$ 284,803
Short-term investments (amortized cost of \$376,908)	376,776	328,359
Grants receivable	433	1,001
Refundable income taxes	235	1,434
Prepaid expenses and other current assets	12,596	12,701
Total current assets	615,401	628,298
Property and equipment, net	2,119	2,121
Long-term investments (amortized cost of \$104,250)	104,484	118,225
Research and development tax credits receivable, net of current portion	1,176	1,128
Restricted cash	235	235
Right of use assets	4,602	4,652
Other assets	329	332
Total assets	<u>\$ 728,346</u>	<u>\$ 754,991</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 5,694	\$ 7,662
Accrued expenses and other current liabilities	17,727	19,727
Deferred income	2,073	1,180
Deferred revenue	-	12,595
Lease liabilities	864	836
Total current liabilities	26,358	42,000
Grants repayable, net of current portion	6,765	6,622
Lease liabilities, net of current portion	3,761	3,837
Unrecognized tax benefits	39,200	39,200
Total liabilities	<u>76,084</u>	<u>91,659</u>
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Common stock, \$0.001 par value: 150,000,000 shares authorized at March 31, 2023 and December 31, 2022 respectively; 35,760,627 and 35,611,219 shares issued and outstanding; respectively	36	36
Additional paid-in capital	442,050	435,665
Accumulated other comprehensive loss	(11,548)	(9,644)
Retained earnings	221,724	237,275
Total stockholders' equity	652,262	663,332
Total liabilities and stockholders' equity	<u>\$ 728,346</u>	<u>\$ 754,991</u>

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

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

(in thousands, except share and per share amounts)	Three Months Ended March 31,	
	2023	2022
Revenue:		
License and collaboration revenue	\$ 12,595	\$ 152,522
Total revenue	12,595	152,522
Operating expenses:		
Research and development expenses	25,598	21,096
General and administrative expenses	11,927	10,615
Total operating expenses	37,525	31,711
(Loss) income from operations	(24,930)	120,811
Other income and expenses:		
Grant income	735	491
Research and development tax credits	343	254
Interest income	7,851	92
Other income (expense), net	1,649	(2,115)
(Loss) Income before income taxes	(14,352)	119,533
Income tax expense	(1,199)	(49,951)
Net (loss) income	\$ (15,551)	\$ 69,582
Basic net (loss) income per common share	\$ (0.44)	\$ 1.96
Diluted net (loss) income per common share	\$ (0.44)	\$ 1.82
Weighted-average common shares outstanding - basic	35,716,037	35,493,272
Weighted-average common shares outstanding - diluted	35,716,037	38,135,957
Net (loss) income	\$ (15,551)	\$ 69,582
Foreign currency translation adjustments	(2,006)	(550)
Unrealized gain on available-for-sale securities	102	
Comprehensive (loss) income	\$ (17,455)	\$ 69,032

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

iTeos Therapeutics, Inc. and subsidiaries
Condensed consolidated statements of stockholders' equity
(unaudited)

In thousands except share amounts	Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Retained earnings	Total stockholders' equity
	Shares	Amount				
	Balance at December 31, 2021	35,466,001				
Stock-based compensation	—	—	4,193	—	—	4,193
Common stock issued upon exercises of options	50,911	1	332	—	—	333
Currency translation adjustment	—	—	—	(550)	—	(550)
Net income	—	—	—	—	69,582	69,582
Balance at March 31, 2022	35,516,912	\$ 36	\$ 417,705	\$ (1,568)	\$ 210,205	\$ 626,378

In thousands except share amounts	Common stock		Additional paid-in capital	Accumulated other comprehensive loss	Retained earnings	Total stockholders' equity
	Shares	Amount				
	Balance at December 31, 2022	35,611,219				
Stock-based compensation	—	—	5,807	—	—	5,807
Common stock issued upon exercises of options	149,408	—	578	—	—	578
Currency translation adjustment	—	—	—	(2,006)	—	(2,006)
Unrealized loss on available-for-sale securities	—	—	—	102	—	102
Net loss	—	—	—	—	(15,551)	(15,551)
Balance at March 31, 2023	35,760,627	\$ 36	\$ 442,050	\$ (11,548)	\$ 221,724	\$ 652,262

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)	Three Months Ended March 31,	
	2023	2022
Cash flows from operating activities		
Net (loss) income	\$ (15,551)	\$ 69,582
Adjustments to reconcile net (loss) income to net cash used in operating activities:		
Depreciation and amortization	222	180
Stock-based compensation	5,807	4,193
Non-cash: Net accretion of available-for-sale debt securities	(2,852)	-
Change in operating lease right-of-use assets	2	2
Changes in operating assets and liabilities:		
Grants receivable	579	(684)
Research and development tax credits receivable	(25)	889
Refundable income taxes	1,199	7,544
Prepaid expenses and other current assets	230	1,810
Accounts payable	(2,104)	5,465
Accrued expenses and other liabilities	(2,325)	(3,062)
Income tax payable	-	20,107
Deferred income	858	194
Deferred revenue	(12,595)	(152,522)
Unrecognized tax benefits	-	22,300
Net cash used in operating activities	(26,555)	(24,002)
Cash flows from investing activities		
Purchases of investments	(52,575)	-
Proceeds from maturities of investments	21,000	-
Purchase of property and equipment	(119)	(227)
Purchase of other assets	-	(96)
Net cash used in investing activities	(31,694)	(323)
Cash flows from financing activities		
Proceeds from issuance of common stock upon exercise of options	578	333
Net cash provided by financing activities	578	333
Effects of exchange rate changes on cash, cash equivalents and restricted cash	(1,771)	(563)
Net decrease in cash, cash equivalents and restricted cash	(59,442)	(24,555)
Cash, cash equivalents and restricted cash at beginning of period	285,038	848,835
Cash, cash equivalents and restricted cash at end of period	\$ 225,596	\$ 824,280
Non-cash investing and financing activities		
Capital expenditure included in accounts payable	\$ 88	\$ 184
Operating lease liabilities arising from obtaining right-of-use assets	79	199
Unrealized gain on available-for-sale securities	102	-
Supplemental disclosure of cash flows		
Cash paid for taxes	-	-

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

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

Note 1. Nature of business and basis of presentation

Description of business

iTeos Therapeutics, Inc. (iTeos" or the Company), a Delaware corporation (incorporated on October 4, 2019) headquartered in Watertown, Massachusetts, is the successor to iTeos Belgium SA (iTeos Belgium) a company organized under the laws of Belgium in 2011 and headquartered in Charleroi, Belgium. The Company is a clinical stage biopharmaceutical company pioneering the discovery and development of a new generation of immuno-oncology therapeutics for people living with cancer. The Company leverages its deep understanding of the tumor immunology and immunosuppressive pathways to design novel product candidates with the aim of restoring the immune response against cancer. The Company's innovative pipeline includes two clinical-stage programs targeting novel, validated immuno-oncology pathways. Each of the Company's therapies in development has optimized pharmacologic properties designed to improve clinical outcomes.

The Company's lead antibody product candidate, belrestotug (formerly EOS-448), also known as GSK4428859A, is an antagonist of TIGIT, or T-cell immunoreceptor with Ig and ITIM domains, an immune checkpoint with multiple mechanisms of action.

On June 11, 2021, the Company's wholly owned subsidiary, iTeos Belgium S.A., and GlaxoSmithKline Intellectual Property (No. 4) Limited, or GSK, executed a Collaboration and License Agreement, or the GSK Collaboration Agreement, which became effective on July 26, 2021. Pursuant to the GSK Collaboration Agreement, the Company agreed to grant GSK a license under certain of its intellectual property rights to develop, manufacture, and commercialize products comprised of or containing belrestotug, which license is exclusive in all countries outside of the United States and co-exclusive, with iTeos, in the United States. GSK and iTeos develop belrestotug in combination with other oncology assets, including assets of GSK, and iTeos and GSK jointly own the intellectual property created under the GSK Collaboration Agreement that covers such combinations.

The Company also is advancing inupadenant, a next-generation adenosine A_{2A}R receptor antagonist tailored to overcome the specific adenosine-mediated immunosuppression found in tumor microenvironment, into proof-of concept trials in several indications following encouraging single-agent activity in Phase 1.

The Company continues to progress research programs focused on additional targets that complement its TIGIT and A_{2A}R programs or address additional immunosuppressive pathways. EOS-984 is a clinical development program that targets a novel mechanism in the adenosine pathway. The Company completed Investigational New Drug Application-enabling activities, including toxicity studies, and anticipates initiating clinical studies for EOS-984 in mid-2023.

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

Liquidity and capital resources

Since inception, the Company's activities have consisted primarily of performing research and development to advance its product candidates. The Company earned income during 2022, which equaled net income of \$96.7 million for the year ended December 31, 2022. The Company had a net loss of \$15.6 million for the three months ended March 31, 2023. As of March 31, 2023, the Company had retained earnings of \$221.7 million. As of May 10, 2023, the issuance date of the condensed consolidated financial statements for the period ended March 31, 2023, the Company expects that its cash and cash equivalents would be sufficient to fund its operating expenses, capital expenditure requirements and debt service payments for at least 12 months.

The Company may seek additional funding in order to reach its development and commercialization objectives. The Company may not be able to obtain funding on acceptable terms, or at all, and the Company may not be able to enter into additional collaborations or other arrangements that add cash or defray expenses. The terms of any funding may adversely affect the holdings or the rights of the Company's stockholders. If the Company is unable to obtain funding, the Company could be forced to delay, reduce or eliminate some or all of its research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects.

The Company's future results of operations involve a number of risks and uncertainties. Factors that could affect the Company's future operating results and adversely impact actual results include, but are not limited to, uncertainty regarding results of clinical trials and reaching milestones, uncertainty of regulatory approval of the Company's current or

future product candidates, uncertainty of market acceptance of the Company's product candidates, if approved, competition from substitute products and larger companies, securing and protecting proprietary technology, strategic relationships and dependence on key individuals and sole source suppliers. Product candidates currently under development will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities and may not ultimately lead to a marketing approval and commercialization of a product.

The Company's product candidates require approvals from the U.S. Food and Drug Administration ("FDA") and comparable foreign regulatory agencies prior to commercial sales in their respective jurisdictions. The Company's product candidates may fail to receive the necessary approvals. If the Company is denied approval, approval is delayed or the Company is unable to maintain approval for any product candidate, it could have a materially adverse impact on the Company. Even if the Company's product development efforts are successful, the Company may never generate significant revenue from product sales. The Company will need to generate significant revenue to achieve sustained profitability, and it may never do so.

Global Economic Conditions

Disruptions to the global economy and disruption of global healthcare systems impact the Company's business, financial condition, results of operations and growth prospects. The COVID-19 pandemic, for example, has presented a substantial public health and economic challenge around the world. While the COVID-19 pandemic has not significantly impacted the Company's business or results of operations, the future challenges of the COVID-19 pandemic on the Company's business and operations are uncertain. See "Risk factors" for a discussion of the potential adverse impact of global economic conditions and of COVID-19 on our business, results of operations and financial condition.

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, 2022 and 2021, and the notes thereto, which are included in the Company's Annual Report on Form 10-K (File No. 001-39401). The results for any interim period are not necessarily indicative of results for any future period.

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

Note 2. Summary of significant accounting policies

The Company's significant accounting policies are disclosed in the audited consolidated financial statements for the year ended December 31, 2022, and notes thereto, which are included in the Company's Annual Report on Form 10-K that was filed with the SEC on March 15, 2023. Since the date of those financial statements, there have been no material changes to significant accounting policies.

Accounting standards recently adopted

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. The Company adopted this standard as of January 1, 2023. The adoption of this standard did not have a material impact on the Company's consolidated financial position and results of operations.

Note 3. Investment securities and fair value measurements

The following tables set forth the Company's financial instruments that were measured at fair value on a recurring basis by level within the fair value hierarchy as of March 31, 2023 and December 31, 2022:

March 31, 2023				
(in thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents (money market funds)	\$ 188,348	\$ -	\$ -	\$ 188,348
U.S. government agency bonds	-	285,935	-	285,935
U.S. treasury bonds	174,968	-	-	174,968
Corporate debt securities	-	20,357	-	20,357
Totals	<u>\$ 363,316</u>	<u>\$ 306,292</u>	<u>\$ -</u>	<u>\$ 669,608</u>

December 31, 2022				
(in thousands)	Level 1	Level 2	Level 3	Total
Cash equivalents (money market funds)	\$ 92,850	\$ -	\$ -	\$ 92,850
U.S. government agency bonds	-	267,748	-	267,748
U.S. treasury bonds	186,477	-	-	186,477
Corporate debt securities	-	5,349	-	5,349
Totals	<u>\$ 279,327</u>	<u>\$ 273,097</u>	<u>\$ -</u>	<u>\$ 552,424</u>

Cash equivalents consist of money market funds, which are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices in an active market. U.S. treasury securities are also classified as Level 1 because they are valued using quoted prices. U.S. government agency and corporate securities are classified within Level 2 of the fair value hierarchy because they are valued using market-based models that consider inputs such as yield, prices of comparable securities, coupon rate, maturity, and credit quality.

During the periods presented, the Company has not changed the manner in which it values assets and liabilities that are measured at fair value. The Company recognizes transfers between levels of the fair value hierarchy as of the end of the reporting period. There were no transfers within the hierarchy during the three months ended March 31, 2023 and 2022.

The Company's fixed income securities held as of March 31, 2023 and December 31, 2022 are classified as available-for-sale. The following table presents the amortized cost, fair value, and unrealized losses by major security type, for the fixed income securities held by the Company:

March 31, 2023				
(in thousands)	Amortized cost	Gross unrealized gains in AOCI	Gross unrealized losses in AOCI	Fair value
U.S. government agency bonds	\$ 285,864	\$ 229	\$ (158)	\$ 285,935
U.S. treasury bonds	174,966	44	(42)	174,968
Corporate debt securities	20,328	29	-	20,357
Totals	<u>\$ 481,158</u>	<u>\$ 302</u>	<u>\$ (200)</u>	<u>\$ 481,260</u>

December 31, 2022				
(in thousands)	Amortized cost	Gross unrealized gains in AOCI	Gross unrealized losses in AOCI	Fair value
U.S. government agency bonds	\$ 254,881	\$ 87	\$ (211)	\$ 254,757
U.S. treasury bonds	186,496	19	(37)	186,478
Corporate debt securities	5,358	-	(9)	5,349
Totals	<u>\$ 446,735</u>	<u>\$ 106</u>	<u>\$ (257)</u>	<u>\$ 446,584</u>

The following table presents the amortized cost and fair value of the Company's fixed income securities by maturity grouping:

(in thousands)	March 31, 2023	
	Amortized cost	Fair value
Due in one year or less	\$ 376,908	\$ 376,776
Due after one year through five years	104,250	104,484
Due after five years through ten years	-	—
Due after ten years	-	—
Total	\$ 481,158	\$ 481,260

(in thousands)	December 31, 2022	
	Amortized cost	Fair value
Due in one year or less	\$ 328,405	\$ 328,359
Due after one year through five years	118,330	118,225
Due after five years through ten years	-	—
Due after ten years	-	—
Total	\$ 446,735	\$ 446,584

There were no securities which were determined to be other-than-temporarily impaired as of March 31, 2023 and December 31, 2022. There were no sales of securities which resulted in a realized loss during the three months ended March 31, 2023. The Company recognized \$5.0 million of interest income earned from its available-for-sale debt securities and money market funds during the three months ended March 31, 2023. The Company also recognized \$2.9 million of accretion on its available-for-sale debt securities, which was recorded to interest income, during the three months ended March 31, 2023.

Note 4. Supplemental balance sheet information

Property and equipment

Property and equipment, net consisted of the following:

(in thousands)	March 31, 2023	December 31, 2022
Scientific equipment	\$ 3,162	\$ 3,008
Furniture & office equipment	1,393	1,332
Leasehold improvements	1,293	1,238
Total	5,848	5,578
Accumulated depreciation and amortization	(3,729)	(3,457)
Property & equipment, net	<u>\$ 2,119</u>	<u>\$ 2,121</u>

Depreciation and amortization expense was \$0.2 million for each of the three months ended March 31, 2023 and 2022.

Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of the following:

(in thousands)	March 31, 2023	December 31, 2022
Accrued clinical trial costs	\$ 13,230	\$ 13,496
Accrued personnel costs	3,573	5,635
Accrued professional fees	60	64
Accrued other	864	532
Total accrued expenses and other current liabilities	<u>\$ 17,727</u>	<u>\$ 19,727</u>

Note 5. License and collaboration agreements

Adimab

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

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

In February 2021, the Company entered into an amendment to the Adimab Agreement (the "Amended Adimab Agreement"). The Amended Adimab Agreement specifies different milestone payments for new products that are derived from research programs beginning after February 22, 2021 (the "New Products"). For New Products, on a per target basis, the Company may be required to pay development, regulatory and commercial milestone payments totaling up to an aggregate of \$45.8 million for the first three products and additional milestone payments up to \$14.5 million for each additional product.

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.

Through March 31, 2023, the Company has paid a total of \$5.4 million to Adimab relating to milestones under the Adimab Agreement. The Company did not make any additional payments to Adimab in the three months ended March 31, 2023 as no milestones were achieved in the quarter. As of the date of these condensed consolidated financial statements, the Company has not pursued any additional targets under the Adimab agreement that could potentially result in such milestone payments.

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

The term of the Adimab Agreement will continue until the last to expire royalty term on a product-by-product and country-by-country basis if the Company exercises its option, or in the event no option is exercised, the conclusion of the last-to-expire evaluation term, unless terminated earlier by either party. Each party has the right to terminate the Adimab Agreement due to the other party's uncured material breach or the Company's abandonment of the product.

GlaxoSmithKline ("GSK")

Summary of Agreement

On June 11, 2021, the Company's wholly owned subsidiary, iTeos Belgium S.A., and GSK executed a Collaboration and License Agreement (the "GSK Collaboration Agreement"), pursuant to which the Company agreed to grant GSK a license under certain of the Company's intellectual property rights to develop, manufacture, and commercialize products comprised of or containing the Company's antibody product, belrestotug. Under the GSK Collaboration Agreement, GSK agreed to make an upfront nonrefundable payment of \$625.0 million to the Company within 10 business days of the date on which the GSK Collaboration Agreement became effective, which occurred on July 26, 2021. Additionally, the Company is eligible to receive up to \$1.45 billion in milestone payments, contingent upon the belrestotug program achieving certain development and commercial milestones. Within the collaboration, GSK and the Company agree to share responsibility and costs for the global development of belrestotug beyond the Phase 1 study (the "Global Development Plan") and will jointly commercialize and equally split profits in the United States. Outside of the United States, GSK will receive an exclusive license for commercialization, and the Company is eligible to receive tiered double digit royalty payments up to 20% during a customary royalty term.

Collaboration

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

The Company determined that the co-development in Phases 2 and 3 and the co-commercialization efforts of the GSK Collaboration Agreement represent joint operating activities in which both parties are active participants and of which both parties are exposed to significant risks and rewards that are dependent on the success of the activities. Accordingly, the Company is accounting for these activities in accordance with ASC No. 808, *Collaborative Arrangements* (ASC 808). Additionally, the Company has determined that in the context of these activities, GSK does not represent a customer as contemplated by ASC 606-10-15, *Revenue from Contracts with Customers – Scope and Scope Exceptions*. As a result, these activities are accounted for as a component of the related expense in the period incurred in accordance with ASC 730, *Research and Development*. Additionally, reimbursements received from GSK in connection with the joint operating activities are recognized as a reduction to research and development expense.

GSK is responsible for 60% of the costs related to the Global Development Plan. During the three months ended March 31, 2023, the Company recorded to research and development expense approximately \$8.3 million related to the cost-sharing provisions of the GSK Collaboration Agreement. \$5.0 million of these costs are payable to GSK, which is recorded in accrued expenses and other current liabilities in the condensed consolidated balance sheet as of March 31, 2023. The Company and GSK have collectively agreed to spend an aggregate of \$900.0 million on the Global Development Plan.

Revenue Recognition

The Company also evaluated the elements of the GSK Collaboration Agreement in accordance with the provisions of ASC 606 and concluded that the contract counterparty, GSK, is a customer. The Company's arrangement with GSK contains the following material promises under the contract at inception: (i) transfer of the license under certain of the Company's intellectual property related to belrestotug, (ii) completion of the Phase 1 clinical study related to belrestotug, (iii) transfer of "Know How" under the belrestotug intellectual property, and (iv) manufacturing until the "Know How" transfer is complete. The Company evaluated the above material promises under ASC 606 and determined that it has one combined performance obligation. These promises are considered to be outputs of the Company's ordinary activities and ongoing major operations. As GSK provided the Company consideration in exchange for these promises, GSK meets the definition of a customer under ASC 606-10-20 in the context of the combined performance obligation. These promises are distinct from the co-development and co-commercialization activities in which the Company and GSK jointly participate. Accordingly, the context in which GSK is a customer is limited to the material promises described above.

The transaction price totaling \$625.0 million was comprised of the upfront license payment. As of March 31, 2023, no development or regulatory milestones have been assessed as probable of being reached and thus have been fully constrained. As part of its evaluation of the constraint, the Company considered numerous factors, including that receipt of the milestones is outside the control of the Company and contingent upon success in future clinical trials and the licensee's efforts. Any consideration related to sales-based milestones will be recognized when the related sales occur as they were determined to relate predominantly to the license granted to GSK and therefore have also been excluded from the transaction price. The Company is applying the royalty exception for sales-based royalties and will not recognize revenue until the subsequent sale of product occurs.

The transaction price is being recognized as revenue over time as the costs to complete the Phase 1 study, perform interim clinical supply manufacturing, and perform the know-how transfer are incurred. The performance obligation was fully completed in the three months ended March 31, 2023. Revenue is recognized using a percent complete method based on costs incurred compared with the total expected costs to be incurred (cost to cost measure of progress). There are no outputs from the performance obligation. As a result, an input method was appropriate. A cost-to-cost measure of progress provides a faithful depiction of the transfer of services to the customer since the predominant inputs to the performance obligation are labor costs, research and development supplies and manufacturing supplies related to the Phase 1 Study, clinical manufacturing and know-how transfer.

During the three months ended March 31, 2023, the Company recognized revenue totaling approximately \$12.6 million with respect to the GSK Collaboration Agreement. The revenue is classified as license and collaboration revenue in the accompanying condensed consolidated statements of operations. There was no deferred revenue remaining as of

March 31, 2023, and there was approximately \$12.6 million of deferred revenue as of December 31, 2022. The deferred revenue related to the GSK Collaboration Agreement, of which all was classified as current deferred revenue in the accompanying condensed consolidated balance sheet based on the performance period of the underlying obligations.

Contract Costs

The Company incurred approximately \$6.8 million of capitalizable costs to obtain the contract. The Company utilized the practical expedient in ASC 340 and recognized such costs immediately in 2021 as the Company expected to complete its performance obligations under the GSK Collaboration Agreement in less than 12 months.

Contract Assets and Liabilities

The following table presents changes in the Company's GSK contract assets and liabilities during the three months ended March 31, 2023:

Three Months Ended March 31, 2023		—			—		
<u>(in thousands)</u>		Balance at Beginning of Period	Additions	Deductions	Balance at End of Period		
Contract Liabilities:							
Deferred Revenue	\$	12,595	\$	—	\$ (12,595)	\$	—

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 sponsors a clinical trial in which both the Company's compound and MSD's compound are dosed in combination. The Company conducts the research at its own cost and MSD contributes its compound towards the study at no cost to the Company. The parties equally own the clinical data and inventions from the study, with the exception of inventions relating solely to each party's compound class. The MSD Agreement will expire upon the delivery of a written report on the results of the study, unless earlier terminated or agreed by the parties.

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

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

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

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

Grants which do not include an obligation to repay

The total amount that the Granting Agencies have agreed to fund in the future if the Company incurs qualifying research and development expenses under these grants is \$6.4 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 \$19.6 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 \$4.5 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 ended in December 2021. The Company decided it would pursue commercialization or out licensing of RCA-1. The Company negotiated an extension on the research period for RCA-2 with the Walloon Region. The original research period for RCA-2 ended February 2021 and was extended to March 2022. The Company must repay 30% of the amount received under the grant by annual installments from 2023 to 2042 (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 0.15% royalty on revenue resulting from RCA-2 (increased from 0.12% effective December 2021). The maximum amount payable to the Walloon Region under each grant, including the fixed annual repayments, the royalty on revenue, and the interest thereon, is twice the amount of funding received.

The Company assessed whether there is an obligation to make a royalty payment based on the probability of successful completion of the research and development and future sales and commercial success of the drug candidate. For the RCA-1, there was no grant repayable related to royalties recorded as of March 31, 2023, or December 31, 2022. For the RCA-2, the Company recorded a royalty accrual of \$0.9 million as of March 31, 2023, and \$0.8 million as of December 31, 2022, due to the upfront payment from the GSK Collaboration Agreement. The royalty accrual is included in the accrued expenses and other current liabilities in the condensed consolidated balance sheets.

The Company recorded grant income in the condensed consolidated statement of operations and comprehensive income (loss) for the three months ended March 31, 2023 and 2022 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 months ended March 31, 2023 and 2022 and end of period balances as of March 31, 2023, and December 31, 2022:

(In thousands)	RCA -1		RCA-2		Other Grants		Total	
	2023	2022	2023	2022	2023	2022	2023	2022
Cash received	\$ —	\$ —	\$ —	\$ —	\$ 2,011	\$ —	\$ 2,011	\$ —
Grant income	\$ —	\$ —	\$ —	\$ 485	\$ 735	\$ 6	\$ 735	\$ 491
Grants receivable at the end of the period	\$ —	\$ 5	\$ —	\$ —	\$ 433	\$ 996	\$ 433	\$ 1,001
Grants repayable at the end of the period	\$ 5,789	\$ 5,665	\$ 1,338	\$ 1,312	\$ —	\$ —	\$ 7,127	\$ 6,977

As of March 31, 2023 and December 31, 2022, \$0.4 million of the grants repayable was included in accrued expenses and other current liabilities and the remaining balance was included in the grants repayable, net of current portion in the condensed consolidated balance sheet.

Note 7. Stockholders' equity

The Company's restated Certificate of Incorporation authorizes the Company to issue up to 160,000,000 shares, of which (i) 150,000,000 shares are designated as common stock, par value \$0.001 per share, and (ii) 10,000,000 shares are designated as undesignated preferred stock, par value \$0.001 per share. Each share of common stock entitles the holders to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are not entitled to receive dividends, unless declared by the board of directors.

Note 8. Stock-based compensation

General

The board of directors, at its sole discretion, shall determine the exercise price. Stock options expire 7 to 10 years from the date of grant. The stock options generally vest 25% upon the one-year anniversary of the service inception date and then ratably each month over the remaining 36 months. Upon termination of service, any unvested stock options are automatically returned to Company. Vested stock options that are not exercised within the specified period, according to the terms and conditions of the option plan, following the termination as an employee, consultant, or service provider to the Company are surrendered back to the Company. Those stock options are added back to the pool and made available for future grants.

2019 Stock Option and Grant Plan

The Company's 2019 Stock Option and Grant Plan (the "2019 Plan") provided for the Company to grant stock options and other stock-based awards to employees and non-employees to purchase the Company's common stock. Total authorized options under the 2019 Stock Option and Grant Plan is 3,464,316. The 2020 Plan (as defined below) replaced the 2019 Plan and no further issuances will be made under the 2019 Plan. However, the 2019 Plan continues to govern outstanding equity awards granted thereunder.

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

2020 Stock Option and Incentive Plan

The 2020 Stock Option and Incentive Plan (the "2020 Plan") was approved by the board of directors on July 15, 2020, and the Company's stockholders on July 20, 2020 and became effective on July 22, 2020. On April 21, 2022, our board of directors adopted an amendment to the 2020 Plan, the amended and restated 2020 Stock Option and Incentive Plan (the "Amended 2020 Plan") to increase the limit on total annual compensation (equity and cash) to non-employee directors. The Amended 2020 Plan was approved by the Company's stockholders and became effective on June 9, 2022. The Amended 2020 Plan provides for the grant of incentive stock options, non-qualified stock options, stock appreciation rights, restricted stock units, restricted stock awards, unrestricted stock awards, cash-based awards and dividend equivalent rights to the Company's officers, employees, directors and consultants. The number of shares of common stock reserved for issuance as of December 31, 2022 under the Amended 2020 Plan was 7,335,355 and will be increased each January 1 by 5% of the number of shares of the Company's common stock outstanding on the immediately preceding December 31 or such lesser number of shares as determined by the Company's compensation committee of the board of directors. Accordingly, on January 1, 2023, the number of shares of common stock reserved and available for issuance under the Amended 2020 Plan increased by 1,780,560. The number of shares of common stock reserved for issuance as of March 31, 2023 under the Amended 2020 Plan was 9,115,915.

Employee Stock Purchase Plan

The 2020 Employee Stock Purchase Plan (the "2020 ESPP") was approved by the board of directors on July 15, 2020, and the Company's stockholders on July 20, 2020, and became effective on July 22, 2020. The number of shares of common stock reserved for issuance as of March 31, 2023 under the 2020 ESPP was 650,191. The ESPP provides that the number of shares reserved and available for issuance will automatically increase each January 1 thereafter by the lesser of 634,969 shares of common stock, 1% of the outstanding number of shares of common stock on the immediately preceding December 31, or such lesser number of shares as determined by the Company's compensation committee. There was no increase to the number of shares of common stock reserved and available for issuance under the 2020 ESPP on January 1, 2023. No shares were issued under the 2020 ESPP during the quarter ended March 31, 2023. The purchase price of the stock is equal to 85% of the lesser of the market value of such shares at either first date of the offering period or the last date of the offering period. The estimated fair value of the purchase options for the offering period open during the quarter ended March 31, 2023 was \$7.65 per share. The assumptions utilized to estimate the fair value are include in the assumption table below.

Stock-Based Compensation Expense

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

(in thousands)	Three Months Ended March 31,	
	2023	2022
Research and development	\$ 1,148	\$ 608
General and administrative	4,659	3,585
Total stock-based compensation expense	\$ 5,807	\$ 4,193

Of the \$5.8 million of stock-based compensation expense recognized during the three months ended March 31, 2023, \$5.6 million related to stock options, \$0.1 million related to restricted stock units, and \$0.1 million related to ESPP.

Stock Options

The following table summarizes stock option activity for the three months ended March 31, 2023:

	Stock Options			
	Shares	Weighted average exercise price	Weighted average remaining contractual life (in years)	Aggregate intrinsic value (in thousands)
Outstanding as of December 31, 2022	6,401,987	\$ 18.50	7.1	
Granted	1,004,800	16.74		
Forfeited	(45,646)	29.04		
Exercised	(149,408)	3.87		
Outstanding as of March 31, 2023	7,211,733	\$ 18.49	7.4	\$ 22,865
Exercisable at March 31, 2023	3,678,442	\$ 14.84	6.3	\$ 17,959

The weighted-average grant-date fair value of options awarded during the three months ended March 31, 2023 and 2022 was approximately \$12.86 per share and \$26.54 per share, respectively. As of March 31, 2023, there was a total of \$55.4 million of unrecognized employee compensation costs related to non-vested stock option awards expected to be recognized over a weighted average period of 2.6 years.

The Company estimates the fair value of stock-based compensation utilizing the Black-Scholes option pricing model, which is dependent upon several variables, such as expected term, volatility, risk-free interest rate, and expected dividends. Each of these inputs is subjective and generally requires significant judgment to determine.

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

	Quarter Ended March 31,	
	2023	2022
Stock Options:		
Risk-free interest rate	3.46% - 4.22%	1.37% - 1.96%
Expected term (in years)	6	6
Expected volatility	91% - 93%	86% - 91%
Expected dividend yield	0%	0%
Estimated fair value of common stock	\$16.66 - \$21.15	\$36.13 - \$46.56
ESPP Awards:		
Risk-free interest rate	1.63%	-
Expected term (in years)	0.5	-
Expected volatility	77%	-
Expected dividend yield	0%	-
Estimated fair value of common stock	\$20.92	-

Restricted Stock Units

The Company issued restricted stock units in the quarter ended March 31, 2023, which vest over a two-year period. The following table summarizes the Company's restricted stock unit activity:

	Shares	Weighted average grant date fair value
Unvested as of December 31, 2022	10,000	\$ 35.86
Issued	83,500	20.08
Vested	(2,500)	35.86
Cancelled	—	—
Unvested as of March 31, 2023	91,000	\$ 21.38

As of March 31, 2023, there was approximately \$1.8 million of unrecognized stock-based compensation expense related to restricted stock units that are expected to vest. These costs are expected to be recognized over a weighted-average period of approximately 2.0 years.

Note 9. Income taxes

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

(Loss) income before income tax expense (in thousands)	Three Months Ended March 31,	
	2023	2022
Domestic	(21,316)	(14,886)
Foreign	6,964	134,419
(Loss) income before income tax expense	(14,352)	119,533
Income tax expense	(1,199)	(49,951)
Effective tax rate	(8.4)%	41.8%

The Company's effective tax rates were (8.4)% and 41.8% for the three months ended March 31, 2023 and 2022, respectively. The rates differed from the federal and foreign statutory rates of 21% and 25%, respectively, primarily due to the mix of income between the U.S. and Belgium, the Innovation Income Deduction in Belgium, which excludes 85% of the net revenue generated from qualifying intellectual property from taxation, the taxation in the U.S. from the inclusion of foreign earnings under the Global Intangible Low-Taxed Income ("GILTI") regime, and capitalized research and development expenses under Section 174 of the Internal Revenue Code. In addition, the Company recorded an additional \$22.3 million liability during the three months ended March 31, 2022, related to an uncertain tax position regarding the Company's allocation of revenue between Belgium and the U.S. The Company incurred income tax expense for the three months ended March 31, 2023, despite a loss before income taxes, due to taxable interest income generated by a subsidiary of iTeos Belgium which cannot be offset by the net operating losses of iTeos or iTeos Belgium.

There was no change in the unrecognized tax benefits during the three months ended March 31, 2023, as no additional revenue was recognized for tax purposes during that period under the GSK Collaboration Agreement. As the uncertain tax position relates to the Company's allocation of that revenue between the U.S. and Belgium under the GSK Agreement, the additional recognition of revenue under that agreement increases the liability for the uncertain tax position. As of March 31, 2023, the Company had accrued interest and penalties relating to uncertain tax positions of \$2.2 million, all of which was included in the unrecognized tax benefits liability in the condensed consolidated balance sheet as of March 31, 2023.

Note 10. Commitments and contingencies

Purchase commitments

The Company has contractual arrangements with research and development organizations and suppliers; however, these contracts are generally cancelable on 30-60 days' notice and the obligations under these contracts are largely based on services performed. The Company may also enter into contracts in the normal course of business with clinical research organizations for clinical trials, with contract manufacturing organizations for clinical supplies and with other vendors for preclinical studies, supplies and other services and products for operating purposes. These contracts generally provide for termination on notice. As of March 31, 2023 and December 31, 2022, there were no amounts accrued related to termination charges.

The Company has entered into a Biologics Master Services Agreement with WuXi Biologics (Hong Kong) Limited ("WuXi") (the "WuXi Agreement"). The WuXi Agreement includes the terms and conditions under which WuXi will coordinate the Company's biologics development and manufacturing services. Pursuant to the WuXi Agreement, the Company may be required to pay WuXi a royalty percentage or a one-time milestone payment on global net sales of third-party manufactured products at the Company's election. The royalty or one-time milestone payment is only payable if the Company does not use WuXi as the manufacturer in part, or in totality. As of March 31, 2023 and December 31, 2022, there are no minimum commitments under the WuXi Agreement. Additionally, as of March 31, 2023 and December 31, 2022, there are no royalties or milestones payable.

Operating leases

The Company's operating leases are as follows:

- An April 2016 lease for 1,577 square meters of office and laboratory space in Gosselies, Belgium, which commenced in May 2016 and terminated in December 2021. In January 2021, the Company entered into an amendment to extend the lease, effective February 2021 with a termination date of January 2030, and increase the office and laboratory space by 201 square meters. In October 2021, the Company entered into an amendment to increase the office and laboratory space by 453 square meters.
- A November 2021 lease for 9,068 square feet of office space in Watertown, Massachusetts, which commenced in November 2021 and terminates in February 2027. The lease is subject to fixed-rate rent escalations.
- Various car leases that the Company enters into from time to time. The life of each car lease ranges from 48 to 60 months.

The Company identified and assessed the following estimates in recognizing the operating lease right of use assets and corresponding liabilities.

Expected lease term: The expected lease term includes non-cancelable lease periods and, when applicable, periods covered by an option to extend the lease if the Company is reasonably certain to exercise that option, as well as periods covered by an option to terminate the lease if the Company is reasonably certain not to exercise that option.

Incremental borrowing rate: As the discount rates in the Company's lease are not implicit, management estimated the incremental borrowing rate based on the rate of interest the Company would have to pay to borrow a similar amount on a collateralized basis over a similar term.

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

Rent expense was \$0.3 million for the three months ended March 31, 2023 and 2022.

The following table summarizes lease terms and discount rate:

	March 31, 2023	December 31, 2022
Weighted-average remaining lease term (years)	4.8	5.0
Weighted-average discount rate	4.79 %	4.79 %

The following table summarizes the cash flow and other information:

(in thousands)	Three Months Ended March 31,	
	2023	2022
Operating lease liabilities arising from obtaining right-of-use assets (non-cash)	\$ 79	\$ 199
Operating cash flows used in operating leases	\$ 271	\$ 250

As of March 31, 2023, the Company had the following future minimum lease payments under non-cancelable operating leases for the remainder of 2023 and the future years thereafter (in thousands):

Year ending December 31:	
2023	\$ 810
2024	1,064
2025	1,032
2026	1,001
2027	508
Thereafter	786
Total lease payments	5,201
Less: interest	(576)
Total lease liability	\$ 4,625
Lease liabilities	\$ 864
Lease liabilities, net of current portion	\$ 3,761

In November 2021, the Company provided a letter of credit for approximately \$142 thousand to secure its obligation under its lease in Watertown, Massachusetts. The Company maintains that amount of cash on hand (restricted) to fund any necessary draws on the letter of credit. In addition, as of March 31, 2023 and December 31, 2022, the Company had approximately \$93 thousand and \$93 thousand on hand, respectively, 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 March 31, 2023 and December 31, 2022.

Note 11. Related party transactions

On June 11, 2018, the Company entered into a Royalty Transfer Agreement with the charitable foundations of two of its investors (MPM Oncology Charitable Foundation, Inc. and UBS Optimus Foundation), which requires it to pay a royalty equal to a total of 1% 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 March 31, 2023.

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

The Company granted certain stock options under the 2019 Plan, and currently grants certain stock options under the 2020 Plan, which are considered common stock equivalents. Unvested restricted stock units granted under the 2020 Plan are also considered common stock equivalents. For the period ending March 31, 2022, the common stock equivalents were included to calculate weighted-average diluted shares outstanding. The Company used the treasury

stock method. For the period ending March 31, 2023, the common stock equivalents were excluded from the calculation of net income (loss) per share due to their anti-dilutive effect.

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

Net (loss) income per share (in thousands, except per share amounts)	Three Months Ended March 31,	
	2023	2022
Numerator		
Net (loss) income attributable to common stockholders	\$ (15,551)	\$ 69,582
Denominator		
Weighted-average shares used in compute net (loss) income per share, basic	35,716,037	35,493,272
Effect of dilutive securities	—	2,642,685
Weighted-average shares used to compute net (loss) income per share, diluted	35,716,037	38,135,957
Net (loss) income per share:		
Basic	\$ (0.44)	\$ 1.96
Diluted	\$ (0.44)	\$ 1.82

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, 2022 included in our Annual Report on Form 10-K filed with the SEC. Some of the information contained in this discussion includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the Special note regarding forward-looking statements included in this Quarterly Report on Form 10-Q, and 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 immuno-oncology therapeutics for people living with cancer. We leverage our deep understanding of tumor immunology and immunosuppressive pathways to design novel product candidates with the aim of restoring the immune response against cancer. Our innovative pipeline includes two clinical-stage programs targeting novel, validated immuno-oncology pathways. Each of our therapies in development has optimized pharmacologic properties designed to improve clinical outcomes.

Our lead antibody product candidate, belrestotug (formerly EOS-448), is an antagonist of TIGIT, or T-cell immunoreceptor with Ig and ITIM domains, an immune checkpoint with multiple mechanisms of action. belrestotug was selected for its affinity for TIGIT, its potency and its potential to engage the Fc gamma receptor, or FcγR, to activate dendritic cells, natural killer cells and macrophages and to promote cytokine release, activation of antigen presenting cells and antibody-dependent cellular cytotoxicity, or ADCC, activity. In 2020, we started an open-label Phase 1/2a clinical trial of belrestotug in adult cancer patients with advanced solid tumors. In April 2021, we reported preliminary safety, pharmacokinetic, engagement and pharmacodynamic data, indicating target engagement and early evidence of clinical activity as a single agent. In September 2021, we dosed the first patients in a Phase 1/2 clinical trial of belrestotug in combination with pembrolizumab and in combination with our A_{2A}R antagonist inupadenant in patients with solid tumors.

On June 11, 2021, our wholly owned subsidiary, iTeos Belgium S.A., and GSK executed the GSK Collaboration Agreement, which became effective on July 26, 2021. Pursuant to the GSK Collaboration Agreement, we granted GSK a license under certain of our intellectual property rights to develop, manufacture, and commercialize products comprised of or containing belrestotug, which license is exclusive in all countries outside of the United States and co-exclusive, with iTeos, in the United States. GSK and iTeos intend to develop belrestotug in combination with other oncology assets of GSK, and iTeos and GSK will jointly own the intellectual property created under the GSK Collaboration Agreement that covers such combinations. In partnership with GSK, we are enrolling patients with first line NSCLC in a randomized Phase 2 trial assessing the doublet of GSK's anti-PD-1 (Jemperli (dostarlimab-gxly)) with belrestotug. In addition, we are enrolling patients with first-line advanced or metastatic head and neck squamous cell carcinoma (HNSCC) for the Phase 2 expansion part of the trial assessing the doublet of GSK's dostarlimab with belrestotug. We and GSK continue to explore two novel triplets in selected advanced solid tumors both in Phase 1b trials: belrestotug with dostarlimab and GSK's investigational anti-CD96 antibody, and belrestotug with dostarlimab and GSK's anti-PVRIG.

Based on favorable preclinical data generated in collaboration with Fred Hutchinson Cancer Research Center, we are also enrolling patients in an open-label dose-escalation/expansion Phase 1/2 trial evaluating the safety, tolerability and preliminary activity of belrestotug as monotherapy and in combination with Bristol Myers Squibb's iberdomide - a novel, potent oral cereblon E3 ligase modulator (CELMoD®) compound with enhanced tumoricidal and immune-stimulatory effects compared with immunomodulatory (IMiD®) agents - with or without dexamethasone, in adults with relapsed or refractory multiple myeloma.

We are also advancing inupadenant, a next-generation adenosine A_{2A} receptor antagonist tailored to overcome the specific adenosine-mediated immunosuppression found in tumor microenvironment, into proof-of concept trials in several indications following encouraging single-agent activity in Phase 1. We are investigating inupadenant in an open-label multi-arm Phase 1/2a clinical trial in adult cancer patients with advanced solid tumors. The single-agent dose-escalation and expansion portions of our Phase 1/2a clinical trial of inupadenant have demonstrated durable monotherapy antitumor activity in some patients with advanced solid tumors and safety consistent with previously reported results. As part of this monotherapy assessment of inupadenant, we identified a potential predictive biomarker and we have completed enrolling patients in the biomarker cohort of the ongoing Phase 1b/2a trial. We confirmed a partial response using inupadenant in monotherapy in a patient who had the highest level of the biomarker that we have recorded. We are also enrolling patients

in the dose ranging part (Part 1) of an ongoing two-part Phase 2 trial in post-IO metastatic non-squamous non-small cell lung cancer (NSCLC) to evaluate the combination of inupadenant with platinum-doublet chemotherapy compared to standard platinum-doublet chemotherapy. We have completed enrollment in the safety evaluation portion of the clinical trial of inupadenant in combination with chemotherapy and with pembrolizumab, as well as the monotherapy expansion cohort in prostate cancer. We have completed enrollment in the Phase 2a trial evaluating inupadenant in combination with pembrolizumab in post-PD-1 melanoma and have decided to prioritize development of inupadenant in our ongoing study in combination with platinum-doublet chemotherapy in patients with chemo-naive NSCLC as we have determined that the post-PD-1 melanoma setting is not a path to accelerated approval. In addition, we are evaluating a salt form of inupadenant in a Phase 1 study.

EOS-984 is a clinical development program that targets a novel mechanism in the adenosine pathway. The Company completed Investigational New Drug Application-enabling activities, including toxicity studies, and anticipates initiating clinical studies for EOS-984 in mid-2023.

Since our inception in August 2011, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, conducting discovery and research activities, filing patent applications, identifying potential product candidates, undertaking preclinical studies and clinical trials and establishing arrangements with third parties for the manufacture of initial quantities of our product candidates and component materials. To date, we have financed our operations primarily through license and collaboration revenue generated through the GSK Collaboration Agreement and through our Initial Public Offering, or IPO. Through March 31, 2023, we had raised an aggregate of \$210.6 million of net proceeds from the IPO and \$177.1 million from the sale of preferred stock and received an up-front payment of \$625.0 million with respect to the GSK Collaboration Agreement. As of March 31, 2023, our principal sources of liquidity were cash and cash equivalents, which totaled \$225.4 million, and available-for-sale securities, which totaled \$481.3 million.

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

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

We are also party to other collaboration and license agreements in addition to the GSK Collaboration Agreement 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 in 2018 to exercise an option to acquire certain licenses from Adimab. One of the antibodies licensed under this agreement is what we now refer to as belrestotug. In February 2021, we entered into an amendment to this agreement (the Amended Adimab Agreement). The Amended Adimab Agreement specifies different milestone payments for new products that are derived from research programs beginning after February 22, 2021 (the New Products). For New Products, on a per target basis, we may be required to pay development, regulatory and commercial milestone payments totaling up to an aggregate of \$45.8 million for the first three products and additional milestone payments up to \$14.5 million for each additional product. As of the date of this Quarterly Report on Form 10-Q, we have not pursued any additional targets under the Amended Adimab Agreement that could potentially result in such milestone payments. We will also pay Adimab low to mid single-digit percentage royalties on a country-by-country and product-by-product basis on worldwide net sales of licensed products. Through March 31, 2023, we have paid a total of \$5.4 million to Adimab relating to milestones, option and other fees pursuant the Adimab Agreement.

We are also party to a biologics master services agreement with WuXi Biologics Hong Kong Limited, or WuXi, pursuant to which we will pay WuXi, at our election, either a low single-digit percentage royalty on global net sales of manufactured products or a one-time milestone payment in the low tens of millions.

On December 10, 2019, we entered into a Clinical Trial Collaboration and Supply Agreement (the MSD Agreement) with MSD International GmbH (MSD), a subsidiary of Merck & Co., Inc. Under the MSD Agreement, we sponsor a clinical trial in which both our compound and MSD's compound are dosed in combination. We conduct the research at our own

cost and MSD contributes its compound towards the study at no cost to us. We will equally own the clinical data and inventions from the study, with the exception of inventions relating solely to each party's compound class. The MSD Agreement will expire upon the delivery of a written report on the results of the study, unless earlier terminated or agreed by the parties. We began receiving compounds from MSD on April 1, 2020 and we began the research study in the third quarter of 2020.

Impact of COVID-19

The COVID-19 pandemic has presented a substantial public health and economic challenge around the world. While the COVID-19 pandemic has not significantly impacted our business or results of operations, the future impact of the COVID-19 pandemic on our industry, the healthcare system, our development timelines for belrestotug and inupadenant, our preclinical research and development, and our current and future operations and financial condition will depend on future developments, which are highly uncertain and cannot be predicted with confidence. Disruptions to the global economy, disruption of global healthcare systems, and other significant impacts of the COVID-19 pandemic could have a material adverse effect on our business, financial condition, results of operations and growth prospects. See "Risk factors" for a discussion of the potential adverse impact of COVID-19 on our business, results of operations and financial condition.

Components of our results of operations

Revenue

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

Research and development expenses

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

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

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

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

Because of the numerous risks and uncertainties associated with product development, we cannot determine with certainty the duration and completion costs of the current or future preclinical studies and clinical trials or if, when, or to

what extent we will generate revenues from the commercialization and sale of any product candidates that receive regulatory approval. We may never succeed in achieving regulatory approval for our product candidates. The duration, costs and timing of preclinical studies and clinical trials and development of our product candidates will depend on a variety of factors, 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.

These factors could result in significant costs and delays in the development of our current and future preclinical and clinical product candidates. For example, the FDA or comparable foreign regulatory authority requiring us to conduct clinical trials beyond those that we currently anticipate will be required for the completion of clinical development, or significant delays in execution of or enrollment in any of our preclinical studies or clinical trials, could require us to expend significant additional financial resources and time on the completion of preclinical and clinical development.

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

(in thousands)	Three Months Ended March 31,	
	2023	2022
Direct research and development expenses by program:		
Belrestotug	\$ 9,649	\$ 7,172
Inupadenant	3,541	6,173
Other programs	3,676	2,822
Indirect research and development expenses (1)	8,732	4,929
Total research and development expense	<u>\$ 25,598</u>	<u>\$ 21,096</u>

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

General and administrative expenses

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

Grant income

We have agreements with granting agencies whereby we receive funding under grants that partially or fully reimburse us for eligible research and development expenditures. Certain grant agreements require us to repay the funding depending on whether we decide to pursue commercial development or out-licensing of any drug candidate that is produced from the research program. The repayment provision includes a portion that is fixed (corresponding to 30% of the grant), payable in annual installments, which is effective unless we decide not to pursue commercial development or

out licensing of the drug candidate. The repayment provision also includes a potential obligation to pay a royalty that is contingent upon achieving sales of a product developed through the program. The maximum amount payable to the granting agency under each grant, including the fixed repayments, the royalty on revenue and the interest thereon, is twice the amount of funding received.

Research and development tax credits

Our wholly owned subsidiary iTeos Belgium S.A., 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 2023 and 2022) 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 condensed consolidated balance sheet.

Interest income

Interest income consists of interest earned on our available-for-sale securities, money market funds, and bank sweep accounts.

Other income (expense), net

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

Income taxes

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

Results of operations

Comparison of the three months ended March 31, 2023 and 2022

The following table summarizes our results of operations for the three months ended March 31, 2023 and 2022, together with the dollar change in those items:

(in thousands)	Three Months Ended March 31,		Period to period change
	2023	2022	
Revenue:			
License Revenue	\$ 12,595	\$ 152,522	\$ (139,927)
Total Revenue	12,595	152,522	(139,927)
Operating expenses:			
Research and development expenses	25,598	21,096	4,502
General and administrative expenses	11,927	10,615	1,312
Total operating expenses	37,525	31,711	5,814
(Loss) income from operations	(24,930)	120,811	(145,741)
Other income and expenses:			
Grant income	735	491	244
Research and development tax credits	343	254	89
Interest income	7,851	92	7,759
Other income (expense), net	1,649	(2,115)	3,764
(Loss) income before income taxes	(14,352)	119,533	(133,885)
Income tax expense	(1,199)	(49,951)	48,752
Net (loss) income	\$ (15,551)	\$ 69,582	\$ (85,133)

License revenue

License revenue equaled \$12.6 million for the three months ended March 31, 2023, resulting from the remainder of revenue recognized in connection with the GSK collaboration. All revenue recognized for the three months ended March 31, 2023 is attributed to the recognition of previously deferred revenue. The decrease of \$140.0 million compared to the three months ended March 31, 2022 is due entirely to less revenue recognized relating to the GSK Collaboration Agreement. Significantly more of the performance obligation had been completed in the three months ended March 31, 2022.

Research and development expenses

Research and development expenses increased by \$4.5 million to \$25.6 million for the three months ended March 31, 2023, from \$21.1 million for the three months ended March 31, 2022. This increase was primarily related to an increase of \$1.9 million of payroll and related costs to support our continued growth, a \$1.2 million increase in professional fees and expenses, a \$1.0 million increase CRO/CMO fees and internal laboratory expenses, a \$0.5 million increase in stock-based compensation, an increase of \$0.3 million related to facilities, and a \$0.3 million increase in other R&D expenses. These increases were partially offset by a \$0.7 million decrease in laboratory expenses.

General and administrative expenses

General and administrative expenses increased by \$1.3 million to \$11.9 million for the three months ended March 31, 2023 from \$10.6 million for the three months ended March 31, 2022. This increase was primarily related to an increase of \$0.3 million of payroll and related costs resulting from additional finance and administrative employees added, a \$1.1 million increase in stock-based compensation, and a \$0.4 million increase related to various other general and administrative expenses. These increases were offset by decreases in recruiting and insurance expenses of \$0.2 million each, and a \$0.1 million decrease in professional fees.

Grant income

Grant income increased by \$0.2 million to \$0.7 million for the three months ended March 31, 2023 from \$0.5 million for the three months ended March 31, 2022. The increase was due primarily to income received from two new grants issued to the Company by the Walloon Region in late 2022.

Interest income

Interest income increased by \$7.8 million to \$7.9 million for the three months ended March 31, 2023 from \$0.1 million for the three months ended March 31, 2022. The increase in interest income of \$7.8 million is due to the Company's purchase of approximately \$445.0 million of fixed income securities in the fourth quarter 2022, combined with significant increases in the interest rate environment since the quarter ended March 31, 2022.

Other income (expense), net

The increase in other income (expense), net in the three months ended March 31, 2023 compared to the three months ended March 31, 2022 is primarily due to a \$3.0 million realized foreign currency exchange gain relating to a capital distribution from one of the Company's Belgian entities which is denominated in U.S. Dollar. The U.S. Dollar had strengthened relative to the Euro since the initial contribution transaction. This gain was partially offset by net unrealized foreign currency exchange losses of \$1.2 million. Further contributing to the increase is the net loss of \$2.1 million in the three months ended March 31, 2022 driven by net realized foreign exchange losses of \$1.2 million and \$0.7 million of miscellaneous expenses.

Income tax expense

The Company's effective tax rates were (8.4)% and 41.8% for the three months ended March 31, 2023 and 2022, respectively. They differed from the federal and foreign statutory rates of 21% and 25%, respectively, primarily due to the mix of income between the U.S. and Belgium, the Innovation Income Deduction in Belgium, which excludes 85% of the net revenue generated from qualifying intellectual property from taxation, the taxation in the U.S. from the inclusion of foreign earnings under the Global Intangible Low-Taxed Income ("GILTI") regime, and capitalized research and development expenses under Section 174 of the Internal Revenue Code. In addition, the Company recorded an additional \$22.3 million liability during the three months ended March 31, 2022, related to an uncertain tax position regarding the Company's allocation of revenue between Belgium and the U.S. The Company incurred income tax expense for the three months ended March 31, 2023, despite a loss before income taxes, due to taxable interest income generated by a subsidiary of iTeos Belgium which cannot be offset by the net operating losses of iTeos or iTeos Belgium.

Liquidity and capital resources

In June 2021, the Company's wholly owned subsidiary, iTeos Belgium S.A., and GSK executed the GSK Collaboration Agreement, pursuant to which we agreed to grant GSK a license under certain of our intellectual property rights to develop, manufacture, and commercialize products comprised of or containing our antibody product, belrestotug. Under the GSK Collaboration Agreement, GSK made an upfront payment of \$625.0 million on August 5, 2021.

To date, we have funded our operations primarily with proceeds from the IPO, the sales of preferred stock, grants and licenses and the upfront payment from the GSK Collaboration Agreement. As of March 31, 2023, we had \$225.4 million in cash and cash equivalents and \$481.3 million in available-for-sale securities. To date we have not generated any revenue from product sales and do not expect to generate revenue from the sales of products for the foreseeable future.

In addition, in the event that we receive revenue from products or services related to the intellectual property developed arising from the programs, we must pay to the Walloon Region a 0.33% royalty on revenue related to the inupadenant grant and a 0.15% royalty on revenue on the belrestotug grant (increased from 0.12% effectively December 2021). 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 grant received. The Company recorded a royalty accrual of \$0.9 million as of March 31, 2023, due to the upfront payment received pursuant to the GSK Collaboration Agreement.

Under the GSK Collaboration Agreement and as part of the Global Development Plan, the Company and GSK agree to spend an aggregate amount of at least \$900 million. GSK is responsible for 60% of the cost, while the Company is responsible for the remaining 40% of the cost related to the Global Development Plan. We have not included such potential expenditures, as the timing of the obligations are not known with certainty.

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 are not included in the table above as they provide for termination on notice, and therefore are cancelable contracts and do not include any minimum purchase commitments.

Cash flows

The following table provides information regarding our cash flows for the three months ended March 31, 2023 and 2022:

(in thousands)	Three Months Ended March 31,	
	2023	2022
Net cash provided by (used in):		
Operating activities	\$ (26,555)	\$ (24,002)
Investing activities	(31,694)	(323)
Financing activities	578	333
Effects of exchange rate changes on cash, cash equivalents and restricted cash	(1,771)	(563)
Net decrease in cash, cash equivalents and restricted cash	<u>\$ (59,442)</u>	<u>\$ (24,555)</u>

Net cash used in operating activities

Net cash used in operating activities was \$26.6 million during the three months ended March 31, 2023. The cash usage was primarily due to the net loss of \$15.6 million, a net change in operating assets and liabilities of \$14.2 million, and non-cash accretion of available-for-sale debt securities of \$2.9 million. The usage was partially offset by \$5.8 million of non-cash stock-based compensation expense and \$0.2 million of non-cash depreciation and amortization expense. Net cash used in operating activities was \$24.0 million during the three months ended March 31, 2022, which was driven by a net change in operating assets and liabilities of \$98.0 million. The usage was partially offset by net income of \$69.6 million, non-cash stock-based compensation expense of \$4.2 million, and \$0.2 of non-cash depreciation and amortization expense.

Net cash used in investing activities

Net cash used in investing activities increased by \$31.4 million for the three months ended March 31, 2023 compared to the three months ended March 31, 2022. The increase was due to the purchase of \$52.6 million of fixed income securities, partially offset by \$21.0 million of proceeds received upon the maturities of fixed income securities during the three months ended March 31, 2023.

Net cash provided by financing activities

Net cash provided by financing activities was \$0.6 million and \$0.3 million during the three months ended March 31, 2023 and 2022, respectively. This was due to the proceeds received from the exercise of stock options during those periods.

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

The \$1.8 million and \$0.5 million reductions of cash, cash equivalents and restricted cash for the three months ended March 31, 2023 and 2022, respectively, were primarily caused by the reduction of the euro to dollar exchange rate during those periods.

Funding requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue our Phase 1/2 trials for both belrestotug and inupadenant and potentially move to larger randomized and registration-directed trials for both programs, 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 June 2021, the Company's wholly owned subsidiary, iTeos Belgium S.A., and GSK executed the GSK Collaboration Agreement, pursuant to which we agreed to grant GSK a license under certain of our intellectual property rights to develop, manufacture, and commercialize products comprised of or containing our antibody product, belrestotug. Under the GSK Collaboration Agreement, GSK made an upfront payment of \$625.0 million on August 5, 2021.

Additionally, we are eligible to receive up to \$1.45 billion in milestone payments, contingent upon the belrestotug program achieving certain development and commercial milestones.

As of March 31, 2023, we had cash and cash equivalents of \$225.4 million and available-for-sale securities of \$481.3 million. We believe our existing cash and cash equivalents and available-for-sale securities could enable us to fund our operating expenses and capital expenditure requirements into 2026.

We have based our projections of operating capital requirements on assumptions that may prove to be incorrect and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with the development and commercialization of belrestotug and inupadenant, and the research, development and potential 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;
- 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.

Critical accounting policies and significant judgments and estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which we have prepared in accordance with U.S. generally accepted accounting principles. We believe that several accounting policies are important to understanding our historical and future performance. We refer to these policies as critical because these specific areas generally require us to make judgments and estimates about matters that are uncertain at the time we make the estimate, and different estimates—which also would have been reasonable—could have been used. On an ongoing basis, we evaluate our estimates and judgments, including those described in greater detail below. We base our estimates on historical experience and other market-specific or other relevant assumptions that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no significant changes to our existing critical accounting policies discussed in our Annual Report on Form 10-K for the year ended December 31, 2022. We believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our financial statements:

Revenue Recognition

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

- (i) identify the contract(s) with a customer;

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

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

Research and development expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed for us and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. The majority of our service providers invoice us monthly in arrears for services performed or when contractual milestones are met. We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known to us at that time, which we periodically confirm with the service providers and make adjustments if necessary. Examples of accrued research and development expenses include fees paid to:

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

We must develop assumptions that require judgment to determine whether the individual promises should be accounted for as separate performance obligations or as a combined performance obligation, and to determine the stand-alone selling price for each performance obligation identified in the contract. Since the upfront license was bundled with other promises, we utilized judgment to assess the nature of the combined performance obligation and determined that the combined performance obligation is satisfied over time. Revenue is recognized using a percent complete method based on costs incurred compared with the total expected costs to be incurred (cost to cost measure of progress). There are no outputs from the performance obligation. As a result, an input method was appropriate. A cost to cost measure of progress provides a faithful depiction of the transfer of services to the customer since the predominant inputs to the performance obligation are labor costs, research and development supplies and manufacturing supplies related to the Phase 1 Study, clinical manufacturing and know-how transfer.

The preceding estimates and judgments materially affect our recognition of revenue. Changes in our estimates of forecasted development costs could impact percentage complete and could have a material effect on revenue recorded in the period in which we determine that change occurs.

Stock-based compensation expense

The fair value of stock options and Employee Stock Purchase Plan awards we grant is estimated using the Black Scholes option pricing model. This option pricing model based on certain subjective assumptions, including (i) the expected stock price volatility, (ii) the expected term of the award, (iii) the risk-free rate of interest, and (iv) expected dividends. The fair value of our common stock utilized in the model is determined based on the quoted market price of our common stock.

There were no significant changes to assumptions used to value options using the Black Scholes option pricing model in 2023, with the exception of the stock and exercise prices.

The fair value of restricted stock units we grant is based on the quoted market price of our common stock on the date of grant.

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 is predicated on whether we decide to pursue commercial development or out licensing of the drug candidate that is produced from the results of the research program. The repayment provision includes a portion that is fixed (corresponding to 30% of the grant) which is effective after we decide to pursue commercial development or out licensing of the drug candidate. The repayment provision also includes a potential obligation to pay a royalty that is contingent upon achieving sales of a product developed through the program. The maximum amount payable to the granting agency under each grant, including the fixed repayments, the royalty on revenue, and the interest thereon, is twice the amount of funding received.

Grant funding for research and development received under grant agreements where there is a repayment provision is recognized as other income to the extent there is no potential obligation to repay this funding. We record the present value of the liability as a grant repayable in the accompanying consolidated balance sheets. The grant repayable is subsequently recorded at amortized cost. There were no significant changes to assumptions in 2023.

Income taxes

We are subject to taxes in the U.S. and Belgium. Significant judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. We make these estimates and judgments about our future taxable income that are based on assumptions that are consistent with our future plans. Tax laws, regulations and administrative practices may be subject to change due to economic or political conditions including fundamental changes to the tax laws applicable to corporate multinationals. The U.S. and many countries in the European Union are actively considering changes in this regard. As of March 31, 2023 and December 31, 2022, we had recorded a full valuation allowance on our net deferred tax assets because we expect that it is more likely than not that our deferred tax assets will not be realized. Should the actual amounts differ from our estimates, the amount of our valuation allowance could be materially impacted.

Furthermore, significant judgment is required in evaluating our tax positions. In the ordinary course of business, there are many transactions and calculations for which the ultimate tax settlement is uncertain. As a result, we recognize the effect of this uncertainty on our tax attributes or taxes payable based on our estimates of the eventual outcome. These effects are recognized when, despite our belief that our tax return positions are supportable, we believe that it is more likely than not that some of those positions may not be fully sustained upon review by tax authorities. We are required to file income tax returns in the U.S. and Belgium, which requires us to interpret the applicable tax laws and regulations in effect in such jurisdictions. Such returns are subject to audit by the various federal, state and foreign taxing authorities, who may disagree with respect to our tax positions. We believe that our consideration is adequate for all open audit years based on our assessment of many factors, including past experience and interpretations of tax law. We review and update our estimates in light of changing facts and circumstances, such as the closing of a tax audit, the lapse of a statute of limitations or a change in estimate. To the extent that the final tax outcome of these matters differs from our expectations, such differences may impact income tax expense in the period in which such determination is made. The eventual impact on our income tax expense depends in part on if we still have a valuation allowance recorded against our deferred tax assets in the period that such determination is made.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are exposed to market risk related to changes in interest rates. As of March 31, 2023 and December 31, 2022, we had cash and cash equivalents of \$225.4 million and \$284.8 million, respectively. We had available-for-sale fixed income securities of \$481.3 million and \$446.6 million as of March 31, 2023 and December 31, 2022, 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 March 31, 2023, our cash and cash equivalents is held primarily in savings, money market accounts and money market funds. Our fixed income securities were held primarily in U.S. treasury obligations and U.S. government agency obligations. The majority of the fixed income securities will mature within one year from March 31, 2023. There are no securities that will mature in a period greater than two years from March 31, 2023. Because of the short-term nature of the instruments in our portfolio, an immediate 10% change in the interest rate would not have a material impact on the fair market value of our investment portfolio or on our financial position or results of operations.

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

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

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

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of March 31, 2023, 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, or 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.

Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving our objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2023, our principal executive officer and principal financial officer 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 have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended March 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 1. Legal Proceedings.

From time to time, we may be a party to litigation or subject to claims incident to the ordinary course of business. We are not currently a party to any material legal proceedings, and our management believes that there are currently no claims or actions pending against us, the ultimate disposition of which could have a material adverse effect on our results of operations or financial condition.

Item 1A. Risk Factors.

Risk factors

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

Risks related to the development of our product candidates

We must complete successful preclinical studies and clinical trials that demonstrate the safety and efficacy of our product candidates before we can begin the commercialization process.

We are focused on the development of inupadenant and belrestotug. 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 product candidates requires substantial funding and remains subject to the risks of failure inherent at each 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. Our 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. We may modify development plans, including selecting different combinations or indications or discontinuing clinical activities, or determine to pursue development of different product candidates as we obtain additional clinical and nonclinical data.

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 and trials. 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, 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, flaws in the design of a clinical trial can negatively impact results. We may not discover such a flaw prior to advance stages of a clinical trial.

Additionally, our clinical trials, to date, have been open-label trials, where both the patient and investigator know whether the patient is receiving the investigational product candidate or an existing approved drug, which may introduce study bias. 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. Positive results observed in open-label trials may not be replicated in later placebo-controlled trials.

We may also experience events during, or as a result of, clinical trials that could delay and could prevent our ability to receive marketing approval or commercialize our 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 may require that we modify or amend our clinical trial protocols;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms for clinical trial contracts or clinical trial protocols with prospective trial sites and/or clinical research organizations, or CROs;
- we may be unable to initiate or complete preclinical studies or clinical trials on time or at all due to the ongoing impacts of the COVID-19 pandemic;
- clinical trials 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 may be larger than we anticipate, enrollment in these clinical trials often is slow, participants may drop out of these clinical trials or be lost to follow-up at a higher rate than we anticipate, or participants may elect to participate in alternative clinical trials sponsored by our competitors with product candidates that treat the same indications as our 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;
- marketing approval policies could change 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 may be greater than we anticipate or we may have insufficient funds to complete a clinical trial;
- the supply or quality of materials necessary to conduct clinical trials may be insufficient or inadequate or may be interrupted or impacted by supply chain challenges;
- we may decide, or regulators may require us, to conduct or gather, as applicable, additional clinical trials, analyses, reports, data, or preclinical studies, 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;
- 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 also will increase if we experience delays in testing or approvals, and we may not have sufficient funding to complete the testing and approval process. We may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization. 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.

Challenges enrolling patients in our clinical trials delay and may prevent completion of clinical trials of our product candidates.

Identifying and qualifying patients to participate in clinical trials 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 our clinical trials. Initiating and continuing clinical trials requires locating, enrolling and retaining sufficient numbers of eligible patients to participate in these trials. Developments, like the COVID-19 pandemic, impact our ability to initiate clinical sites and recruit, enroll and retain patients and divert healthcare resources away from clinical trials.

In addition to the competitive trial environment, the eligibility criteria of our planned clinical trials limits the pool of available participants as we require that participants have specific, measurable characteristics to assure their cancer is severe enough but not too advanced for inclusion in a trial and exclude participants who have conditions that may increase the risk associated with participation in a trial. Additionally, the process of finding patients is costly. Delays in recruiting and conducting our clinical trials result when patients are unwilling to participate in our trials, which may delay our efforts to obtain regulatory approval of potential products.

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, including as a result of lack of efficacy or adverse events observed in similar or competing product candidates;
- the efforts to facilitate timely enrollment in clinical trials;
- the proximity and availability of clinical trial sites for prospective patients;
- the design of the clinical trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents;
- reporting of preliminary results of any of our clinical trials, and/or reporting of results of clinical trials of our competitors; and
- the risk that patients enrolled in clinical trials will drop out of the clinical trials before clinical trial completion.

Our clinical trials compete with other clinical trials for product candidates that treat the same indications or are in the same therapeutic areas, and this competition may reduce the number and types of eligible patients available to us because some patients who might have opted to enroll in our clinical trials may instead opt to enroll in a competitor's clinical trial. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining participation of such patients in our clinical trials.

We anticipate that our 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 product candidates have the potential to be administered or co-formulated in combination with checkpoint inhibitor immunotherapies or other standards of care like chemotherapies, targeted therapies or radiotherapy. For example, we are currently conducting a multi-arm Phase 1/2a clinical trial of inupadenant as a single agent and in combination with pembrolizumab. In addition, in collaboration with GSK, we are exploring the development of belrestotug with multiple combinations, including with dostarlimab. Our ability to develop and ultimately commercialize our 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 commercial relationships, including our collaborations with Merck and GSK, will provide us with a steady supply of such drugs or biologics on commercially reasonable terms or at all.

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

Moreover, the development of product candidates for use in combination with another product or product candidate may present challenges that are not faced for single agent product candidates. We are currently developing inupadenant and belrestotug for use in combination with checkpoint inhibitor immunotherapies and with other therapies and may develop inupadenant, belrestotug, 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. The results of such trials could show that any positive previous trial results are attributable to the combination therapy and not our 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, which may require us to work with a third party to satisfy such a requirement. Additionally, 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, GSK or any other collaborator or supplier cannot continue to supply their products on commercially reasonable terms, we would need to identify alternatives for accessing such products. Additionally, should the supply of products from Merck, GSK or any other collaborator or supplier be interrupted, delayed or otherwise be unavailable to us, our clinical trials may be delayed. In the event we are unable to source an

alternative supply, or are unable to do so on commercially reasonable terms, our business, financial condition, results of operations, stock price and prospects may be materially harmed.

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

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

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

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

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

The FDA or comparable foreign regulatory authorities may require us to file separate INDs for additional clinical trials we plan to conduct with our current lead product candidates, inupadenant and belrestotug. We may not be able to file any additional INDs 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 or submission of a trial to 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 lead us to suspend or terminate clinical trials. Additionally, even if regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND, such regulatory authorities may change their requirements in the future. The FDA or comparable foreign regulatory authorities may require the analysis of data from trials assessing different doses of the product candidate alone or in combination with other therapies to justify the selected dose prior to the initiation of large trials in a specific indication. Any delays or failure to file INDs, initiate clinical trials, or 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. We are subject to similar risks related to the review and authorization of our protocols and amendments by comparable foreign regulatory authorities.

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

We are conducting and in the future may conduct one or more clinical trials outside the United States, including in Europe and in Asia. The acceptance of data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and medical practice; and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to good clinical practice, or GCP, regulations. In general, the patient population for any clinical trials conducted outside the United States must be representative of the population for whom we intend to label the product candidate in the United States. Additionally, the FDA's clinical trial requirements, including applicable study design, sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory authorities have similar approval requirements. In addition, foreign trials are 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, additional trials would be needed, which could

be costly and time-consuming, and which may result in our product candidates not receiving approval for commercialization in the applicable jurisdiction.

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

We will need to successfully complete pivotal clinical trials in order to obtain the approval of the FDA or comparable foreign regulatory authorities to market inupadenant, belrestotug, 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 continue to expand our clinical development and regulatory capabilities, and we may be unable to recruit and train qualified personnel. We also expect to continue to rely on third parties to conduct our pivotal clinical trials. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to BLA or NDA submission and approval of inupadenant, belrestotug, or future product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in commercializing our product candidates.

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

The development and commercialization of cancer immunotherapy products is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary rights. We face competition with respect to our product candidates, from major biopharmaceutical companies, specialty biopharmaceutical companies, and biotechnology companies worldwide. A number of large biopharmaceutical and biotechnology companies currently market and sell products, or are pursuing the development of products, for the treatment of solid and liquid 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 compete with a number of drugs and biologics that are currently marketed or in development.

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 products 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 do, 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 by insurers, government, or other third-party payor coverage decisions.

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

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

The potential market opportunities for our product candidates are difficult to estimate and depend on the drugs with which our product candidates are co-administered or co-formulated and the success of competing therapies and therapeutic approaches. Our estimates of potential market opportunities are predicated on many assumptions that 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. New information may change the estimated incidence or prevalence of indications, and regulatory approvals, if received, 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 or in the field of TIGIT or adenosine pathway therapeutics could damage public perception of our product candidates or negatively affect our business.

The commercial success of our product candidates will depend in part on public acceptance of the use of cancer immunotherapies and our mechanisms of action and developments in TIGIT or adenosine pathway programs of other companies. Adverse events or disappointing results in clinical trials of our product candidates, or in clinical trials of similar products, as well as any other negative developments in the field of immuno-oncology, including in connection with competitor therapies, could reduce expectations regarding the potential success of our programs and potentially have a negative impact on collaborations. These events also could 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 or ineffective, whether related to our therapies or those of our competitors, our 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. Negative developments could result in reduced probability of success of clinical trials involving our product candidates, challenges enrolling clinical trials, greater governmental regulation, stricter labeling requirements, and potential regulatory delays in the testing or approvals of our product candidates.

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

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

- launching commercial sales, whether alone or in collaboration with others;
- receiving an approved label with claims that are necessary or desirable for successful marketing and does not contain limitations that impede our ability to market the product;
- creating market demand through marketing, sales and promotion activities;
- hiring, training, and deploying a sales force or contracting with third parties to commercialize our product candidates in the United States;
- manufacturing the product in sufficient quantities and at acceptable quality and cost to meet commercial demand;
- 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 our product candidates in foreign markets where we receive marketing approval;
- maintaining patent and trade secret protection or regulatory exclusivity;
- achieving market acceptance of our current product candidates or any future product candidates by patients, the medical community, and third-party payors;
- reimbursement decisions;
- effectively competing with other therapies; and
- maintaining a continued acceptable safety profile of our products.

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

Risks related to government regulation

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

We are not permitted to market, promote, or sell our 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 for each therapeutic indication. Securing marketing approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the regulatory authorities. Even if our product candidates are approved, they may:

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

We have not previously submitted a BLA or NDA to the FDA, or a similar marketing application to comparable foreign regulatory authorities, for any product candidate, and we may not 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 experience delays in obtaining required regulatory approvals, 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 discretion of regulatory authorities. 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, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change 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.

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

Serious adverse events or undesirable side effects caused by our 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 trials, a more restrictive label, or delay or denial of marketing approval. We have identified in the past and may in the future identify serious adverse events suspected to be related to our product candidates. If concerns are raised regarding undesirable side effects or serious adverse events identified during clinical or preclinical testing, including any dose-limiting toxicities, the FDA or comparable foreign regulatory authority may request additional data or information or order us to pause or cease further development, e.g., by issuing a clinical hold on ongoing or planned clinical trials, declining to approve the product candidate, or issuing a letter requesting additional data or information prior to making a final decision regarding whether or not to approve the product candidate. The FDA or comparable foreign regulatory authorities, or IRBs and other reviewing entities, may also require, or we may voluntarily develop, strategies for managing adverse events during clinical development, which could include restrictions on our enrollment criteria, the use of stopping criteria, adjustments to a study's design, re-consent of enrolled patients, or the monitoring of safety data by a data monitoring committee, among other strategies. Requests for additional data or information from the FDA or a comparable foreign regulatory authority also could result in substantial delays in the approval of our 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.

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 product candidates are associated with serious adverse events or undesirable side effects or have properties that are unexpected, we may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. The therapeutic-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may materially harm our business, financial condition, results of operations, stock price and prospects.

Regulatory approval by the FDA or comparable foreign regulatory authorities is limited to specific indications and conditions, 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 and comparable foreign regulatory authorities. 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 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, prospects and reputation may 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 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, 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. If we market our medicines for off-label use, we may be subject to enforcement action for off-label marketing by the FDA and other federal and state enforcement agencies, including the Department of Justice. A company that is found to have promoted off-label uses may be subject to significant liability, including civil and administrative remedies as well as criminal sanctions. Even if it is later determined that we were not in violation of these laws, we may be faced with negative publicity, incur significant expenses defending our actions and have to divert significant management resources from other matters.

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

Any product candidate for which we obtain marketing approval will be subject to extensive and ongoing requirements of and review by the FDA and comparable foreign regulatory authorities, including requirements related to the manufacturing processes, post-approval clinical data, labeling, packaging, distribution, adverse event reporting, storage, recordkeeping, applicable tracking and tracing requirements, export, import, advertising, marketing, and promotional activities. 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 the FDA's cGMP, requirements relating to manufacturing, quality control, quality assurance, and corresponding maintenance of records and documents, and GCPs for any clinical trials that we conduct post-approval.

We and any of our suppliers or collaborators, including our CMOs, would be subject to periodic 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 either before or 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.

We may seek orphan drug status for our product candidates, but we may be unable to obtain such designations or to maintain the benefits associated with orphan drug status, including market exclusivity, which may cause our revenue, if any, to be reduced.

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

The FDA may reevaluate the Orphan Drug Act and its regulations and policies. We do not know if, when, or how the FDA may change the orphan drug regulations and policies in the future, and it is uncertain how any changes

might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

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

FDA's Fast Track and Breakthrough Therapy designations programs are intended to expedite the development of certain qualifying products intended for the treatment of serious diseases and conditions. While we may seek Fast Track or Breakthrough Therapy designation, there is no guarantee that we will be successful in obtaining any such designation. Even if we do obtain such designation, we may not experience a faster development process, review, or approval compared to conventional FDA procedures. Fast Track or Breakthrough Designation alone do not guarantee qualification for the FDA's priority review procedures. A Fast Track or Breakthrough Therapy designation does not ensure that the product candidate will receive marketing approval or that approval will be granted within any particular timeframe. In addition, the FDA may withdraw Fast Track or Breakthrough Therapy designation if it believes that the designation is no longer supported by data from our clinical development program.

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, likely will require the conduct of clinical trials to demonstrate the safety and effectiveness of any diagnostics we or our collaborators may develop, which we expect will require separate regulatory clearance or approval prior to commercialization.

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.

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.

The FDA generally is continuing to ensure timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals. However, FDA may not be able to continue its current pace and review timelines could be extended. In addition, where a pre-approval inspection or an inspection of

clinical sites is required and due to the COVID-19 pandemic and travel restrictions FDA is unable to complete such required inspections during the review period, action on such applications may be delayed or prevented. Similarly, regulatory authorities outside the United States may experience delays in their regulatory activities.

Even if we are able to commercialize any 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 product candidates, even if our product candidates obtain marketing approval.

In the United States, the availability and adequacy of coverage and reimbursement by third-party payors, including governmental healthcare programs such as Medicare and Medicaid, as well as private health insurance, will likely be essential for most patients to be able to afford our product candidates, assuming regulatory approval. There is significant uncertainty related to third party payor coverage and reimbursement of newly-approved products. No uniform policy for coverage and reimbursement for products exists among third-party payors. Coverage and reimbursement for products can differ significantly from payor to payor and coverage and reimbursement by one payor does not guarantee coverage and reimbursement by another payor. Third-party payors increasingly are limiting coverage and utilization of pharmaceutical products and challenging prices charged for pharmaceutical products and services. Assuming we obtain coverage for a product by a third-party payor, the third-party payor may implement utilization management controls, such as requiring pre-approval before our product will be covered for a particular patient, which may limit access to our product. In addition, the reimbursement rates may not be adequate or may require co-payments that patients find unacceptably high. Net prices for our products may be reduced by mandatory discounts or rebates that we are required to provide to certain government healthcare programs or private payors or by discounts we negotiate with third party payors. If coverage is limited, access to our products is subject to utilization management controls or reimbursement is inadequate, we may not be able to successfully commercialize our product candidates, and may not be able to obtain a satisfactory financial return on our product candidates.

Healthcare 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 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, numerous legislative and regulatory initiatives seek to contain healthcare costs. We expect that federal and state healthcare reform measures will limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. See "Government Regulation - Healthcare Reform".

Limitations in coverage or reduction in reimbursement from Medicare or other government programs may result in similar actions 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 fraud and abuse, privacy and price reporting and payment 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.

Our 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 that constrain the business or financial

arrangements and relationships through which we research, market, sell, and distribute our 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;
- the federal civil and federal false claims laws and civil monetary penalty laws, including the False Claims Act which can be enforced through civil whistleblower or qui tam actions, impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- 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;
- HIPAA, as amended, and its implementing regulations which also establish privacy and security standards applicable to healthcare providers and other entities and their business associates that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information;
- federal laws including the Medicaid Drug Rebate Program, which require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;
- the so-called "federal sunshine" law, which requires pharmaceutical and medical device companies to monitor and report certain financial interactions with physicians, certain non-physician practitioners and teaching hospitals to the federal government for re-disclosure to the public; and
- federal consumer protection and unfair competition laws and regulations, which broadly regulate marketplace activities and that potentially harm consumers.
- Also, many states have similar laws and regulations, such as anti-kickback and false claims laws that may be broader in scope and may apply to claims reimbursed by private payors as well as government programs regardless of reimbursement. Additionally, we may be subject to state laws that require pharmaceutical companies to comply with the federal government's and/or pharmaceutical industry's voluntary compliance guidelines, impose specific restrictions on interactions between pharmaceutical companies and healthcare providers or require pharmaceutical companies to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures. Other state laws may require pharmaceutical companies to file reports relating to pricing and marketing information and state and local laws that require the registration of pharmaceutical sales representatives. The distribution of drugs and biological products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products. Finally, there are state laws governing the privacy and security of health information, many of which differ from each other in significant ways and often are not preempted by HIPAA. Many of these laws and regulations also contain ambiguous requirements or require administrative guidance for implementation.

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. Given the breadth of the laws and regulations, limited guidance for certain laws and regulations and evolving government interpretations of the laws and regulations, governmental authorities may possibly conclude that our business practices may not comply with such laws and regulations. If our operations were to be found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, and the curtailment or restructuring of our operations.

Failure to comply with environmental, health, and safety laws and regulations, may subject us to fines or penalties, or 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 are subject to the Foreign Corrupt Practices Act, or FCPA, and similar anti-bribery and anti-corruption laws.

Expanding our business activities outside of the United States, including our clinical trial efforts, subjects us to the FCPA and similar anti-bribery or anti-corruption laws, regulations, or rules of other countries. 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. Failure by our employees, agents, suppliers, manufacturers, contractors, or collaborators, or those of our affiliates, to comply with applicable laws and regulations, particularly given the high level of complexity of these laws, could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of facilities, including those of our suppliers and manufacturers, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries as well as difficulties in manufacturing or continuing to develop our products, and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

Risks related to reliance on third parties

We rely on third parties to conduct our clinical trials and perform some of our research and preclinical studies. Failure by these third parties to satisfactorily carry out their contractual duties or to meet expected deadlines may delay and increase the costs of our development programs, adversely impacting 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 preclinical and clinical trials and any future preclinical and clinical trials of our product candidates. The timing of the initiation and completion of these trials, therefore, is 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. We are not 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 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 or prevent marketing.

CROs, clinical trial investigators or other third parties on which we rely may fail to devote adequate time and resources to our development activities or perform as contractually required. The performance of our CROs may also be interrupted by the COVID-19 pandemic, including due to travel or quarantine policies, heightened exposure of CRO staff to COVID-19, prioritization of resources toward the pandemic or high turnover rate, including as a result of the "great resignation". 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 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 our relationships with these third-party CROs or others terminate, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms.

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

We may not realize the benefits of our collaborations, alliances or licensing arrangements, including our collaboration with GSK for the global development of belrestotug.

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.

Currently we are party to the GSK Collaboration Agreement, pursuant to which we share with GSK responsibility and costs for the global development of belrestotug. Under the GSK Collaboration Agreement, in the United States we and GSK will jointly commercialize and equally split profits while outside of the United States GSK will receive an exclusive license for commercialization. We are also eligible to receive tiered double digit royalty payments up to 20% during a customary royalty term. Our collaboration with GSK is not without risks, which include the following:

- Our control over the development and commercialization activities of belrestotug may be limited;
- GSK's commercialization activities outside the United States may adversely impact our own efforts in the United States;

- Relying on GSK to commercialize any products containing or comprising belrestotug that obtain regulatory approval, may cause us to receive less revenues than if we commercialized these products ourselves, which could materially harm our prospects;
- GSK may compete with us, or collaborate with our competitors;
- GSK may not properly maintain or defend our intellectual property rights or may improperly use our intellectual property or proprietary information;
- GSK may fail to meet its obligations under the GSK Collaboration Agreement to apply sufficient efforts at developing and commercializing belrestotug, or to comply with applicable legal or regulatory requirements;
- GSK may terminate the GSK Collaboration Agreement, which could damage perception of our product candidates, slow down our execution and timelines, and negatively affect the clinical development or commercialization of belrestotug; and
- disputes may arise between us and GSK that cause the delay or termination of the development or commercialization of our product candidates, or that result in costly litigation or arbitration that diverts management attention and resources.

The occurrence of any of the risks detailed above may materially adversely affect our business and our results of operations. Future collaborations will likely be subject to similar risks as outlined above. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex.

We may not realize the benefits of collaborations related to companion diagnostic tests for our therapeutic product candidates.

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 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. 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.

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. The development of our 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 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 also may be subject to inspections 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. We may not 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 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 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. Changes to the manufacturing process often require preclinical and clinical data showing the comparable identity, strength, quality, purity, or potency of the products before and after such changes. Microbial, viral or other contaminations may require closure of facilities 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 also can lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination.

In addition, risks associated with large scale manufacturing for clinical trials or commercial scale include, 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 product candidates, our manufacturers may not be able to manufacture the approved product to specifications acceptable to the FDA or other comparable foreign regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential commercial launch of the product, or to meet potential future demand. If our manufacturers are unable to produce sufficient quantities for clinical trials

or for commercialization, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility of competitor discovery, misappropriation, or disclosure.

Because we rely on third parties to research and develop and to manufacture our product candidates, we must share trade secrets. 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. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. However, our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with often 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. Sharing trade secrets and other confidential information increases the risk that such information becomes known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements.

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. 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. 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. Enforcing a claim that a third party illegally obtained and is using our trade secrets, like patent litigation, is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets.

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

Our limited operating history may make it difficult for you to evaluate our business and to assess our future viability.

We are a clinical-stage immuno-oncology company with a limited operating history. 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.

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. Inupadenant and belrestotug are each in ongoing Phase 2 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.

Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product candidates.

We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase substantially if and as we:

- conduct preclinical studies and clinical trials for our current and future product candidates;
- continue our research and development efforts and submit INDs for future product candidates;
- seek marketing approvals for any product candidates that successfully complete clinical trials;

- build commercial infrastructure to support sales and marketing for any approved product candidates;
- scale up external manufacturing and distribution capabilities for clinical and, if approved, commercial supply of our product candidates;
- expand, maintain and protect our intellectual property portfolio;
- hire additional clinical, regulatory and scientific personnel and scale up such capabilities; and
- operate as a public company.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses we will incur or when, if ever, we will be able to achieve profitability. Even if we succeed in 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 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.

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

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

- initiating and completing research regarding, and preclinical and clinical development of, inupadenant, belrestotug, and any other product candidates;
- obtaining marketing approvals for inupadenant, belrestotug, and any other product candidates for which we complete clinical trials;
- developing a sustainable and scalable manufacturing process for inupadenant, belrestotug, and any other product candidates, including establishing and maintaining commercially viable supply and manufacturing relationships with third parties;
- launching and commercializing inupadenant, belrestotug, and any other product candidates for which we obtain marketing approvals, either directly or with a collaborator or distributor;
- obtaining market acceptance of inupadenant, belrestotug, and any other 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.

We will require additional financing to achieve our goals, and 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 clinical trials for inupadenant and belrestotug 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.

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

Our future capital requirements depend on many factors, including:

- the scope, progress, results, and costs of researching and developing inupadenant, belrestotug, and any other product candidates, and conducting preclinical studies and clinical trials;
- the timing of, and the costs involved in, obtaining marketing approvals for inupadenant, belrestotug, and any other product candidates if clinical trials are successful;
- the extent to which we develop, in-license or acquire other product candidates and technologies;
- the number and development requirements of other product candidates we may pursue;
- the success of the GSK collaboration and any other collaborations;
- the cost of commercialization activities for any approved product, including marketing, sales and distribution costs;
- the cost of manufacturing inupadenant, belrestotug, and any other product candidates for clinical trials in preparation for marketing approval and commercialization;
- our ability to establish and maintain strategic licensing or other arrangements and the financial terms of such agreements;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the timing, receipt, and amount of sales of, or royalties on, future approved products, if any; and
- the emergence of competing cancer therapies and other adverse market developments.

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

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

Risks related to intellectual property

If we are unable to obtain and maintain sufficient intellectual property protection for our 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 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. Additionally, we may 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, CROs, CMOs, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

We also cannot be certain that the claims in our pending patent applications directed to our product candidates and/or technologies will be considered patentable by the United States Patent and Trademark Office, or the USPTO, or by patent offices in foreign countries. One aspect of the determination of patentability of our inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our patent claims or, if issued, affect the validity or enforceability of a patent claim. Even if the patents do issue based on our patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our 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 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. We must correctly interpret the relevance or the scope of a patent or a pending application, determine whether our products are covered by a third-party patent, predict whether a third party's pending application will issue with claims of relevant scope, and determine the expiration date of any patent in the United States or abroad that we consider relevant. Failure to do so may negatively impact our ability to develop and market our products.

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, which may cause us to operate our business in a more costly or otherwise adverse manner that was not anticipated.

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

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

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

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

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 in recent years has been the subject of much litigation, resulting in court decisions, including Supreme Court decisions, that have increased uncertainties as to the ability to obtain and enforce patent rights in the future. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries could increase the uncertainties and costs. For example, in September 2011 the Leahy-Smith America Invents Act, or the America Invents Act, was signed into law and included a number of significant changes to United States patent law as then existed. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. Such avenues 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. The America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

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.

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

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

We may become involved in lawsuits alleging that we have infringed the intellectual property rights of third parties or to protect or enforce our patents or other intellectual property, which litigation could be expensive, time consuming and adversely affect our ability to develop or commercialize our 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 product 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 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, which may not be able to do. 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 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.

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 be subject to claims that we or our employees, consultants, or independent contractors have inadvertently or otherwise used or disclosed alleged trade secrets or other confidential information of former employers or competitors.

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 product candidates, if such technologies or features are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. Moreover, any such litigation or the threat thereof may adversely affect our reputation, our ability to form strategic alliances or sublicense our rights to collaborators, engage with scientific advisors or hire employees or consultants, each of which would have an adverse effect on our business, results of operations and financial condition.

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

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

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

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

The COVID-19 pandemic has presented a substantial public health and economic challenge around the world. To date, the COVID-19 pandemic has caused widespread disruptions to the United States and global economy and has contributed to significant volatility and negative pressure in financial markets.

The continued spread of COVID-19 and identification of new strains of the virus could adversely impact our clinical trials, manufacturing and other operations, including:

- **Clinical trials:** The COVID-19 pandemic may cause delays in some of our clinical trials. Responses to COVID-19 by healthcare providers and regulatory agencies or staffing issues related to the COVID-19 response or the "great resignation" could impact the ability of clinical trial sites to participate in new clinical trials and could delay the commencement of trials, site initiation, compliance in the trials, the completion of trials, slow down enrollment, and make the ongoing collection of data for patients enrolled in studies more difficult or intermittent. Missing data could undermine data integrity and probability of success. In addition, due to COVID-19, some participants and clinical investigators may be unable or unwilling to comply with clinical trial protocols. Any negative impact COVID-19 has on study start-up, patient enrollment, retention or treatment, or data collection and validation 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.
- **Manufacturing:** The COVID-19 pandemic may negatively affect 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. Demand for vaccines and treatments for COVID-19 may make it

more difficult to obtain materials or manufacturing slots for the products needed for our clinical trials, which could lead to delays in clinical trials.

- **Operations:** As a result of the challenges the COVID-19 pandemic brought, we took various steps to support our employees, including transitioning to a hybrid work model and offering flexible schedules. We will continue to monitor and make adjustments in response to the public health environment, together with local, state and federal guidance regarding workplace protective measures. These measures entail risk. For instance, remote work may delay our preclinical programs development, disrupt our operations and increase the risk of a cybersecurity incident. If there is an increase in COVID-19 infection rates or new outbreaks, our business may be adversely impacted, the extent of which will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as new variants, the duration of outbreaks, 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.
- **Stock Price:** 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.

In addition, to the extent the 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 we advance our research and development programs and as we continue to operate 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 product candidates receive marketing approval, sales, marketing, and distribution. To manage our anticipated future growth, we must:

- identify, recruit, integrate, retain, 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 product candidates will depend, in part, on our ability to effectively manage any future growth. 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 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, and on our other executives. Although we have entered into employment agreements with each of our executives, such agreements are not for a specific term and each executive may terminate their employment with us at any time. We are not aware of any present intention of any of these key personnel to leave us. We do not maintain “key person” insurance for any of our executives or employees. We believe that any of our executives would be difficult to replace.

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 in Massachusetts, 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 our competitors have greater financial and other resources, different risk profiles and a longer history in the industry than we do, and 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 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.

Cyberattacks on our information systems risk disclosure of confidential or proprietary information, including personal data, and could 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. Successful cyberattacks 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. Successful cyberattacks cause serious negative consequences, 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. Information security breaches can result in business, legal, financial, or reputational harm, or 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., GDPR) and may cause a material adverse impact to our reputation, affect our ability to conduct new studies and potentially disrupt our business.

Failure to prevent or mitigate the impact of security or data privacy breaches exposes us to litigation and governmental investigations, which could lead to a potential disruption to our business. Failure by us or third-party CMOs, CROs or other contractors or consultants to comply with United States and international data protection laws and regulations 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.

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, political instability and military or other conflicts, including Russia's invasion of Ukraine and the potential for a wider European or global conflict, 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 negatively impact our supply chain, manufacturing costs or productivity, the economies in geographies in which we operate, or 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. 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. 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, our insurance may not be sufficient to satisfy any damages and losses. If our facilities or the manufacturing facilities of our third-party CMOs are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed. Any business interruption may have a material and adverse effect on our business, financial condition, results of operations and prospects. Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets and global trade. We conduct, and we expect to continue to conduct, portions of our clinical trials outside the United States, and unfavorable economic conditions resulting in the weakening of the United States dollar would make those clinical trials more costly to operate. Furthermore, the most recent global financial crisis caused extreme volatility and disruptions in the capital and credit markets. A severe or prolonged economic downturn could result in a variety of risks to our business, such as a reduced ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy, including supply chain disruptions, labor shortages and persistent inflation, could also strain our suppliers, possibly resulting in supply disruption, and could negatively impact our access to liquidity and banking relationships. 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 and expect to continue to contract manufacturing operations to third parties, and clinical quantities of our lead product candidates inupadenant and belrestotug are manufactured by these third parties outside the United States, including in China. 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 and in 2017, the United States proposed tariffs of 25% on raw ingredients for pharmaceuticals, such as the active pharmaceutical ingredients for our proposed product candidates. 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.

We may be exposed to significant foreign exchange risk.

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

Our operations subject us to potentially adverse tax consequences.

We are required to file income tax returns in the U.S. and Belgium, which requires us to interpret the applicable tax laws and regulations in effect in such jurisdictions. Furthermore, significant judgment is required in evaluating our tax positions, including our provision for income taxes, our deferred tax assets and liabilities and any valuation

allowance recorded against our net deferred tax assets. Our interpretation or application of accounting policies may be questioned by the relevant tax authorities, and the relevant tax laws and regulations, or the interpretation thereof, including through tax rulings, by the relevant tax authorities, may be subject to change. Any adverse outcome of such a review or change, including any adverse resolution of one or more uncertain tax positions, 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.

United States federal income tax reform or changes in Belgian tax laws and regulations could adversely affect our business and financial condition.

We are subject to taxes in the U.S. and Belgium, as well as laws and regulations regarding taxes, levies, and other charges in different countries. These tax rules, which are subject to change, affect tax liabilities imposed in respect of our assets, income, and operations, including transactions with third parties, affiliates and employees. Dealings and other intercompany transactions between current group companies 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 imposed by jurisdictions in which such companies are resident and can affect the income tax liability of each company.

Our effective tax rates and liability for tax in Belgium, the United States, and other jurisdictions 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.

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.

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

At March 31, 2023, we had an estimated cumulative carry forward tax losses of \$44.4 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 the availability of the Belgian research and development tax credit which can offset the Belgian corporate income tax due or it can be refunded if not used. We also expect to benefit from the innovation income deduction, or IID, in Belgium, which allows net profits attributable to revenue from patented products (or products for which the parent application is pending), among other things, be taxed at a lower rate than other revenues. 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.

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 €23.2 million for our research and development programs for belrestotug and inupadenant. During the three months ended March 31, 2023, we did not receive cash under the belrestotug grant and the inupadenant grant.

We must repay 30% of the amount received under the grants unless we decide not to pursue commercial development or out licensing of the drug candidate, inform the Walloon Region of our decision and justify our decision based upon the failure of the program, and transfer the intellectual property rights 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 0.15% royalty on revenue resulting from the second RCA grant (increased from 0.12% effective December 2021). The maximum amount payable to the Walloon Region under each grant, including the fixed repayment, the royalty on revenue, and the interest thereon, is twice the amount of funding received.

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

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

We face an inherent risk of product liability exposure related to the testing of our 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 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.

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

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

Risks related to ownership of our common stock

The trading price of our common stock has been volatile.

The trading price of our common stock has been 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 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.

Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance.

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

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

To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholder's ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect the rights of our stockholders. 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 63.5% of our outstanding voting stock as of March 31, 2023. These stockholders 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 the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act 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 \$1.235 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.

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.

As of March 31, 2023, we no longer qualified as a smaller reporting company, and can no longer take advantage of many of the same exemptions from disclosure requirements, including regarding executive compensation in our periodic reports and proxy statements.

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

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

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

In addition, we are governed by the provisions of Section 203 of the Delaware General Corporate Law, which may prohibit certain business combinations with stockholders owning 15% or more of our outstanding voting stock. These anti-takeover provisions and other provisions in our amended and restated certificate of incorporation and amended and restated bylaws could make it more difficult for stockholders or potential acquirers to obtain control of our board of directors or initiate actions that are opposed by the then-current board of directors and could also delay or impede a merger, tender offer, or proxy contest involving our company. These provisions could also discourage proxy contests and make it more difficult for 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.

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

None.

Item 3. Defaults Upon Senior Securities.

Not applicable.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

Not applicable.

Item 6. Exhibits.

Exhibit Number	Description
3.1	<u>Second Amended and Restated Certificate of Incorporation of the Registrant (Incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-39401) filed with the Securities and Exchange Commission on July 28, 2020)</u>
3.2	<u>Amended and Restated Bylaws of the Registrant (Incorporated by reference to Exhibit 3.3 to the Registrant's Current Report on Form 8-K (File No. 001-39401) filed with the Securities and Exchange Commission on July 28, 2020)</u>
4.1	<u>Specimen Common Stock Certificate (Incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1/A (File No. 333-239415) filed with the Securities and Exchange Commission on July 20, 2020)</u>
31.1*	<u>Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
31.2*	<u>Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.</u>
32.1*+	<u>Certification Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.</u>
101.INS	XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

Management contract or compensatory plan or arrangement.

+ 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.

Date: May 10, 2023

iTeos Therapeutics, Inc.

By: /s/ Michel Detheux

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

Date: May 10, 2023

By: /s/ Matthew Gall

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

**CERTIFICATION 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**

I, Michel Detheux, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended March 31, 2023 of iTeos Therapeutics, Inc., (the "Registrant");
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(s) 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (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(s) 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: May 10, 2023

By:

/s/ Michel Detheux

Michel Detheux
Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION 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**

I, Matthew Gall, certify that:

1. I have reviewed this Quarterly Report on 10-Q for the period ended March 31, 2023 of iTeos Therapeutics, Inc., (the "Registrant");
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(s) 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (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(s) 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: May 10, 2023

By:

/s/ Matthew Gall

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

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

In connection with the Quarterly Report of iTeos Therapeutics, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that:

- (1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; 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: May 10, 2023

By: _____
/s/ Michel Detheux
Michel Detheux
Chief Executive Officer
(Principal Executive Officer)

Date: May 10, 2023

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

A signed original of this written statement required by Section 906 of the Sarbanes-Oxley Act of 2002 has been provided to iTeos Therapeutics, Inc. and will be retained by iTeos Therapeutics, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.
