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, 2026

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: 001-43250

Hemab Therapeutics Holdings, Inc.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**41-4241952**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
101 Main Street, Suite 1220 Cambridge, Massachusetts	**02142**
(Address of principal executive offices)	**(Zip Code)**

(617) 553-3952
(Registrant's telephone number, including area code)

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, $0.0001 par value per share	**COAG**	**Nasdaq Global Select Market**

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

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

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

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

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

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

As of May 8, 2026, the registrant had 46,705,410 shares of common stock, $0.0001 par value per share, outstanding.

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q, or this Quarterly Report, contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act and Section 21E of the Securities Exchange Act of 1934, as amended, that involve substantial risk and uncertainties. All statements, other than statements of historical fact, contained in this Quarterly Report, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “might,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would,” or the negative of these words or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this Quarterly Report include, among other things, statements about:

- the initiation, timing, progress and results of our research and development programs and preclinical studies and clinical trials, including the timing of our planned Phase 3 clinical trial of sutacimig in patients with Glanzmann thrombasthenia;
- our estimates regarding expenses, future revenue, capital requirements, need for additional financing and the period over which we believe our cash, cash equivalents, and marketable securities will be sufficient to fund our operating expenses and capital expenditure requirements;
- the timing of and our ability to complete clinical development of, submit applications for and obtain and maintain regulatory approvals for our current and future product candidates;
- the potential advantages of our current and future product candidates;
- our plans to develop and, if approved, subsequently commercialize any product candidates we may develop;
- the rate and degree of market acceptance and clinical utility of our products, if approved;
- our estimates regarding the addressable patient population and potential market opportunity for our current and future product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our expectations regarding our ability to obtain and maintain intellectual property protection and to remain in compliance with our existing license agreements;
- our ability to identify additional products, product candidates or technologies with significant commercial potential that are consistent with our commercial objectives;
- our ability to attract and retain key scientific and management personnel;
- our expectations regarding milestone and/or royalty payments under any of our current or future license agreements;
- the impact of government laws and regulations, including any new regulatory requirements in the countries in which we operate;
- our competitive position and expectations regarding developments and projections relating to our competitors and any competing therapies that are or become available;
- developments relating to our competitors and our industry;
- our reliance on and the performance of third parties that conduct clinical trials of our product candidates and manufacture our product candidates;
- our ability to identify, establish and maintain collaborations or obtain additional funding;
- general economic, industry and market conditions, including rising interest rates, inflation and tariffs; and
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act or a smaller reporting company.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in this Quarterly Report, particularly in Item 1A. “Risk Factors” in this Quarterly Report, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Moreover, we operate in a competitive and rapidly changing environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for us to predict all risk factors and uncertainties that could have an impact on us, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments we may make or enter into.

You should read this Quarterly Report and the documents that we have filed or incorporated by reference as exhibits to this Quarterly Report with the understanding that our actual future results may be materially different from what we expect. The forward-looking statements contained in this Quarterly Report are made as of the date of this Quarterly Report, and we do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by applicable law.

RISK FACTOR SUMMARY

Our business is subject to a number of risks that, if realized, could materially affect our business, prospects, operating results and financial condition. These risks are discussed more fully in the "Risk Factors" section of this Quarterly Report. These risks include, but are not limited to, the following:

- We have incurred significant losses since our inception and have no products approved for sale. We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability.
- We have never generated revenue from product sales and may never achieve or maintain profitability.
- We are heavily dependent on the success of sutacimig and HMB-002, which are our only clinical-stage product candidates.
- We will need substantial additional funding. If we are unable to raise capital on acceptable terms when needed, or at all, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.
- Our limited operating history may make it difficult to evaluate the success of our business to date and to assess our future viability.
- We are early in our clinical development efforts. If we are unable to successfully complete clinical development, obtain marketing approval for, and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.
- Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We will be required to incur substantial costs and may experience delays in completing, or ultimately be unable to complete, the development and commercialization of any product candidates.
- The outcome of preclinical studies and earlier-stage clinical trials may not be predictive of the success of later-stage clinical trials.
- Serious adverse events of thrombosis have been identified in the development of sutacimig, and if additional serious adverse events or unacceptable side effects are identified during the development of our product candidates and any other product candidates we may develop, we may need to abandon or limit our development of those product candidates.
- If we engage in future acquisitions, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.
- Even if any product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- We rely, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, which may harm our business.
- We contract with third parties for the manufacture of our product candidates, plan to contract with third parties for any other product candidates we may develop for preclinical and clinical testing and expect to continue to do so for commercialization. This reliance on third parties entails risks, including that such third parties may not be able to comply with applicable regulatory requirements. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval.
- We may enter into collaborations with third parties for the development or commercialization of product candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates and our business could be adversely affected.
- If we fail to comply with our obligations under our existing license agreements with Novo Nordisk A/S and Genmab A/S, or under any future intellectual property licenses, or otherwise experience disruptions to our business relationships with our current or any future licensors, we could lose intellectual property rights that are important to our business.

- If we are unable to obtain, maintain, enforce, defend and otherwise protect the intellectual property relating to our technology and product candidates, and if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and product candidates may be adversely affected.
- Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. As a result, we cannot predict when or if, and in which territories, we will obtain marketing approval to commercialize a product candidate.
- We have identified material weaknesses in our internal control over financial reporting. If we are unable to remedy our material weaknesses, or if we fail to establish and maintain an effective system of internal control over financial reporting, we may be unable to produce timely and accurate financial statements or prevent fraud, which could adversely impact our business and our stock price.
- An active trading market for our common stock may not continue to develop or be sustained.

PART I—FINANCIAL INFORMATION

Item 1. Condensed Consolidated Financial Statements (Unaudited)

HEMAB THERAPEUTICS HOLDINGS, INC.
Condensed Consolidated Balance Sheets
(in thousands, except share and per share amounts)
(unaudited)

	March 31, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 49,860	$ 87,974
Marketable securities	113,671	97,511
Prepaid expenses and other current assets	5,900	7,066
Total current assets	169,431	192,551
Property and equipment, net	648	609
Operating right-of-use assets	939	1,092
Other non-current assets	4,240	531
Total assets	$ 175,258	$ 194,783
Liabilities, convertible preference shares, convertible preferred stock and stockholders' deficit		
Current liabilities:		
Accounts payable	$ 5,682	$ 5,734
Accrued expenses and other current liabilities	6,963	4,296
Operating lease liabilities	544	647
Total current liabilities	13,189	10,677
Operating lease liabilities, net of current portion	519	573
Total liabilities	13,708	11,250
Commitments and contingencies (Note 8)		
Convertible preferred stock and convertible preference shares:		
Series Seed convertible preferred stock and convertible preference shares, $0.0001 par value and DKK 1 par value as of March 31, 2026 and December 31, 2025, respectively; 23,343 shares authorized, issued and outstanding as of March 31, 2026 and December 31, 2025; liquidation preference of $3,126 and $2,939 as of March 31, 2026 and December 31, 2025, respectively	5,236	5,236
Series A convertible preferred stock and convertible preference shares, $0.0001 par value and DKK 1 par value as of March 31, 2026 and December 31, 2025, respectively; 225,866 shares authorized, issued and outstanding as of March 31, 2026 and December 31, 2025; liquidation preference of $53,392 and $54,528 as of March 31, 2026 and December 31, 2025, respectively	63,536	63,536
Series B convertible preferred stock and convertible preference shares, $0.0001 par value and DKK 1 par value as of March 31, 2026 and December 31, 2025, respectively; 442,205 shares authorized, issued and outstanding as of March 31, 2026 and December 31, 2025; liquidation preference of $135,248 as of March 31, 2026 and December 31, 2025, respectively	134,975	134,975
Series C convertible preferred stock and convertible preference shares, $0.0001 par value and DKK 1 par value as of March 31, 2026 and December 31, 2025, respectively; 512,991 shares authorized, issued, and outstanding as of March 31, 2026 and December 31, 2025; liquidation preference of $156,898 as of March 31, 2026 and December 31, 2025, respectively	156,421	156,421
Stockholders' deficit:		
Ordinary shares, DKK 1 par value; no shares and 946,000 shares authorized, issued, and outstanding as of March 31, 2026 and December 31, 2025, respectively	—	132
Common stock, $0.0001 par value; 1,446,166 shares and no shares authorized as of March 31, 2026 and December 31, 2025, respectively; 946,000 shares and no shares issued and outstanding as of March 31, 2026 and December 31, 2025, respectively	—	—
Additional paid-in capital	6,366	4,916
Accumulated other comprehensive (loss) income	(439)	175
Accumulated deficit	(204,545)	(181,858)
Total stockholders' deficit	(198,618)	(176,635)
Total liabilities, convertible preference shares, convertible preferred stock and stockholders' deficit	$ 175,258	$ 194,783

See accompanying notes to the financial statements.

HEMAB THERAPEUTICS HOLDINGS, INC.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)
(unaudited)

	Three Months Ended March 31,	
	2026	2025
Operating expenses:		
Research and development	$ 19,461	$ 14,101
General and administrative	4,151	2,459
Total operating expenses	23,612	16,560
Loss from operations	(23,612)	(16,560)
Other income (expense), net:		
Interest income	1,219	473
Other (expense) income, net	(282)	591
Total other income, net	937	1,064
Loss before income tax expense	(22,675)	(15,496)
Income tax (expense) benefit	(12)	190
Net loss	$ (22,687)	$ (15,306)
Net loss per share, basic and diluted	$ (23.98)	$ (16.18)
Weighted average common stock outstanding, basic and diluted	946,000	946,000
Other comprehensive (loss) income:		
Net loss	(22,687)	(15,306)
Net unrealized gain (loss) on available-for-sale debt securities	(614)	974
Total comprehensive loss	$ (23,301)	$ (14,332)

See accompanying notes to the financial statements.

HEMAB THERAPEUTICS HOLDINGS, INC.
Condensed Consolidated Statements of Changes in Convertible Preference Shares, Convertible Preferred Stock and Stockholders' Deficit
(in thousands, except share amounts)
(unaudited)

	Series Seed Convertible Preference Shares		Series A Convertible Preference Shares		Series B Convertible Preference Shares		Series C Convertible Preference Shares		Series Seed Convertible Preferred Stock		Series A Convertible Preferred Stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Ordinary Shares		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount		
Balance at December 31, 2024	23,343	$ 5,236	225,866	$ 63,536	442,205	$ 134,975	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	946,000	$ 132	—	$ —	$ 2,905	$ (365)
Equity-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	459	—
Other comprehensive income	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	974
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Balance at March 31, 2025	23,343	$ 5,236	225,866	$ 63,536	442,205	$ 134,975	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	946,000	$ 132	—	$ —	$ 3,364	$ 609
Balance at December 31, 2025	23,343	$ 5,236	225,866	$ 63,536	442,205	$ 134,975	512,991	$ 156,421	—	$ —	—	$ —	—	$ —	—	$ —	946,000	$ 132	—	$ —	$ 4,916	$ 175
Effect of Reorganization	(23,343)	(5,236)	(225,866)	(63,536)	(442,205)	(134,975)	(512,991)	(156,421)	23,343	5,236	225,866	63,536	442,205	134,975	512,991	156,421	(946,000)	(132)	946,000	—	132	—
Equity-based compensation	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	1,318	—
Other comprehensive income	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(614)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Balance at March 31, 2026	—	$ —	—	$ —	—	$ —	—	$ —	23,343	$ 5,236	225,866	$ 63,536	442,205	$ 134,975	512,991	$ 156,421	—	$ —	946,000	$ —	$ 6,366	$ (439)

See accompanying notes to the financial statements

HEMAB THERAPEUTICS HOLDINGS, INC.
Condensed Consolidated Statements of Cash Flows
(in thousands)
(unaudited)

	Three Months Ended March 31,	
	2026	2025
Cash flows from operating activities:		
Net loss	$ (22,687)	$ (15,306)
Adjustments to reconcile net loss to net cash used in operating activities:		
Equity-based compensation	1,318	459
Depreciation and amortization	73	75
Non-cash lease expense	153	140
Accretion of discount on available-for-sale debt securities	(816)	(208)
Other non-cash items	—	381
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,166	(65)
Other non-current assets	(1,016)	(800)
Accounts payable	(52)	2,881
Accrued expenses and other current liabilities	434	(434)
Operating lease liabilities	(157)	(139)
Other non-current liabilities	—	(17)
Net cash used in operating activities	(21,584)	(13,033)
Cash flows from investing activities:		
Purchases of available-for-sale debt securities	(15,735)	(19,948)
Maturities of available-for-sale debt securities	—	13,970
Purchases of property and equipment	(112)	(16)
Net cash used in investing activities	(15,847)	(5,994)
Cash flows from financing activities:		
Payment of offering costs	(414)	—
Principal payments on finance lease	(46)	(29)
Net cash used in financing activities	(460)	(29)
Effect of foreign exchange rate changes on cash and cash equivalents	(223)	—
Net decrease in cash and cash equivalents	(38,114)	(19,056)
Cash and cash equivalents at beginning of period	87,974	74,407
Cash and cash equivalents at end of period	$ 49,860	$ 55,351
Supplemental disclosure of cash flow activities:		
Cash paid for interest	$ —	$ 3
Supplemental disclosure of non-cash investing and financing activities:		
Deferred offering costs included in accrued expenses and accounts payable	$ 2,279	$ —

See accompanying notes to the financial statements.

HEMAB THERAPEUTICS HOLDINGS, INC.
Notes to Condensed Consolidated Financial Statements
(unaudited)

1. Description of Business and Liquidity

Nature of Business

Hemab Therapeutics Holdings, Inc. (the "Company") is a clinical-stage biotechnology company developing therapies that reimagine the treatment of blood coagulation disorders to sustain life and human resilience. Based in Denmark and the United States, the Company's mission is to build the leading coagulation company by discovering, developing, and commercializing innovative therapies for the millions of patients worldwide suffering from serious bleeding and thrombotic diseases, including Glanzmann thrombasthenia, Factor VII deficiency, Von Willebrand Disease and other conditions of abnormal bleeding, all of which can cause significant life-long burden to patients.

The Company's lead asset, sutacimig (HMB-001), is a bispecific antibody currently in Phase 1/2 clinical development for the prophylactic treatment of Glanzmann thrombasthenia and Phase 2 clinical development for the prophylactic treatment of Factor VII deficiency. The Company's second clinical-stage asset, HMB-002, is a monovalent antibody in Phase 1/2 clinical development for the subcutaneous prophylactic treatment of Von Willebrand Disease. The Company is also advancing multiple preclinical and discovery-stage assets.

Corporate Reorganization

On March 30, 2026, the Company completed a corporate reorganization pursuant to which the shareholders of Hemab ApS exchanged their shares in Hemab ApS for the same number, class and series of newly issued shares, on a one to one basis, in the newly incorporated Delaware company, Hemab Therapeutics Holdings, Inc. and, as a result, Hemab ApS became a wholly owned subsidiary of Hemab Therapeutics Holdings, Inc. The newly issued shares of Hemab Therapeutics Holdings, Inc. had substantially identical rights to the exchanged shares of Hemab ApS. As a result of the exchange, Hemab Therapeutics Holdings, Inc. became the sole shareholder of Hemab ApS, and the prior shareholders of Hemab ApS solely held shares of Hemab Therapeutics Holdings, Inc. Hemab Therapeutics Holdings, Inc. had nominal assets and liabilities and did not conduct any operations prior to the corporate reorganization other than its incorporation. Upon completion of the corporate reorganization, the historical consolidated financial statements of Hemab ApS became the historical consolidated financial statements of Hemab Therapeutics Holdings, Inc.

In connection with the corporate reorganization, the original issue price for the Company's Series Seed Convertible Stock and Series A Convertible Stock were converted from Euros and Danish Kroners ("DKK"), respectively, into U.S. dollars.The original issue price was set for each series of convertible preferred stock so the convertible preferred stock would be convertible into common stock on a one-for-one basis.

In connection with the corporate reorganization, each outstanding warrant to subscribe for the purchase of ordinary shares of Hemab ApS was assumed by Hemab Therapeutics Holdings, Inc. and converted into a warrant to purchase the same number of shares of common stock of Hemab Therapeutics Holdings, Inc. Each new warrant otherwise had and was subject to the same terms and conditions as were in effect immediately prior to the assumption and conversion, except that any warrant exercise price that had been denominated in DKK prior to the corporate reorganization was converted into an exercise price in U.S. dollars at the exchange rate as in effect at the close of business on the business day prior to the corporate reorganization. No warrants of Hemab ApS were outstanding following such assumption and conversion.

Additionally, on April 1, 2026, Hemab ApS transferred its shares of Hemab Therapeutics Inc., a Delaware corporation and wholly owned subsidiary of Hemab ApS, to Hemab Therapeutics Holdings, Inc. in exchange for the issuance of a promissory note and, as a result, Hemab Therapeutics Inc. became a wholly owned subsidiary of Hemab Therapeutics Holdings, Inc.

Risks and Uncertainties

The Company is subject to risks common to companies in the biotechnology industry including, but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations and the need to obtain additional financing. 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.

The Company's product candidates and programs are in preclinical and clinical development. There can be no assurance that the Company's research and development efforts will be successfully completed, that adequate protection for its intellectual property will be obtained, that any product candidates developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees and consultants.

Stock Split

The Company's board of directors and stockholders approved a 22-for-one forward stock split of the Company's issued and outstanding common stock and a proportional adjustment to the existing conversion ratios for the outstanding shares of convertible preferred stock, which became effective on April 24, 2026. Accordingly, all share and per share amounts for all periods presented in the accompanying condensed consolidated financial statements and the notes thereto have been retroactively adjusted, where applicable, to reflect the stock split.

Liquidity and Managements Plan

Since inception, the Company has devoted substantially all its efforts to business planning, conducting research and development, recruiting management and technical staff, and raising capital. The Company has financed its operations primarily through private placements of convertible preference shares and issuance of convertible debt and, most recently, from the sale of common stock in its initial public offering (the "IPO") in May 2026.

The Company's continued discovery and development of product candidates will require significant additional research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel, infrastructure, and compliance-reporting capabilities. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales.

The Company has incurred losses since inception and had an accumulated deficit of $204.5 million as of March 31, 2026. The Company expects that its operating losses and negative cash flows will continue for the foreseeable future as it continues development of its product candidates.

As of March 31, 2026, the Company had cash and cash equivalents, and marketable securities of $163.5 million. The Company believes that its existing cash, cash equivalents, and marketable securities, together with the net proceeds from the IPO of approximately $317.2 million, will enable it to fund its operating expenses and capital expenditure requirements for at least one year from the date of the issuance of these unaudited condensed consolidated financial statements.

Until such a time when the Company can generate significant revenue from product sales, if ever, the Company expects to finance its operations through a combination of equity offerings, debt financings, collaborations, strategic alliances, and marketing, distribution or licensing arrangements. The Company may be unable to raise additional funds or enter into such other agreements or arrangements when needed, on favorable terms, or at all. The Company's failure to raise capital or enter into such agreements or arrangements as, and when needed, could have a material adverse effect on its business, results of operations and financial condition, including potentially requiring it to delay, limit, reduce or eliminate product development or future commercialization efforts, or grant rights to develop and market current or future development product candidates that the Company would otherwise prefer to develop and market itself.

2. Summary of Significant Accounting Policies

There have been no significant changes from the significant accounting policies and estimates disclosed in Note 2 of the "Notes to Consolidated Financial Statements" in the audited consolidated financial statements for the year ended December 31, 2025 and notes thereto, included in the Company's final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, with the U.S. Securities Exchange Commission on May 1, 2026, except as noted below.

Principles of Consolidation

The Company's condensed consolidated financial statements include the accounts of its subsidiaries, Hemab ApS and Hemab Therapeutics, Inc., which was a wholly owned subsidiary of Hemab ApS until April 1, 2026. As a result of the corporate reorganization described in Note 1 "Description of Business and Liquidity—Corporate Reorganization", Hemab ApS became a wholly owned subsidiary of Hemab Therapeutics Holdings, Inc. and, accordingly, the Company's consolidated financial statements are those of Hemab Therapeutics Holdings, Inc. for the periods after the corporate reorganization and are those of Hemab ApS for historical periods before the corporate reorganization. Management has concluded the Company has a single reporting segment for purposes of reporting financial condition and results of operations. All intercompany transactions and balances have been eliminated in accordance with ASC 810, *Consolidation*.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

Unaudited Interim Consolidated Financial Information

The accompanying unaudited condensed consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements of Hemab ApS and reflect, in the opinion of management, all adjustments of a normal and recurring nature that are necessary for the fair statement of the Company's financial position as of March 31, 2026 and its results of operations and cash flows for the three months ended March 31, 2026 and 2025. The results of operations for the three months ended March 31, 2026 are not necessarily indicative of the results to be expected for the year ending December 31, 2026, or for any other future annual or interim period. The condensed consolidated balance sheet as of December 31, 2025 included herein was derived from the audited financial statements of Hemab ApS as of that date. Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with GAAP have been condensed or omitted from these unaudited condensed consolidated financial statements.

Foreign Currency

The financial statements are presented in U.S. dollars, the Company's reporting currency. The functional currency of Hemab ApS and Hemab Therapeutics, Inc. is the U.S. dollar. Transaction gains and losses resulting from exchange rate changes on transactions denominated in currencies other than the U.S. dollar are recognized in other (expense) income, net in the consolidated statements of operations and comprehensive loss.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and in these accompanying notes. The Company bases its estimates on historical experience, known trends and other market-specific or other relevant factors and assumptions that it believes to be reasonable under the circumstances. On an ongoing basis, management evaluates its estimates, which include, but are not limited to, accrued research and development expenses, the fair value of the ordinary shares and warrants for equity-based compensation expense, and the valuation of the Company's deferred tax assets. Changes in estimates are recorded in the period in which they become known.

Concentrations of Credit Risk

Financial instruments that potentially expose the Company to concentrations of credit risk primarily consist of cash, cash equivalents, and marketable securities. The Company's investment portfolio is primarily comprised of short term debt securities issued by the U.S., Danish, and German governments. The Company places its cash in financial institutions that management believes to be of high credit quality and, consequently, the Company does not believe it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships. Bank accounts in the United States are insured by the Federal Deposit Insurance Corporation up to $250,000.

Deferred Offering Costs

Deferred offering costs consist of certain legal, professional, accounting and other third-party fees that are directly associated with the IPO. These direct costs are capitalized and recorded as other non-current assets on the condensed consolidated balance sheets. The deferred offering costs will be recorded against the IPO proceeds upon the consummation of the IPO, which was completed on May 4, 2026. As of March 31, 2026, the Company had $2.7 million of deferred offering costs.

Comprehensive Loss

Comprehensive loss includes net loss as well as other changes in stockholders' deficit that result from transactions and events other than those with stockholders. The Company's unrealized gains and losses on available-for sale-debt securities represent the only component of other comprehensive income (loss).

Recently Issued Accounting Standards

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* ("ASU 2023-09"). ASU 2023-09 will require disclosure of additional information in specified categories with respect to the reconciliation of the effective tax rate to the statutory rate (the rate reconciliation) for federal, state and foreign income taxes. ASU 2023-09 will also require information pertaining to taxes paid (net of refunds received) to be disaggregated for federal, state and foreign taxes and further disaggregated for specific jurisdictions to the extent the related amounts exceed a quantitative threshold. ASU 2023-09 will be effective for the Company in the annual periods beginning after December 15, 2025. Early adoption is permitted for annual financial statements that have not yet been issued or made available for issuance. The Company is currently assessing the impact adoption of ASU 2023-09 will have on its consolidated financial statements and related disclosures.

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* ("ASU 2024-03"). ASU 2024-03 will require disclosure of disaggregated information about certain income statement expense line items on an annual and interim basis, including purchases of inventory, employee compensation, depreciation, intangible asset amortization and depletion for each income statement line item that contains those expenses. ASU 2024-03 also will require certain amounts already disclosed under existing U.S. GAAP to also be disclosed as a separate category in disaggregated expense table(s), if those amounts are recognized in the relevant expense line item. The amendments in ASU 2024-03 will be effective for the Company in annual reporting periods beginning after December 15, 2026, and interim reporting periods within annual reporting periods beginning after December 15, 2027. The Company is currently assessing the impact adoption of ASU 2024-03 will have on its consolidated financial statements and related disclosures.

In December 2025, the FASB issued ASU 2025-11, *Interim Reporting (Topic 270): Narrow-Scope Improvements* ("ASU 2025-11") to provide clarifications intended to improve the consistency and usability of interim disclosure requirements. ASU 2025-11 includes a comprehensive listing of required interim disclosures and a new disclosure principle for reporting material events occurring after the most recent annual period. ASU 2025-11 is effective for interim periods within annual reporting periods beginning after December 15, 2027, and early adoption is permitted. The amendments in this update permit an entity to apply the new guidance using a prospective or retrospective approach. The Company is currently assessing the impact adoption of ASU 2025-11 will have on its consolidated financial statements and related disclosures.

3. Fair Value Measurements

The following tables present information about the Company's financial assets measured at fair value on a recurring basis and indicate the level of the fair value hierarchy utilized to determine such fair values as of March 31, 2026 and December 31, 2025 (in thousands):

	March 31, 2026			
	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Marketable securities:				
U.S. treasury securities	$ —	$ 98,281	—	$ 98,281
Non-U.S. debt securities	—	15,390	—	15,390
Total assets measured at fair value	$ —	$ 113,671	$ —	$ 113,671

	December 31, 2025			
	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Cash equivalents:				
Certificates of deposit	$ —	$ 50,930	—	$ 50,930
Non-U.S. debt securities	—	17,638	—	17,638
Marketable securities:				
U.S. treasury securities	$ —	$ 97,511	$ —	$ 97,511
Total assets measured at fair value	$ —	$ 166,079	$ —	$ 166,079

The Company's cash equivalents and marketable securities were valued based on Level 2 inputs and in determining the fair value the Company relied on quoted prices for similar securities in active markets or other inputs that are observable or can be corroborated by observable market data.

4. Available-For-Sale Debt Securities

Available-for-sale debt securities consisted of the following as of March 31, 2026 and December 31, 2025 (in thousands):

	March 31, 2026			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Marketable securities:				
U.S. treasury securities	$ 98,393	$ —	$ (112)	$ 98,281
Non-U.S. debt securities	15,717	—	(327)	15,390
Total	$ 114,110	$ —	$ (439)	$ 113,671

	December 31, 2025			
	Amortized Cost	Unrealized Gains	Unrealized Losses	Fair Value
Cash equivalents:				
Non-U.S. debt securities	$ 17,415	$ 223	$ —	$ 17,638
Marketable securities:				
U.S. treasury securities	97,559	—	(48)	97,511
Total	$ 114,974	$ 223	$ (48)	$ 115,149

All of the Company's available-for-sale debt securities as of March 31, 2026 and December 31, 2025 had a contractual maturity of less than 12 months. The Company did not realize any gains or losses recognized on the sale of available-for-sale debt securities during the three months ended March 31, 2026 and year ended December 31, 2025, and, as a result, the Company did not reclassify any amounts out of accumulated comprehensive loss. All of the Company's available-for-sale debt securities as of March 31, 2026 and December 31, 2025 are classified as current as they mature within one year from the balance sheet date.

As of March 31, 2026, the Company held four securities in an unrealized loss position with an aggregate fair value of $113.7 million. As of December 31, 2025, the Company held three securities in an unrealized loss position with an aggregate fair value of $97.5 million. None of the securities were in an unrealized loss position for greater than 12 months.

The Company has the intent and ability to hold its debt securities until recovery of their amortized cost bases, which may be maturity. As a result, the Company did not recognize any differences between the fair value and amortized cost basis as a loss in its consolidated statements of operations and comprehensive loss for the three months ended March 31, 2026 and year ended December 31, 2025. The Company did not record any credit-related impairments for its available-for-sale debt securities for the three months ended March 31, 2026 and year ended December 31, 2025.

5. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consisted of the following (in thousands):

	As of March 31, 2026	As of December 31, 2025
Prepaid expenses	$ 4,470	$ 4,437
Other receivables	1,430	2,629
Total	$ 5,900	$ 7,066

6. Property and Equipment, net

Property and equipment, net, consisted of the following (in thousands):

	As of March 31, 2026	As of December 31, 2025
Laboratory equipment	$ 887	$ 775
Furniture and fixtures	413	413
Leasehold improvements	82	82
Computer equipment	62	62
Total property and equipment, at cost	1,444	1,332
Less: accumulated depreciation	(796)	(723)
Property and equipment, net	$ 648	$ 609

As of March 31, 2026, there were no finance leased assets included in property and equipment, net. As of December 31, 2025, property and equipment, net included finance leased assets of approximately $0.5 million, with accumulated depreciation of approximately $0.3 million. Depreciation expense for the three months ended March 31, 2026 and 2025 was approximately $0.1 million.

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

	As of March 31, 2026	As of December 31, 2025
Accrued contract research and development costs	$ 3,015	$ 949
Accrued employee compensation	1,286	3,007
Other	2,662	340
Total	$ 6,963	$ 4,296

8. Commitments and Contingencies

License and Collaboration Agreements

The Company is party to certain agreements that may require future payments upon the achievement of specified development, regulatory, and commercial milestones, as well as royalty payments. These potential obligations are not recorded as liabilities until the underlying milestone event is deemed probable of occurrence and the related amount is reasonably estimable.

Agreement with Novo Nordisk

In November 2019, the Company entered into a license agreement with Novo Nordisk A/S (“Novo Nordisk”), pursuant to which Novo Nordisk granted the Company an exclusive (even as to Novo Nordisk), worldwide and sublicensable license under specified patent rights, and a non-exclusive, worldwide and sublicensable license under specified know-how, to research, develop, make, have made, use, offer for sale, sell, import, export or otherwise exploit, or transfer possession of or title in, products (“Novo Licensed Products”), containing bispecific IgG antibodies targeting TLT-1 and Factor VII, including sutacimig, for the treatment of bleeding conditions, including hemophilia (the “Novo Nordisk Agreement”). Under the terms of the Novo Nordisk Agreement, the Company has agreed to use commercially reasonable efforts to develop and commercialize a Novo Licensed Product.

The Company is obligated to pay to Novo Nordisk a one-time DKK 40 million milestone payment upon achievement by a Novo Licensed Product of a specified regulatory milestone event, and the Company is also obligated to pay Novo Nordisk tiered royalties, in the low single-digit percentages, on aggregate annual net sales of all Novo Licensed Products, on a Novo Licensed Product-by-Novo Licensed Product and country-by-country basis, until the later of the expiration of the last valid claim in the licensed patents under the Novo Nordisk Agreement covering such Novo Licensed Product in such country and ten years following the first commercial sale of such Novo Licensed Product in such country. The Company currently expects that all of the licensed patents under the Novo Nordisk Agreement will expire by 2040, potentially extending to 2045 with patent term extension. To date, the Company has not made any payments to Novo Nordisk under the Novo Nordisk Agreement.

The Novo Nordisk Agreement will continue in force until it is terminated. On expiration of each royalty term, the Company's license becomes royalty-free, perpetual, and irrevocable with respect to the applicable Novo Licensed Product in the applicable country. Either party may terminate the Novo Nordisk Agreement for the other party's uncured material breach or insolvency. The Company may terminate the Novo Nordisk Agreement for any reason upon 90 days' written notice to Novo Nordisk. In the event that Novo Nordisk regains control of the exclusive right to exploit the Novo Licensed Product, the Novo Nordisk Agreement will automatically terminate.

Agreement with Genmab

In April 2020, the Company entered into a license agreement with Genmab A/S ("Genmab"), pursuant to which Genmab granted the Company an exclusive (even as to Genmab and its affiliates), worldwide and sublicensable license under platform technology patent rights and know-how relating to Genmab's proprietary DuoBody® platform to research, develop, make, have made, use, manufacture, import, export and commercialize products comprising bispecific IgG antibodies targeting TLT-1 and Factor VII (the "TLT-1/Factor VII Antibody Products"), including sutacimig, for the treatment of bleeding conditions, including hemophilia (the "Genmab Agreement"). Under the terms of the Genmab Agreement, the Company has agreed to use commercially reasonable efforts to develop, manufacture, obtain regulatory approval for and commercialize TLT-1/Factor VII Antibody Products worldwide.

Under the Genmab Agreement, the Company is obligated to pay Genmab a percentage of all net profit (i.e., revenue and other proceeds less specified direct costs the Company incurs to conduct research, development, manufacture and commercialization of TLT-1/Factor VII Antibody Products) the Company or its affiliates receive with respect to any TLT-1/Factor VII Antibody Products, including (1) net profit from commercial sales of TLT-1/Factor VII Antibody Products and any revenue from third parties, other than Novo Nordisk, in respect of a sublicense or assignment with respect to TLT-1/Factor VII Antibody Products, including assignment fees, sublicensing fees, upfront and milestone fees, royalties and other consideration, whether in kind or cash, and (2) the net profit allocated to TLT-1/Factor VII Antibody Products that the Company or its affiliates receive if the Company undergoes a change of control (other than an acquisition by Novo Nordisk). The percentage of net profit the Company owes with respect to each TLT-1/Factor VII Antibody Product is in the low teens from the effective date of the Genmab Agreement until the first commercial sale of such TLT-1/Factor VII Antibody Product. From and after the first commercial sale of a TLT-1/Factor VII Antibody Product, the percentage of net profit the Company owes with respect to such TLT-1/Factor VII Antibody Product is in the high single digits in all territories in which the Company commercializes such TLT-1/Factor VII Antibody Product and in the mid-teens in all territories in which a third party, other than Novo Nordisk, commercializes such TLT-1/Factor VII Antibody Product. The Company is obligated to pay such percentage of net profit on a country-by-country and TLT-1/Factor VII Antibody Product-by-TLT-1/Factor VII Antibody Product basis until the later of the expiration of the last-to-expire of the platform technology patent rights licensed under the Genmab Agreement covering such TLT-1/Factor VII Antibody Product in such country and twelve years following the first commercial sale of such TLT-1/Factor VII Antibody Product in such country, which the Company refers to as the net profit share term. Following the expiration of the last-to-expire of the platform technology patent rights licensed under the Genmab Agreement covering a given TLT-1/Factor VII Antibody Product in a given country, the percentage of net profit that the Company is obligated to pay with respect to sales of such TLT-1/Factor VII Antibody Product in such country will be reduced by a specified percentage for the remainder of the net profit share term for such TLT-1/Factor VII Antibody Product in such country. The Company currently expects that all of the platform technology patent rights licensed under the Genmab Agreement will expire by 2032, though this date may be extended if, for example, Genmab files additional patents covering its platform technology. To date, the Company has not made any payments to Genmab under the Genmab Agreement.

In the event the Company seeks to sell, license or otherwise dispose of its rights to TLT-1/Factor VII Antibody Products, including through a change of control to any third party other than Novo Nordisk, the Company is obligated to provide Genmab the right to participate in any bidding process as a *bona fide* potential acquirer of such rights.

Unless earlier terminated, the Genmab Agreement will expire, on a TLT-1/Factor VII Antibody Product-by-TLT-1/Factor VII Antibody Product and country-by-country basis, upon the expiration of the last net profit share term for such

TLT-1/Factor VII Antibody Product in such country. On expiration of each net profit share term, the Company's license becomes perpetual, fully paid-up and non-exclusive with respect to the applicable TLT-1/Factor VII Antibody Product in the applicable country. Either party may terminate the Genmab Agreement for the other party's uncured material breach or insolvency or in certain events of force majeure. Genmab may terminate the Genmab Agreement if the Company or its affiliates or sublicensees challenge any of the platform technology patent rights licensed under the Genmab Agreement. The Company may terminate the Genmab Agreement for any reason upon 120 days written notice to Genmab. If Novo Nordisk obtains from us the exclusive right to exploit TLT-1/Factor VII Antibody Products, including upon termination of the Novo Nordisk Agreement, then the Genmab Agreement will terminate in all territories in which Novo Nordisk obtains such exclusive rights.

Indemnification Agreements

In the ordinary course of business, the Company may provide indemnification of varying scope and terms to vendors, lessors, business partners and other parties with respect to certain matters arising out of the relationship between such parties and the Company. In addition, the Company has entered into indemnification agreements with members of its board of directors that will require the Company, among other things, to indemnify them against certain liabilities that may arise by reason of their status or service as directors. The maximum potential amount of future payments the Company could be required to make under these indemnification agreements is, in many cases, unlimited. To date, the Company has not incurred any material costs as a result of such indemnifications. The Company is not aware of any claims under indemnification arrangements, and it has not accrued any liabilities related to such obligations as of March 31, 2026 and December 31, 2025.

Legal Proceedings

The Company, from time to time, may be party to litigation arising in the ordinary course of business. The Company was not subject to any material legal proceedings during the three months ended March 31, 2026 and year ended December 31, 2025 and, to the best of its knowledge, no material legal proceedings are currently pending or threatened.

9. Convertible Preferred Stock and Convertible Preference Shares

Series Seed Convertible Preference Shares

In November 2020, the Company executed an investment agreement under which it issued and sold 23,343 shares of Series Seed convertible preference shares ("Series Seed Convertible Preference Shares") for gross cash proceeds of €2.5 million ($3.0 million).

Series A Convertible Preference Shares

In July 2021, the Company executed an investment agreement ("Series A Investment Agreement") to issue and sell up to 225,866 shares of Series A convertible preference shares ("Series A Convertible Preference Shares") for gross proceeds of up to DKK 346.4 million ($50.9 million). In the initial closing in July 2021, the Company issued 61,600 shares of Series A Convertible Preference Shares. This included DKK 57.2 million ($9.0 million) in gross cash proceeds (37,297 shares) and DKK 37.3 million ($5.9 million) from the conversion of the principal and interest balance of debt (24,303 shares). Pursuant to the Series A Investment Agreement, the Company was obligated to issue and the investors were obligated to purchase an additional 164,266 shares of Series A Convertible Preference Shares for total cash proceeds of DKK 251.9 million ($36.0 million) in three separate closings upon the satisfaction of certain conditions related to clinical development. All of the conditions were achieved prior to February 2023. The Company incurred DKK 1.8 million ($0.3 million) of issuance costs.

Series B Convertible Preference Shares

In February 2023, the Company executed an investment agreement under which it issued and sold 442,205 shares of Series B convertible preference shares ("Series B Convertible Preference Shares") for gross cash proceeds of $135.2 million. The Company incurred $0.3 million of issuance costs.

Series C Convertible Preference Shares

In October 2025, the Company executed an investment agreement under which it issued and sold 512,991 shares of Series C convertible preference shares ("Series C Convertible Preference Shares") for gross cash proceeds of $156.9 million. The Company incurred $0.5 million of issuance costs.

In connection with the corporate reorganization, the shareholders of Hemab ApS exchanged their convertible preference shares of Hemab ApS for the same number, class and series of newly issued shares of convertible preferred stock, on a one-for-one basis, in Hemab Therapeutic Holdings, Inc.

As of March 31, 2026 and December 31, 2025, the convertible preferred stock and convertible preference shares consisted of the following (in thousands, except share data):

	March 31, 2026				
	Preferred Stock Authorized	Preferred Stock Issued and Outstanding	Carrying Value	Liquidation Preference	Common Stock Issuable Upon Conversion
Series Seed	23,343	23,343	$ 5,236	$ 3,126	513,546
Series A	225,866	225,866	63,536	53,392	4,969,052
Series B	442,205	442,205	134,975	135,248	9,728,510
Series C	512,991	512,991	156,421	156,898	11,285,802
	1,204,405	1,204,405	$360,068	$348,664	26,496,910

	December 31, 2025				
	Preference Shares Authorized	Preference Shares Issued and Outstanding	Carrying Value	Liquidation Preference	Ordinary Shares Issuable Upon Conversion
Series Seed	23,343	23,343	$ 5,236	$ 2,939	513,546
Series A	225,866	225,866	63,536	54,528	4,969,052
Series B	442,205	442,205	134,975	135,248	9,728,510
Series C	512,991	512,991	156,421	156,898	11,285,802
	1,204,405	1,204,405	$360,068	$349,613	26,496,910

The convertible preferred stock had substantially identical rights to the convertible preference shares. The rights, preferences, and privileges of the convertible preferred stock were as follows as of March 31, 2026:

Liquidation Preference

The Deemed Liquidation Events (as defined in the Company's amended and restated certificate of incorporation, as amended) included: (a) a merger, consolidation, statutory conversion, transfer of the Company, domestication, or continuance in which (i) the Company is a constituent party or (ii) a subsidiary of the Company is a constituent party and the Company issues shares of its capital stock pursuant to such merger, consolidation, statutory conversion, transfer of the Company, domestication, or continuance, (b) (i) the sale, lease, transfer, exclusive license or other disposition, in a single transaction or series of related transactions, by the Company or any subsidiary of the Company of all or substantially all the assets of the Company and its subsidiaries taken as a whole, or (ii) the sale, lease, transfer, exclusive license or other disposition (whether by merger, consolidation, statutory conversion, transfer of the Company, domestication, continuance or otherwise, and whether in a single transaction or a series of related transactions) of one or more subsidiaries of the Company if substantially all of the assets of the Company and its subsidiaries taken as a whole are held by such subsidiary or subsidiaries, except where such sale, lease, transfer, exclusive license or other disposition is to a wholly owned subsidiary of the Company. In the event of any Deemed Liquidation Event, the proceeds, if any, would have been distributed to the stockholders in accordance with the following priority:

(i) First, the holders of Series C Convertible Preferred Stock would have, for every share of Series C Convertible Preferred Stock, been entitled to be paid out an amount equal to the greater of (a) one times the applicable Original Issue Price ($305.85), plus any dividends declared but unpaid thereon, or (b) such amount per share as would have been payable had all shares of Series C Convertible Preferred Stock been converted into Common Stock. If the available proceeds were insufficient to make payment in full on the Series C Convertible Preferred Stock, then the available proceeds would have been allocated pro rata amongst the holders in proportion to their holdings of Series C Convertible Preferred Stock.

(ii) Second, the holders of Series B and/or Series A Convertible Preferred Stock would have, for every share of Series B and/or Series A Convertible Preferred Stock, been entitled to be paid out an amount equal to the greater of (a) one times the applicable Original Issue Price ($305.85 for Series B and $236.39 for Series A Convertible Preferred Stock), plus any dividends declared but unpaid thereon, or (b) such amount per share as would have been payable had all shares of Series B Convertible Preferred Stock and Series A Convertible Preferred Stock been converted into Common Stock. If the available proceeds were insufficient to make payment in full on the Series B and/or Series A Convertible Preferred Stock, then the available proceeds would have been allocated pro rata amongst the holders in proportion to their holdings of Series B and/or Series A Convertible Preferred Stock.

(iii) Third, the holders of Series Seed Convertible Preferred Stock would have, for every share of Series Seed Convertible Preferred Stock, been entitled to be paid out an amount equal to the greater of (a) one times the applicable Original Issue Price ($133.92), plus any dividends declared but unpaid thereon, or (b) such amount per share as would have been payable had all shares of Series Seed Convertible Preferred Stock been converted into Common Stock. If the available proceeds were insufficient to make payment in full on the Series Seed Convertible Preferred Stock, then the available proceeds would have been allocated pro rata amongst the holders in proportion to their holdings of Series Seed Convertible Preferred Stock (together with clauses (i) and (ii) above, the "Liquidation Amount").

The remaining proceeds, if any, following distribution of the Liquidation Amount would have been distributed to the holder of common stock on a pro rata basis.

Conversion

Shares of convertible preferred stock were convertible into common stock at the option of the holder at any time by dividing the applicable Original Issue Price by the applicable Conversion Price (each as defined in the Company's amended and restated certificate of incorporation, as amended) in effect at the time of conversion. In connection with the corporate reorganization, the Conversion Prices were set for each series of preferred stock based on the Original Issuance Price, so the convertible preferred stock would be convertible into common stock on a one-for-one basis. In addition, the convertible preferred stock was automatically convertible into common stock on a one-for-one basis (i) in the event that 50% of all convertible preferred stock voting as one share class, including 60% of the Series C Convertible Preferred Stock (the "Investor Majority"), consented to such conversion, or (ii) in the event of a public offering which generated gross proceeds of not less than $100.0 million.

On May 4, 2026, the Company completed the IPO of 19,262,500 shares of its common stock for gross proceeds of approximately $346.7 million before deducting underwriting discounts and commissions and estimated offering expenses payable by the Company. In connection with the completion of the IPO, all of the Company's convertible preferred stock converted into 26,496,910 shares of common stock, and no shares of preferred stock were outstanding. See Note 14 titled "*Subsequent Events*" for additional information.

Voting

The holders of convertible preferred stock were entitled to the number of votes equal to the number of shares of common stock into which their shares of convertible preferred stock were then convertible, on all matters to be voted upon at all general meetings and written actions in lieu of meetings.

Redemption

Shares of convertible preferred stock were not subject to mandatory redemption. Upon certain events that were outside of the Company's control, the shares of convertible preferred stock were contingently redeemable at a price equal to the greater of the Liquidation Amount or the amount that would be received on an as-converted to common stock basis.

10. Common Stock and Ordinary Shares

As of March 31, 2026, the Company had 1,446,166 shares of common stock authorized for issuance, and 946,000 shares of common stock issued and outstanding.

The holders of shares of common stock and ordinary shares were entitled to an allocation and distribution of proceeds in a Liquidation Event subject to the Liquidation Amount due to the holders of convertible preferred stock. When the Liquidation Amount had been paid in full, any remaining proceeds would have been distributed to the holders of common stock or ordinary shares, as applicable, on a pro rata basis.

The holders of common stock and ordinary shares are entitled to one vote per share on all matters to be voted upon at all general meetings and written actions in lieu of meetings.

On May 4, 2026, the Company completed the IPO of 19,262,500 shares of its common stock. See Note 14 titled "*Subsequent Events*" for additional information.

11. Equity-Based Compensation

Warrants

As of March 31, 2026, the Company had 5,227,222 warrant grants outstanding. Each vested warrant entitles the warrant holder the right to subscribe for one share of common stock. Holders of stock warrants are entitled to exercise the vested portion of the warrant. The service-based warrant grants generally vest over a four-year service period, with the first 25% vesting on the one-year anniversary of the vesting start date and the remaining vesting in equal monthly installments over the following 36 months. The service-based and performance-based warrant grants vest in the same manner as the service-based only awards to the extent the performance condition is met. The Company's warrants expire ten years after the initial grant date if they remain unexercised. Upon the exercise date, the Company issues new shares of common stock to the participant.

No warrants were exercised during the three months ended March 31, 2026.

The following assumptions were used in determining the fair value of warrants granted during the three months ended March 31, 2026:

	Three Months Ended March 31, 2026
Expected volatility	89.1% - 91.2%
Risk-free interest rate	3.8% - 3.9%
Expected term (in years)	5.8 - 6.2
Expected dividend yield	0%
Fair value per share	$9.37

The following table summarizes the Company's warrants for the three months ended March 31, 2026:

	Number of Warrants	Weighted-average exercise price per share	Weighted-average remaining contractual term (in years)	Aggregate intrinsic value (in thousands)
Outstanding, December 31, 2025	2,101,352	$ 5.68	7.4	$ 2,409
Granted	2,294,798	$ 6.00	—	$ —
Forfeited	(23,408)	$ 6.97	—	$ —
Outstanding, March 31, 2026	4,372,742	$ 5.84	8.6	$ 28,045
Exercisable at March 31, 2026	1,568,666	$ 5.12	6.9	$ 11,141
Vested and expected to vest, March 31, 2026	4,372,742	$ 5.84	8.6	$ 28,045

The weighted-average grant date fair value of the shares underlying warrants granted during the three months ended March 31, 2026 was $7.40 per share. The total fair value of the shares underlying warrants that vested during the three months ended March 31, 2026 was $0.8 million.

Performance-Based Warrants

During 2022, the Company issued warrants to certain employees that included two components: (i) a performance condition that is achieved upon the separate closings of the Series A Convertible Preferred Shares, and (ii) a service condition where the employee provides service over a four-year period. Upon the final closing of the Series A Convertible Preferred Shares in January 2023, all performance conditions had been satisfied and the warrants were subject to ongoing service conditions. Equity-based compensation expense is recognized using an accelerated attribution method over the remaining requisite service period.

Equity-Based Compensation

Equity-based compensation expense recorded as research and development and general and administrative expenses is as follows (in thousands):

	Three Months Ended March 31,	
	2026	2025
Research and development	$ 565	$ 180
General and administrative	753	279
Total	$ 1,318	$ 459

As of March 31, 2026, the total unrecognized compensation expense related to the Company's warrants was $18.8 million, which the Company expects to recognize over a weighted-average period of approximately 3.4 years.

12. Net Loss Per Share

The following table sets forth the outstanding shares of common stock and ordinary share equivalents, presented based on amounts outstanding at each period end, that were excluded from the calculation of diluted net loss per share for the periods indicated because including them would have been anti-dilutive:

	Three Months Ended March 31,	
	2026	2025
Convertible preference shares	—	15,211,108
Convertible preferred stock	26,496,910	—
Warrants to purchase ordinary shares	—	2,001,010
Warrants to purchase common stock	4,372,742	—

13. Segment Reporting

The Company has one operating segment. The Company's operating segment is engaged in the research and development of prophylactic therapeutics for bleeding disorders. The Company's Chief Executive Officer and Chief Financial Officer/General Manager are together considered the Company's CODM and together manage the Company's operations on a consolidated basis for the purposes of assessing performance and allocating resources based on net loss that also is reported on the consolidated statement of operations as consolidated net loss. This financial metric is used by the CODM to make key operating decisions such as the allocation of capital between program expenses, early-stage discovery expenses, and general and administrative expense, including headcount and facilities decisions. The measure of segment assets is reported on the balance sheet as total consolidated assets. The following table presents long-lived assets by geographic location as of March 31, 2026 and 2025 (in thousands):

	Three Months Ended March 31,	
	2026	2025
United States of America	$ 348	$ 786
Denmark	1,239	1,582
	$ 1,587	$ 2,368

The following table presents selected financial information about the Company's single operating segment for the three months ended March 31, 2026 and 2025 (in thousands):

	Three Months Ended March 31,	
	2026	2025
Operating Expenses[a]:		
Research and development personnel-related (excluding equity-based compensation)	$ 4,701	$ 2,424
External research and development costs – sutacimig	5,795	5,953
External research and development costs – HMB-002	3,506	4,563
External – discovery related costs and other	4,894	981
Personnel-related (excluding equity-based compensation)	1,032	760
External – general and administrative	2,298	1,343
Equity-based compensation expense	1,318	459
Depreciation expense	68	77
Other segment (income) expenses[b]	282	(591)
Interest income	(1,219)	(473)
Income tax expense (benefit)	12	(190)
Consolidated net loss	$ 22,687	$ 15,306

(a) The significant expense categories and amounts align with the segment-level information that is regularly provided to the CODM.
(b) Other segment expenses include foreign currency exchange loss and other income/expense.

14. Subsequent Events

The Company evaluated subsequent events through the date on which these financial statements were issued to ensure that these condensed consolidated financial statements include appropriate disclosure of events both recognized in the financial statements as of March 31, 2026 and events which occurred subsequently but not recognized in the financial statements.

Corporate Reorganization

On April 1, 2026, following the corporate reorganization, on March 31, 2026, Hemab ApS transferred its shares of Hemab Therapeutics Inc., a Delaware corporation and wholly-owned subsidiary of Hemab ApS, to Hemab Therapeutics Holdings, Inc. in exchange for the issuance of a promissory note and, as a result, Hemab Therapeutics Inc. became a wholly owned subsidiary of Hemab Therapeutics Holdings, Inc. See Note 1 titled "Description of Business and Liquidity—Corporate Reorganization" for additional information on the corporate reorganization.

Initial Public Offering

On May 4, 2026, the Company completed the IPO of 19,262,500 shares of its common stock, which included the exercise in full by the underwriters of their option to purchase 2,512,500 additional shares of common stock, at a public offering price of $18.00 per share. The net proceeds to the Company from the IPO were approximately $317.2 million after deducting underwriting discounts and commissions and offering expenses payable by the Company. In connection with the completion of the IPO, all shares of the Company's preferred stock were converted into 26,496,910 shares of common stock, and no shares of preferred stock were thereafter outstanding.

In connection with the closing of the IPO, on May 4, 2026, the Company's filed a restated certificate of incorporation with the Secretary of State of the State of Delaware, which authorizes 400,000,000 shares of common stock, par value $0.0001 per share, and 5,000,000 shares of undesignated preferred stock, par value $0.0001 per share.

Stock Split

The Company's board of directors and stockholders approved a 22-for-one forward stock split of the Company's issued and outstanding common stock and a proportional adjustment to the existing conversion ratios for the outstanding shares of convertible preferred stock, which became effective on April 24, 2026. Accordingly, all share and per share amounts for all periods presented in the accompanying condensed consolidated financial statements and the notes thereto have been retroactively adjusted, where applicable, to reflect the stock split.

2026 Equity Plans

In April 2026, the Company's board of directors adopted and the Company's stockholders approved the 2026 Equity Incentive Plan (the "2026 Plan"), which became effective immediately prior to the effectiveness of the registration statement for the IPO. The 2026 Plan initially provides for the grant of awards with respect to 4,180,000 shares of common stock, of which the Company granted stock options to purchase an aggregate of 306,900 shares of common stock, at an exercise price per share equal to the initial public offering price of $18.00, in connection with the IPO.

In April 2026 the Company's board of directors adopted and the Company's stockholders approved the 2026 Employee Stock Purchase Plan (the "2026 ESPP"), which became effective immediately prior to the effectiveness of the registration statement for the IPO. The 2026 ESPP initially provides participating employees with the opportunity to purchase up to an aggregate of 418,000 shares of common stock.

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

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q, or this Quarterly Report, and our audited consolidated financial statements and related notes included in the final prospectus for our initial public offering, or IPO, dated April 30, 2026, and filed with the U.S. Securities and Exchange Commission, or SEC, pursuant to Rule 424(b)(4) under the Securities Act of 1933, as amended, or the Securities Act, on May 1, 2026. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report, 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 biotechnology company developing therapies that reimagine the treatment of blood coagulation disorders to sustain life and human resilience. Our mission is to build the leading coagulation company by discovering, developing, and commercializing innovative therapies for the millions of patients worldwide suffering from serious bleeding and thrombotic diseases, including Glanzmann thrombasthenia, Factor VII deficiency, Von Willebrand Disease and other conditions of abnormal bleeding, all of which can cause significant life-long burden to patients. We are building a comprehensive franchise of investigational therapeutics spanning from Phase 2 clinical development through discovery research. Our assets address critical gaps in the treatment of coagulation disorders, with multiple value-driving clinical data events anticipated in 2026, 2027 and beyond.

Our lead asset, sutacimig, is a bispecific antibody currently in Phase 1/2 clinical development for the prophylactic treatment of Glanzmann thrombasthenia and Phase 2 clinical development for the prophylactic treatment of Factor VII deficiency. Our second clinical-stage asset, HMB-002, is a monovalent antibody in Phase 1/2 clinical development for the subcutaneous prophylactic treatment of Von Willebrand Disease. We are also advancing multiple preclinical and discovery-stage assets.

Since our inception in 2020, we have devoted substantially all of our resources to drug discovery, the development of our lead product candidates, sutacimig and HMB-002, along with several preclinical programs focusing on coagulation disorders. In addition to our research and development efforts, our operations to date have been limited to organizing and staffing our company, business planning, raising capital, securing intellectual property rights, in-licensing technology, discovering product candidates, undertaking preclinical studies, conducting clinical trials and providing general and administrative support for these operations.

We have no approved products, and we have not generated any revenue from product sales. On May 4, 2026, we closed our initial public offering ("IPO") of 19,262,500 shares of common stock, which included the exercise in full by the underwriters of their option to purchase additional shares of common stock. The net proceeds from the IPO were approximately $317.2 million, after deducting underwriting discounts and commissions and offering expenses payable by us. Prior to our IPO, we financed our operations primarily through private placements of convertible preference shares and issuance of convertible debt. Since our inception through May 21, 2026, we have received aggregate gross proceeds of approximately $692.7 million from such transactions.

We have incurred significant operating losses since inception. Our net losses were $22.7 million and $15.3 million for the three months ended March 31, 2026 and 2025, respectively. As of March 31, 2026, we had an accumulated deficit of $204.5 million. We expect to continue to incur significant operating expenses and net losses for the foreseeable future.

We anticipate that our expenses will increase substantially if and as we:

- continue to advance the clinical development of our product candidates, including our ongoing Phase 1/2 clinical trial of sutacimig in patients with Glanzmann thrombasthenia, our ongoing Phase 2 clinical trial of sutacimig in patients with Factor VII deficiency, and our ongoing Phase 1/2 clinical trial of HMB-002 in patients with Von Willebrand Disease, as well as any other product candidates that we may develop;
- advance our clinical-stage product candidates into later-stage clinical trials, including our planned Phase 3 clinical trial of sutacimig in patients with Glanzmann thrombasthenia, which will be required in order to seek marketing approval of our product candidates, and which we expect will be substantially more expensive than our earlier-stage clinical trials;
- continue to advance our research and preclinical activities and seek to discover and develop additional product candidates;

- establish and scale-up manufacturing processes and capabilities, or arrange for a third party to do so on our behalf, to support our clinical trials of our product candidates and commercialization of any of our product candidates for which we obtain marketing approval;
- seek regulatory and marketing approvals for any of our product candidates that successfully complete clinical trials;
- ultimately establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- continue to develop, maintain, expand and protect our intellectual property portfolio (including intellectual property obtained through license agreements) and provide reimbursement of third-party expenses related to our patent portfolio;
- acquire or in-license products, product candidates or technologies;
- establish or maintain collaborations;
- maintain, expand, enforce, defend and protect our intellectual property;
- hire additional clinical, medical, regulatory, quality control, manufacturing and other scientific and technical personnel;
- add operational, financial, clinical, quality and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts of our product candidates and our operations as a public company;
- incur additional audit, legal, regulatory, tax and other expenses with being a public company; and
- make any milestone, royalty, or other payments to Novo Nordisk A/S, or Novo Nordisk, under our license agreement with Novo Nordisk, or the Novo Nordisk Agreement, and to Genmab A/S, or Genmab, under our license agreement with Genmab, or the Genmab Agreement, and under any additional future collaboration or license agreements that we may enter into.

In addition, our expenses will further increase if, among other things:

- we are required by the U.S. Food and Drug Administration, the European Medicines Agency, or other regulatory authorities to perform clinical trials or preclinical studies that are in addition to, or different than, those expected;
- there are any delays in completing our clinical trials or preclinical studies or the development of any of our product candidates; or
- there are any third-party challenges to our intellectual property or we need to defend against any intellectual property-related claim.

We will not generate revenue from product sales unless and until we successfully complete the clinical development or future clinical development of, and obtain regulatory approval for, one or more of our current or future product candidates, which may not occur for several years, if at all. In addition, if we obtain marketing approval for our product candidates and any other product candidates we may identify and pursue, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution.

Our net losses may fluctuate significantly from period to period, depending on the timing of our current and potential future clinical trials and expenditures related to our research and developmental activities. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding to support our continuing operations and pursue our growth strategy. Until such a time when we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of equity offerings, debt financings, royalty financings, collaborations, strategic alliances, and marketing, distribution or licensing arrangements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed, on favorable terms, or at all. Our failure to raise capital or enter into such agreements or arrangements as, and when needed, could have a material adverse effect on our business, results of operations and financial condition, including potentially requiring us to delay, limit, reduce or eliminate product development or future commercialization efforts, or grant rights to develop and market current or future development product candidates that we would otherwise prefer to develop and market ourselves.

As there are numerous risks and uncertainties associated with product development, we are unable to accurately predict the timing or amount of increased expenses or when or if we will be able to achieve or maintain profitability. Even if we are able to generate product sales, we may not become profitable. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As of March 31, 2026, we had cash, cash equivalents and marketable securities of $163.5 million. We believe that our existing cash, cash equivalents and marketable securities, together with net proceeds from the IPO of approximately $317.2 million, will enable us to fund our operating expenses and capital expenditure requirements into 2029. For more information, see the section titled "*Liquidity and Capital Resources*" below.

Corporate Reorganization

On March 30, 2026, we completed a corporate reorganization pursuant to which the shareholders of Hemab ApS exchanged their shares in Hemab ApS for the same number, class and series of newly issued shares, on a one to one basis, in the newly incorporated Delaware company, Hemab Therapeutics Holdings, Inc. and, as a result, Hemab ApS became a wholly owned subsidiary of Hemab Therapeutics Holdings, Inc. The newly issued shares of Hemab Therapeutics Holdings, Inc. have substantially identical rights to the exchanged shares of Hemab ApS. As a result of the exchange, Hemab Therapeutics Holdings, Inc. became the sole shareholder of Hemab ApS, and the prior shareholders of Hemab ApS solely hold shares of Hemab Therapeutics Holdings, Inc. Hemab Therapeutics Holdings, Inc. had nominal assets and liabilities and did not conduct any operations prior to the corporate reorganization other than its incorporation. Upon completion of the corporate reorganization, the historical consolidated financial statements of Hemab ApS became the historical consolidated financial statements of Hemab Therapeutics Holdings, Inc.

In connection with the corporate reorganization, each outstanding warrant to subscribe for the purchase of ordinary shares of Hemab ApS was assumed by Hemab Therapeutics Holdings, Inc. and converted into a warrant to purchase the same number of shares of common stock of Hemab Therapeutics Holdings, Inc. Each new warrant otherwise has and is subject to the same terms and conditions as were in effect immediately prior to the assumption and conversion, except that any warrant exercise price that had been denominated in DKK prior to the corporate reorganization was converted into an exercise price in U.S. dollars at the exchange rate as in effect at the close of business on the business day prior to the corporate reorganization. No warrants of Hemab ApS are outstanding following the assumption and conversion.

Additionally, promptly following the corporate reorganization, on April 1, 2026, Hemab ApS transferred its shares of Hemab Therapeutics Inc., a Delaware corporation and wholly-owned subsidiary of Hemab ApS, to Hemab Therapeutics Holdings, Inc. in exchange for the issuance of a promissory note and, as a result, Hemab Therapeutics Inc. became a wholly owned subsidiary of Hemab Therapeutics Holdings, Inc.

Components of Results of Operations

Revenue

We have not generated any revenues from the sale of products to date and do not expect to generate any revenue from the sale of products until we successfully complete development and obtain regulatory approval for one or more of our product candidates, which may not occur for several years, if at all. If our development efforts for our product candidates are successful and result in regulatory approval or we successfully enter into collaboration or license agreements with third parties, we may generate revenues in the future from product sales, or payments from such collaboration or license agreements, or a combination thereof.

Operating Expenses

Our operating expenses consist of research and development expenses and general and administrative expenses.

Research and Development Expenses

Research and development expenses consist primarily of external and internal costs incurred for our research and development activities, including our product candidate discovery and development efforts. These expenses include:

- external costs, including expenses incurred under arrangements with third-parties, such as contract manufacturing organizations, or CMOs, contract research organizations, or CROs, providers of sponsored research, consultants and our scientific advisors;
- laboratory and vendor costs related to the execution of preclinical studies and planned and ongoing clinical trials;
- costs related to compliance with regulatory requirements;
- direct costs of conducting internal research and development for our internal preclinical programs;
- acquisition of intellectual property and related future payments should certain development and regulatory milestones be achieved;
- personnel-related costs, including salaries, bonuses, benefits and equity-based compensation for employees engaged in research and development functions;
- expenses incurred for the procurement of materials, laboratory supplies and non-capital equipment used in the research and development process; and
- depreciation, amortization and other direct and allocated expenses, including rent, insurance, maintenance of facilities and other operating costs, incurred as a result of our research and development activities.

We expense research and development costs as incurred. Non-refundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

We record accruals for estimated ongoing research costs and receive updated estimates of costs and amounts owed on a monthly basis from our third-party service providers. When evaluating the adequacy of the prepaid expenses and accrued liabilities, we analyze progress of the studies, including the phase or completion of events, invoices received and contracted cost estimates from its third-party service providers. Estimates are made in determining the balances at the end of any reporting period.

A significant portion of our research and development costs have been, and will continue to be, external costs. External costs, which are specific to a product candidate, are tracked on a product candidate-by-product candidate basis upon our designation of a preclinical asset as a product candidate. Because we can use certain resources across several product candidates, personnel-related expenses and indirect or shared operating costs incurred for our research and development activities are not recorded or allocated on a product candidate-by-product candidate basis.

We have historically met the requirements to receive a tax credit in Denmark of up to 5.5 million Danish Kroner, or DKK, per year for losses resulting from research and development costs of up to DKK 25 million per year. The tax credit is presented as a reduction to research and development expense in the condensed consolidated statements of operations and comprehensive loss.

We anticipate that our research and development expenses will increase substantially for the foreseeable future in connection with our ongoing clinical trials and our planned clinical development activities. However, we cannot reasonably estimate the costs or timing of the efforts that will be necessary to complete the development of any of our product candidates due to the numerous risks and uncertainties associated with their development, including the uncertainty of:

- the scope, progress, costs and results of our current and future preclinical studies and clinical trials for our product candidates;
- the number of clinical trials required for regulatory approval of our current or future product candidates;
- whether we partner our programs with collaborators for later-stage clinical development or commercialization;
- the number and development requirements of any other product candidates we may identify and develop;
- the costs, timing and outcome of regulatory review of our product candidates and any other product candidates we may identify and develop;

- the costs of obtaining clinical and commercial supplies of our product candidates and any other product candidates we may identify and develop;
- our ability to successfully commercialize our product candidates and any other product candidates we may identify and develop;
- the time and cost necessary to respond to technological and market developments;
- the extent to which we may acquire or in-license other product candidates and technologies;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- milestone payments and other collaboration-based payments, if any;
- our ability to attract, hire and retain qualified personnel; and
- the effect of macroeconomic trends including inflation, foreign exchange rate, interest rates and tariffs.

Any changes in the outcome of any of these variables with respect to the development of our programs and product candidates or any future programs and product candidates that we may develop could result in a significant change in the costs and timing associated with the development of that program or product candidate. We may never succeed in achieving regulatory approval for any of our product candidates or any future product candidates that we may identify and develop.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel-related costs, including salaries, bonuses, benefits and equity-based compensation expenses for employees in executive, accounting and finance, business development, human resources, legal and other administrative functions. Other significant general and administrative expenses include facility related costs including depreciation, legal fees relating to corporate and intellectual property matters and other corporate matters, professional fees for accounting, audit and tax services, consulting fees and insurance costs.

We anticipate that our general and administrative expenses will increase as we increase our headcount to support our research and development activities and the potential commercialization of our product candidates, if approved. Additionally, these increases will likely include increased costs related to the hiring of additional personnel, among other expenses. We also expect to incur increased expenses associated with being a public company, including increased costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with Nasdaq listing requirements and the requirements of the Securities and Exchange Commission, or the SEC, director and officer insurance costs, and investor and public relations costs. We also expect to incur additional intellectual property-related expenses as we file patent applications to protect innovations arising from our research and development activities.

Other Income (Expense), Net

Other income (expense), net primarily consists of interest income generated from interest on cash, cash equivalents and marketable securities, realized and unrealized gains and losses on foreign currency transactions and interest expense associated with our finance lease for certain laboratory equipment.

Income Taxes

We are subject to taxation in the United States and Denmark. As of December 31, 2025, we had $170.9 million of net operating loss carryforwards that can be carried forward indefinitely according to Danish Tax Authority regulations. These loss carryforwards are available to reduce future taxable income, if any.

Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, and operating losses and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted statutory tax rates expected to apply to taxable income in the jurisdictions and years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date.

Based on the level of historical operating results and projections for the taxable income for the future, we have determined that it is more likely than not that our net deferred tax assets will not be realized. Accordingly, we have recorded a full valuation allowance to reduce our net deferred tax assets.

We recognize tax benefits from uncertain tax positions only if, based on the technical merits of the position, it is more likely than not that the tax positions will be sustained on examination by the tax authority. The tax benefits recognized in the financial statements from such positions are measured based on the largest amount that is more than 50% likely to be realized upon ultimate settlement. We recognize interest and penalties related to unrecognized tax benefits within the provision for taxes in our statements of operations and comprehensive loss.

We operate in Denmark and the United States and may be subject to audits from various tax authorities. Management's judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities, liabilities for uncertain tax positions, and any valuation allowance recorded against our net deferred tax assets. We plan to monitor the extent to which our deferred tax assets may be realized and adjust the valuation allowance accordingly.

Results of Operations

Comparison of the Three Months Ended March 31, 2026 and 2025

The following table summarizes our results of operations for the periods presented (in thousands):

	Three Months Ended March 31,		
	2026	2025	Change
Operating expenses:			
Research and development	$ 19,461	$ 14,101	$ 5,360
General and administrative	4,151	2,459	1,692
Total operating expenses	23,612	16,560	7,052
Loss from operations	(23,612)	(16,560)	(7,052)
Other income (expense), net:			
Interest income	1,219	473	746
Other (expense) income, net	(282)	591	(873)
Total other income (expense), net	937	1,064	(127)
Loss before income tax (expense) benefit	(22,675)	(15,496)	(7,179)
Income tax (expense) benefit	(12)	190	(202)
Net loss	$(22,687)	$(15,306)	$(7,381)

Research and Development Expenses

The following table summarizes our research and development expenses for the periods presented (in thousands):

	Three Months Ended March 31,		
	2026	2025	Change
External research and development costs by product candidate:			
sutacimig	$ 5,795	$ 5,953	$ (158)
HMB-002	3,506	4,563	(1,057)
Other	2,058	262	1,796
Other research and development costs:			
Personnel-related (excluding equity-based compensation)	4,701	2,424	2,277
Equity-based compensation	565	180	385
Discovery and other	2,836	719	2,117
Total research and development expense	$19,461	$14,101	$ 5,360

Total research and development expenses were $19.5 million for the three months ended March 31, 2026, compared to $14.1 million for the three months ended March 31, 2025. The $5.4 million increase in research and development expenses for the three months ended March 31, 2026 was primarily due to an increase of $2.3 million in personnel-related costs and an increase of $2.2 million in discovery and other costs related to adding consultancy resources for medical and clinical operations.

External research and development expenses related to sutacimig for the three months ended March 31, 2026 and 2025 were $5.8 million and $6.0 million, respectively. The decrease of $0.2 million for the three months ended March 31, 2026 was primarily driven by reduced Chemistry, Manufacturing, and Controls, or CMC, costs.

External research and development expenses related to HMB-002 for the three months ended March 31, 2026 and 2025 were $3.5 million and $4.6 million, respectively. The decrease of $1.1 million for the three months ended March 31, 2026 was primarily driven by start-up costs related to the Phase 1/2 clinical trial of HMB-002 during the three months ended March 31, 2025 as compared to the three months ended March 31, 2026.

Other external research and development expenses increased by $1.8 million for the three months ended March 31, 2026 compared to the three months ended March 31, 2025, primarily driven by continued CMC activities related to our preclinical programs and other increased preclinical development costs.

Personnel-related expenses and equity-based compensation increased by $2.3 million and $0.4 million in the three months ended March 31, 2026, respectively, compared to the three months ended March 31, 2025, primarily driven by a significant increase in average headcount across clinical development, CMC, and clinical operations related to the pursuit of identifying and developing product candidates.

Discovery and other costs increased by $2.1 million for the three months ended March 31, 2026 compared to the three months ended March 31, 2025, primarily driven by an increase in discovery activities and consultancy expense related to clinical operations, clinical research, and regulatory research.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the periods presented (in thousands):

	Three Months Ended March 31,		
	2026	2025	Change
Personnel-related (excluding equity-based compensation)	$1,032	$ 760	$ 272
Equity-based compensation expense	753	279	474
Professional services	1,481	648	833
Other	885	772	113
Total general and administrative expense	$4,151	$2,459	$1,692

Total general and administrative expenses were $4.2 million for the three months ended March 31, 2026, compared to $2.5 million for the three months ended March 31, 2025. The $1.7 million increase was primarily due to an increase in personnel-related costs and equity-based compensation of $0.3 million and $0.5 million, respectively, driven by an increase in average headcount as well as an increase in professional service fees of $0.8 million.

Other Income (Expense), Net

Other income (expense), net for the three months ended March 31, 2026 and 2025 were net income of $1.0 million and $1.1 million, respectively. The $0.1 million decrease was primarily related to foreign currency losses recognized due to unfavorable movements between the currencies which we regularly transact in, including DKK, Euros, British Pounds and our functional currency, the U.S. Dollar. This was offset by an increase in interest income of $0.7 million due to an increase in accretion income related to our available-for-sale debt securities.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred significant operating losses. To date, we have financed our operations primarily through private placements of convertible preference shares and issuance of convertible debt and, most recently, from the sale of common stock in our IPO in May 2026. Through May 21, 2026, we have received aggregate gross proceeds of approximately $692.7 million from such transactions.

Cash Flows

The following table provides information regarding our cash flows for the periods presented (in thousands):

	Three Months Ended March 31,		
	2026	2025	Change
Net cash used in operating activities	$(21,584)	$(13,033)	$ (8,551)
Net cash used in investing activities	(15,847)	(5,994)	(9,853)
Net cash used in financing activities	(460)	(29)	(431)
Effect of foreign exchange rate changes on cash and cash equivalents	(223)	—	(223)
Net decrease in cash and cash equivalents	$(38,114)	$(19,056)	$(19,058)

Operating Activities

Our cash flows from operating activities are significantly influenced by our use of cash for operating expenses and working capital requirements to support our business. We have historically experienced negative cash flows from operating activities as we invested in the research and development of our product candidates and programs, including preclinical studies, clinical trials, manufacturing and manufacturing process development. The cash used in operating activities resulted primarily from our net losses adjusted for non-cash charges, which are generally due to equity-based compensation, depreciation and amortization and non-cash lease expense, non-cash interest income, as well as changes in components of operating assets and liabilities, which are generally due to increased expenses and timing of vendor payments.

During the three months ended March 31, 2026, net cash used in operating activities was $21.6 million, due to a net loss of $22.7 million, which was partially offset by changes in operating assets and liabilities that provided $0.4 million in cash and net non-cash expenses of $0.7 million.

During the three months ended March 31, 2025, net cash used in operating activities was $13.0 million, due to a net loss of $15.9 million, which was partially offset by changes in operating assets and liabilities that provided $2.0 million in cash and net non-cash expenses of $0.9 million.

Investing Activities

During the three months ended March 31, 2026, net cash used in investing activities was $15.8 million, which primarily consisted of purchases of marketable securities and property and equipment.

During the three months ended March 31, 2025, net cash used in investing activities was $6.0 million, which primarily consisted of purchases of marketable securities, which were partially offset by maturities of marketable securities.

Financing Activities

During the three months ended March 31, 2026, net cash used in financing activities was $0.1 million, related to principal payments on finance lease obligations and payment of deferred offering costs associated with the IPO.

During the three months ended March 31, 2025, net cash used in financing activities was $0.1 million, related to principal payments on finance lease obligations.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing and planned activities, particularly as we commence our planned Phase 3 clinical trial of sutacimig in patients with Glanzmann thrombasthenia and continue our ongoing Phase 1/2 clinical trial of sutacimig in patients with Glanzmann thrombasthenia, Phase 2 clinical trial of sutacimig in patients with Factor VII deficiency and Phase 1/2 trial of HMB-002 in patients with Von Willebrand Disease, continue research and development and initiate additional clinical trials of, and seek marketing approval for, these and other product candidates. In addition, if we obtain marketing approval for our product candidates and any other product candidates we may identify and pursue, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution. Furthermore, we expect to incur additional costs associated with operating as a public company. As a result, we expect to continue to incur significant operating expenses and net losses for the foreseeable future.

As of March 31, 2026, we had total cash, cash equivalents and marketable securities of $163.5 million. We believe that our existing cash, cash equivalents and marketable securities, together with net proceeds from the IPO of approximately $317.2 million, will enable us to fund our operating expenses and capital expenditure requirements into 2029. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

Because of the numerous risks and uncertainties associated with product development, and because the extent to which we may enter into collaborations with third-parties for the development of our product candidates is unknown, we may incorrectly estimate the timing and amounts of increased capital outlays and operating expenses associated with completing the research and development of our product candidates. Our funding requirements and timing and amount of our operating expenditures will depend on many factors. We anticipate that our expenses will increase substantially if and as we:

- continue to advance the clinical development of our product candidates, including our ongoing Phase 1/2 clinical trial of sutacimig in patients with Glanzmann thrombasthenia, our ongoing Phase 2 clinical trial of sutacimig in patients with Factor VII deficiency, and our ongoing Phase 1/2 clinical trial of HMB-002 in patients with Von Willebrand Disease, as well as any other product candidates that we may develop;
- advance our clinical-stage product candidates into later-stage clinical trials, including our planned Phase 3 clinical trial of sutacimig in patients with Glanzmann thrombasthenia, which will be required in order to seek marketing approval of our product candidates and which we expect will be substantially more expensive than our earlier-stage clinical trials;
- continue to advance our research and preclinical activities and seek to discover and develop additional product candidates;
- establish and scale-up manufacturing processes and capabilities, or arrange for a third party to do so on our behalf, to support our clinical trials of our product candidates and commercialization of any of our product candidates for which we obtain marketing approval;
- seek regulatory and marketing approvals for any of our product candidates that successfully complete clinical trials;
- ultimately establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- continue to develop, maintain, expand and protect our intellectual property portfolio (including intellectual property obtained through license agreements) and provide reimbursement of third-party expenses related to our patent portfolio;
- acquire or in-license products, product candidates or technologies;
- establish or maintain collaborations;
- maintain, expand, enforce, defend and protect our intellectual property;
- hire additional clinical, medical, regulatory, quality control, manufacturing and other scientific and technical personnel;
- add operational, financial, clinical, quality and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts of our product candidates and our operations as a public company;
- incur additional audit, legal, regulatory, tax and other expenses with being a public company; and

- make any milestone, royalty, or other payments under the Novo Nordisk Agreement, under the Genmab Agreement, and under any additional future collaboration or license agreements that we may enter into.

In addition, our expenses will further increase if, among other things:

- we are required by the U.S. Food and Drug Administration, the European Medicines Agency, or other regulatory authorities to perform clinical trials or preclinical studies that are in addition to, or different than, those expected;
- there are any delays in completing our clinical trials or preclinical studies or the development of any of our product candidates; or
- there are any third-party challenges to our intellectual property or we need to defend against any intellectual property-related claim.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for many years, if ever. Accordingly, we will need to obtain substantial additional funds to achieve our business objectives.

Our expectation with respect to our ability to fund current planned operations is based on estimates that are subject to risks and uncertainties. Our operating plan may change as a result of many factors currently unknown to management and there can be no assurance that the current operating plan will be achieved in the time frame anticipated by us, and we may need to seek additional funds sooner than planned. If we are unable to raise this capital when needed, we may be forced to delay, limit, reduce or eliminate one or more of our research and development programs or other operations.

Adequate additional funds may not be available to us on acceptable terms, or at all. We do not have any source of committed capital or external funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as stockholder. Additional debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring debt, selling or licensing our assets, making capital expenditures or declaring dividends or encumbering our assets to secure future indebtedness. If we raise additional funds through equity offerings, debt financings, royalty financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or development product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds when needed or on terms acceptable to us, we may be required to delay, limit, reduce or terminate our product development programs or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

For additional information on risks associated with our substantial capital requirements, please see "*Risk Factors — We will need substantial additional funding. If we are unable to raise capital on acceptable terms when needed, or at all, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts*."

Contractual Obligations and Commitments

Leases

In January 2023, we entered into a finance lease for certain laboratory equipment in Copenhagen, Denmark. The laboratory equipment was classified as a finance lease due to the existence of a bargain purchase option in the lease agreement. In connection with this lease, we recorded a finance lease right-of-use asset and finance lease liability of approximately $0.5 million.

In September 2023, we entered into a non-cancelable operating lease for office space in Cambridge, Massachusetts. The lease requires us to pay annual base rent of approximately $0.4 million, which is subject to a 2% annual increase over the term of the lease. The lease expires in October 2026 and contains a two-year renewal option.

In March 2024, we entered into a non-cancelable operating sublease for office and laboratory space in Copenhagen, Denmark. The lease requires us to pay annual base rent of approximately $0.3 million, which is subject to a 3% annual increase over the term of the lease. The lease expires in February 2029 and contains a one-year renewal option.

For additional information on our future commitments relating to our leasing obligations, see Note 9, "Leases" of the "Notes to Consolidated Financial Statements" in the audited consolidated financial statements for the year ended December 31, 2025 and notes thereto, included in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on May 1, 2026.

Purchase and Other Obligations

We enter into contracts in the normal course of business with CROs, CMOs and other third-parties for preclinical research studies, clinical trials and testing and manufacturing services. These contracts typically do not contain minimum purchase commitments and are cancellable by us upon written notice. Payments due upon cancellation generally consist of payments for services provided or expenses incurred up to the date of cancellation, including non-cancelable obligations of our service providers and, in some cases, wind-down costs. For further information regarding certain of our license agreements and amounts that could become payable in the future under those agreements, please see Note 8 in our condensed consolidated financial statements appearing elsewhere in this Quarterly Report.

License Agreements

Below is a summary of the key terms for certain of our license agreements.

License Agreement with Novo Nordisk

In November 2019, we entered into a license agreement with Novo Nordisk A/S, or Novo Nordisk, pursuant to which Novo Nordisk granted us an exclusive (even as to Novo Nordisk), worldwide and sublicensable license under specified patent rights, and a non-exclusive, worldwide and sublicensable license under specified know-how, to research, develop, make, have made, use, offer for sale, sell, import, export or otherwise exploit, or transfer possession of or title in, products, or Novo Licensed Products, containing bispecific IgG antibodies targeting TLT-1 and Factor VII, including sutacimig, for the treatment of bleeding conditions, including hemophilia. We refer to this agreement as the Novo Nordisk Agreement. Under the terms of the Novo Nordisk Agreement, we have agreed to use commercially reasonable efforts to develop and commercialize a Novo Licensed Product.

We are obligated to pay to Novo Nordisk a one-time DKK 40 million milestone payment upon achievement by a Novo Licensed Product of a specified regulatory milestone event, and we are also obligated to pay Novo Nordisk tiered royalties, in the low single-digit percentages, on aggregate annual net sales of all Novo Licensed Products, on a Novo Licensed Product-by-Novo Licensed Product and country-by-country basis, until the later of the expiration of the last valid claim in the licensed patents under the Novo Nordisk Agreement covering such Novo Licensed Product in such country and ten years following the first commercial sale of such Novo Licensed Product in such country. We currently expect that all of the licensed patents under the Novo Nordisk Agreement will expire by 2040, potentially extending to 2045 with patent term extension. To date, we have not made any payments to Novo Nordisk under the Novo Nordisk Agreement. Under the Novo Nordisk Agreement, we initially granted to Novo Nordisk a right of first negotiation, following a specified clinical event and during a specified period of time, to obtain a license back from us to exploit Novo Licensed Products if we determined to engage with a third party with respect to a license of any Novo Licensed Products. However, Novo Nordisk's right of first negotiation under the Novo Nordisk Agreement has expired.

The Novo Nordisk Agreement will continue in force until it is terminated. On expiration of each royalty term, our license becomes royalty-free, perpetual, and irrevocable with respect to the applicable Novo Licensed Product in the applicable country. Either party may terminate the Novo Nordisk Agreement for the other party's uncured material breach or insolvency. We may terminate the Novo Nordisk Agreement for any reason upon 90 days' written notice to Novo Nordisk. In the event that Novo Nordisk regains control of the exclusive right to exploit the Novo Licensed Product, the Novo Nordisk Agreement will automatically terminate.

License Agreement with Genmab

In April 2020, we entered into a license agreement with Genmab A/S, or Genmab, pursuant to which Genmab granted us an exclusive (even as to Genmab and its affiliates), worldwide and sublicensable license under platform technology patent rights and know-how relating to Genmab's proprietary DuoBody® platform to research, develop, make, have made, use, manufacture, import, export and commercialize products, comprising bispecific IgG antibodies targeting TLT-1 and Factor VII, or TLT-1/Factor VII Antibody Products, including sutacimig, for the treatment of bleeding conditions, including hemophilia. Under the terms of the Genmab Agreement, we have agreed to use commercially reasonable efforts to develop, manufacture, obtain regulatory approval for and commercialize TLT-1/Factor VII Antibody Products worldwide.

Under the Genmab Agreement, we are obligated to pay Genmab a percentage of all net profit (i.e., revenue and other proceeds less specified direct costs we incur to conduct research, development, manufacture and commercialization of TLT-1/Factor VII Antibody Products) we or our affiliates receive with respect to any TLT-1/Factor VII Antibody Products, including (1) net profit from commercial sales of TLT-1/Factor VII Antibody Products and any revenue from third parties, other than Novo Nordisk, in respect of a sublicense or assignment with respect to TLT-1/Factor VII Antibody Products, including assignment fees, sublicensing fees, upfront and milestone fees, royalties and other consideration, whether in kind or cash, and (2) the net profit allocated to TLT-1/Factor VII Antibody Products that we or our affiliates receive if we undergo a change of control (other than an acquisition by Novo Nordisk). The percentage of net profit we owe with respect to each TLT-1/Factor VII Antibody Product is in the low teens from the effective date of the Genmab Agreement until the first commercial sale of such TLT-1/Factor VII Antibody Product. From and after the first commercial sale of a TLT-1/Factor VII Antibody Product, the percentage of net profit we owe with respect to such TLT-1/Factor VII Antibody Product is in the high single digits in all territories in which we commercialize such TLT-1/Factor VII Antibody Product and in the mid-teens in all territories in which a third party, other than Novo Nordisk, commercializes such TLT-1/Factor VII Antibody Product. We are obligated to pay such percentage of net profit on a country-by-country and TLT-1/Factor VII Antibody Product-by-TLT-1/Factor VII Antibody Product basis until the later of the expiration of the last-to-expire of the platform technology patent rights licensed under the Genmab Agreement covering such TLT-1/Factor VII Antibody Product in such country and twelve years following the first commercial sale of such TLT-1/Factor VII Antibody Product in such country, which we refer to as the net profit share term. Following the expiration of the last-to-expire of the platform technology patent rights licensed under the Genmab Agreement covering a given TLT-1/Factor VII Antibody Product in a given country, the percentage of net profit that we are obligated to pay with respect to sales of such TLT-1/Factor VII

Antibody Product in such country will be reduced by a specified percentage for the remainder of the net profit share term for such TLT-1/Factor VII Antibody Product in such country. We currently expect that all of the platform technology patent rights licensed under the Genmab Agreement will expire by 2032, though this date may be extended if, for example, Genmab files additional patents covering its platform technology. To date, we have not made any payments to Genmab under the Genmab Agreement.

In the event we seek to sell, license or otherwise dispose of our rights to TLT-1/Factor VII Antibody Products, including through a change of control to any third party other than Novo Nordisk, we are obligated to provide Genmab the right to participate in any bidding process as a bona fide potential acquirer of such rights.

Unless earlier terminated, the Genmab Agreement will expire, on a TLT-1/Factor VII Antibody Product-by-TLT-1/Factor VII Antibody Product and country-by-country basis, upon the expiration of the last net profit share term for such TLT-1/Factor VII Antibody Product in such country. On expiration of each net profit share term, our license becomes perpetual, fully paid-up and non-exclusive with respect to the applicable TLT-1/Factor VII Antibody Product in the applicable country. Either party may terminate the Genmab Agreement for the other party's uncured material breach or insolvency or in certain events of force majeure. Genmab may terminate the Genmab Agreement if we or our affiliates or sublicensees challenge any of the platform technology patent rights licensed under the Genmab Agreement. We may terminate the Genmab Agreement for any reason upon 120 days written notice to Genmab. If Novo Nordisk obtains from us the exclusive right to exploit TLT-1/Factor VII Antibody Products, including upon termination of the Novo Nordisk Agreement, then the Genmab Agreement will terminate in all territories in which Novo Nordisk obtains such exclusive rights.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. The preparation of these condensed consolidated financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, costs and expenses and the disclosure of contingent assets and liabilities at the date of the condensed consolidated financial statements, as well as the reported expenses incurred during the reporting periods. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no significant changes from critical accounting estimates described under "Management's Discussion and Analysis of Financial Condition and Results of Operations – Critical Accounting Estimates" included in our final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on May 1, 2026.

Emerging Growth Company and Smaller Reporting Company Status

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act, or the JOBS Act. As a result, we are able to take advantage of certain reduced reporting requirements that are otherwise applicable to public companies, including delaying auditor attestation of internal control over financial reporting, providing only two years of audited financial statements and related management's discussion and analysis of financial condition and results of operations and reduced executive compensation disclosures.

We may remain an emerging growth company until December 31, 2031. However, if certain events occurs prior to the end of such period, including if we become a "large accelerated filer" under SEC rules, our annual gross revenue exceeds $1.235 billion, or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to such date.

We have elected to take advantage of certain of the reduced disclosure obligations available to emerging growth companies and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than what you might receive from other public reporting companies in which you hold equity interests. In addition, the JOBS Act provides that an "emerging growth company" can take advantage of an extended transition period for complying with new or revised accounting standards. We have elected not to "opt out" of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we can adopt the new or revised standard at the time private companies adopt the new or revised standard and may do so until such time that we either (1) irrevocably elect to "opt out" of such extended transition period or (2) no longer qualify as an emerging growth company.

We are also a “smaller reporting company” as defined in the Securities Exchange Act of 1934, as amended. We may continue to be a smaller reporting company even after we are no longer an “emerging growth company”. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

Recently Issued Accounting Pronouncements

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Not required.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer (our principal executive officer and principal financial officer, respectively), evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2025. 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 an issuer that are designed to ensure that information required to be disclosed by an issuer 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 Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by an issuer in the reports that it files or submits under the Exchange Act is accumulated and communicated to the issuer's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

Management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of March 31, 2026, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were not effective at the reasonable assurance level because of the material weaknesses in our internal control over financial reporting described below.

In connection with the audit of our consolidated financial statements for the years ended December 31, 2024 and 2025, we identified material weaknesses in our internal control over financial reporting. As defined in the standards of the Public Company Accounting Oversight Board (United States), a material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

The material weaknesses were (1) controls around the financial statement close process were not designed or operating effectively, including as a result of an inappropriate segregation of conflicting duties and insufficient evidence of performance and review of controls, and (2) information system controls around user access, segregation of conflicting duties and change management were not designed or operating effectively.

Remediation Plans

To remediate these material weaknesses, we have made and plan to continue to make improvements to the design and operating effectiveness of our internal controls over financial reporting, including the monitoring, oversight and evaluation of our internal controls. We also plan to allocate more internal resources to our internal controls, including by hiring additional staff, and intend to engage external advisors to provide training and to reassess and redesign processes and develop new controls as appropriate, including information technology controls covering access and change management as well as cyber risks, and assisting with the evaluation and documentation of the risk assessment, design and operating effectiveness of our internal controls over financial reporting. See the section titled "*Risk Factors—We have identified material weaknesses in our internal control over financial reporting. If we are unable to remedy our material weaknesses, or if we fail to establish and maintain an effective system of internal control over financial reporting, we may be unable to produce timely and accurate financial statements or prevent fraud, which could adversely impact our business and our stock price.*"

Changes in Internal Control over Financial Reporting

Except as discussed above under "Remediation Plans", there were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the three months ended March 31, 2026 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors.

Our business is subject to numerous risks. You should carefully consider the risks and uncertainties described below together with all of the other information contained in this Quarterly Report on Form 10-Q, or this Quarterly Report, including our condensed consolidated financial statements and the related notes thereto in evaluating our company. The risks described below are not the only risks facing our company. The occurrence of any of the following risks, or of additional risks and uncertainties not presently known to us or that we currently believe to be immaterial, could cause our business, prospects, operating results and financial condition to suffer materially.

Risks Related to Our Financial Position, Need for Additional Capital and Limited Operating History

We are a clinical-stage biopharmaceutical company, have no products approved for sale and have incurred significant losses since our inception. We expect to incur significant losses for the foreseeable future and may never achieve or maintain profitability.

We are a clinical-stage biopharmaceutical company with a limited operating history. Since our inception, we have devoted substantially all of our financial resources and efforts to research and development, including clinical trials and preclinical studies of our product candidates, sutacimig and HMB-002, and have incurred significant operating losses. Our net losses were $22.7 million for the three months ended March 31, 2026 and $63.9 million for the year ended December 31, 2025. As of March 31, 2026, we had an accumulated deficit of $204.5 million. We have no approved products, and we have not generated any revenue from product sales. We have financed our operations primarily through private placements of convertible preference shares, issuances of convertible debt and, most recently, from the sale of common stock in our initial public offering, or IPO, in May 2026. We are still continuing to research and develop our product candidates, and we have not yet completed the development of any of our product candidates. We expect to continue to incur significant operating expenses and net losses for the foreseeable future. Our operating expenses and net losses may fluctuate significantly from quarter to quarter and year to year. Accordingly, our stockholders should not rely upon the results of any particular quarterly or annual period as indications of future operating performance. Because of the numerous risks and uncertainties associated with developing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis.

We anticipate that our expenses will increase substantially, if and as, we:

- continue to advance the clinical development of our product candidates, including our ongoing Phase 1/2 clinical trial of sutacimig in patients with Glanzmann thrombasthenia, our ongoing Phase 2 clinical trial of sutacimig in patients with Factor VII deficiency, and our ongoing Phase 1/2 clinical trial of HMB-002 in patients with Von Willebrand Disease, as well as any other product candidates that we may develop;
- advance our clinical-stage product candidates into later-stage clinical trials, including our planned Phase 3 clinical trial of sutacimig in patients with Glanzmann thrombasthenia, which will be required in order to seek marketing approval of our product candidates, and which we expect will be substantially more expensive than our earlier-stage clinical trials;
- continue to advance our research and preclinical activities and seek to discover and develop additional product candidates;
- establish and scale-up manufacturing processes and capabilities, or arrange for a third party to do so on our behalf, to support our clinical trials of our product candidates and commercialization of any of our product candidates for which we obtain marketing approval;
- seek regulatory and marketing approvals for any of our product candidates that successfully complete clinical trials;
- ultimately establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- continue to develop, maintain, expand and protect our intellectual property portfolio (including intellectual property obtained through license agreements) and provide reimbursement of third-party expenses related to our patent portfolio;
- acquire or in-license products, product candidates or technologies;
- establish or maintain collaborations;
- maintain, expand, enforce, defend and protect our intellectual property;

- hire additional clinical, medical, regulatory, quality control, manufacturing and other scientific and technical personnel;
- add operational, financial, clinical, quality and management information systems and personnel, including personnel to support our product development and planned future commercialization efforts of our product candidates and our operations as a public company;
- incur additional audit, legal, regulatory, tax and other expenses with being a public company; and
- make any milestone, royalty, or other payments to Novo Nordisk A/S, or Novo Nordisk, under our license agreement with Novo Nordisk, or the Novo Nordisk Agreement, and to Genmab A/S, or Genmab, under our license agreement with Genmab, or the Genmab Agreement, and under any additional future collaboration or license agreements that we may enter into.

In addition, our expenses will further increase if, among other things:

- we are required by the U.S. Food and Drug Administration, or the FDA, the European Medicines Agency, or the EMA, or other regulatory authorities to perform clinical trials or preclinical studies that are in addition to, or different than, those expected;
- there are any delays in completing our clinical trials or preclinical studies or the development of any of our product candidates; or
- there are any third-party challenges to our intellectual property or we need to defend against any intellectual property-related claim.

Even if we obtain marketing approval for, and are successful in commercializing, one or more of our product candidates, we expect to incur substantial additional research and development and other expenditures to develop and market additional product candidates and/or to expand the approved indications of any marketed product. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue.

We have never generated revenue from product sales and may never achieve or maintain profitability.

We expect that it will be several years before we have a product candidate ready for commercialization, if ever. To become and remain profitable, we must succeed in developing, obtaining the necessary marketing approvals and eventually commercializing, a product or products that generate significant revenue. The ability to achieve this success will require us to be effective in a range of challenging activities, including completing preclinical testing and clinical trials of our product candidates and any other product candidates we may identify and pursue, obtaining marketing approval for these product candidates and manufacturing, marketing and selling any products for which we may obtain marketing approval. We may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. 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 or when, or if, we will be able to generate revenue or achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable may have an adverse effect on the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product candidates, achieve our strategic objectives or even continue our operations. A decline in the value of our company could also cause our stockholders to lose all or part of their investment.

Even if we are able to generate revenue from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations. Our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain marketing approval, the accepted price for the product, the ability to obtain coverage and reimbursement, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved.

We will need substantial additional funding. If we are unable to raise capital on acceptable terms when needed, or at all, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

Our operations have consumed substantial amounts of cash since inception. Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approvals and achieve product sales. We expect to devote substantial financial resources to our ongoing and planned

activities, particularly as we commence our planned Phase 3 clinical trial of sutacimig in patients with Glanzmann thrombasthenia and continue our ongoing Phase 1/2 clinical trial of sutacimig in patients with Glanzmann thrombasthenia, Phase 2 clinical trial of sutacimig in patients with Factor VII deficiency and Phase 1/2 trial of HMB-002 in patients with Von Willebrand Disease, continue research and development and initiate additional clinical trials of, and seek marketing approval for, these and other product candidates. We expect our expenses to increase substantially in connection with our ongoing and planned activities, particularly as we advance our preclinical activities and clinical trials of and potentially seek marketing approval for our product candidates and other product candidates we may identify, and if and as we expand our research and development and scale-up and manufacture our product candidates for our current and future indications. We will be required to incur substantial costs and may experience delays in completing, or ultimately be unable to complete, the development and commercialization of any product candidates.

In addition, if we obtain marketing approval for our product candidates and any other product candidates we may identify and pursue, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution. Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding to support our continuing operations and pursue our growth strategy.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, any product candidates, if approved, may not achieve commercial success. We will not generate commercial revenues, if any, unless and until we, alone or with partners, can achieve sales of products, which we do not anticipate will occur for many years, if at all.

As of March 31, 2026, we had cash, cash equivalents and marketable securities of $163.5 million. We believe that our cash, cash equivalents and marketable securities as of March 31, 2026, together with net proceeds from the IPO of approximately $317.2 million, will enable us to fund our operating expenses and capital expenditure requirements into 2029. However, we have based this estimate on assumptions that may prove to be wrong, and our operating plan may change as a result of many factors currently unknown to us. As a result, we could deplete our capital resources sooner than we currently expect and could be forced to seek additional funding sooner than planned. We would be required to obtain substantial additional funding in order to initiate and conduct registrational and other clinical trials for our product candidates.

We currently do not have a credit facility or any committed sources of capital. If we are unable to raise capital or obtain adequate funds when needed or on acceptable terms, we may be forced to delay, limit, reduce or terminate our research and development programs or any future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Our future capital requirements will depend on many factors, including:

- the scope, progress, costs and results of our current and future preclinical studies and clinical trials for our product candidates;
- the number of clinical trials required for regulatory approval of our current or future product candidates;
- whether we partner our programs with collaborators for later-stage clinical development or commercialization;
- the number and development requirements of any other product candidates we may identify and develop;
- the costs, timing and outcome of regulatory review of our product candidates and any other product candidates we may identify and develop;
- the costs of obtaining clinical and commercial supplies of our product candidates and any other product candidates we may identify and develop;
- our ability to successfully commercialize our product candidates and any other product candidates we may identify and develop;
- the manufacturing, selling and marketing costs associated with our product candidates and any other product candidates we may identify and develop, including the cost and timing of establishing sales and marketing capabilities;
- the scope, progress, costs and results of any post-marketing studies that could be required by regulatory authorities;
- the amount and timing of sales and other revenues from our product candidates and any other product candidates we may identify and develop, including the sales price and the availability of coverage and adequate third-party reimbursement;
- the time and cost necessary to respond to technological and market developments;
- the extent to which we may acquire or in-license other product candidates and technologies;

- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such arrangements;
- milestone payments and other collaboration-based payments, if any;
- our ability to attract, hire and retain qualified personnel;
- our ability to establish a commercially viable pricing structure and obtain approval for coverage and adequate reimbursement from third-party and government payors;
- the effect of macroeconomic trends including inflation, foreign exchange rate, interest rates and tariffs; and
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining, enforcing and protecting our intellectual property and proprietary rights and defending any intellectual property-related claims.

Any additional fundraising efforts may divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize any product candidates. Additionally, volatility in the financial markets and general economic conditions may be a significant obstacle to raising the required funds. We cannot be certain that adequate additional financing will be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. If adequate funds are not available to us on a timely basis or on terms acceptable to us, we may be required to delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for one or more product candidates or discovery stage programs or delay, limit, reduce or terminate our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize any product candidates.

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

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, royalty financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements. We do not have any source of committed capital or external funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interests will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of common stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, selling or licensing our assets, making capital expenditures, declaring dividends or encumbering our assets to secure future indebtedness.

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

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

We commenced operations in 2020 and are a clinical-stage biotechnology company. Our operations to date have been limited to organizing and staffing our company, business planning, raising capital, securing intellectual property rights, in-licensing technology, discovering product candidates, undertaking preclinical studies and conducting clinical trials. While we are in the process of conducting Phase 1/2 and Phase 2 trials, we have not yet initiated or completed a Phase 3 clinical trial of any product candidate. We have not yet demonstrated our ability to successfully develop any product candidate, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. Therefore, we cannot be certain that our ongoing preclinical studies and clinical trials will be completed on time or that our planned preclinical studies and clinical trials will begin or be completed on time, if at all. Further, biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. Our stockholders should consider our prospects in light of the costs, uncertainties, delays, and difficulties frequently encountered by companies in clinical development, especially clinical-stage biopharmaceutical companies such as ours. Any predictions our stockholders make about our future success or viability may not be as accurate as they could be if we had a longer operating history or a history of successfully developing and commercializing products.

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

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

Our future ability to use our net operating losses and research and development tax credit carryforwards to offset future taxable income may be subject to certain limitations.

As of December 31, 2025, we had $170.9 million of net operating losses, or NOLs. Our anticipated activities are also expected to result in future significant NOLs in Denmark and the United States resulting in additional deferred tax assets. Utilization of most deferred tax assets is dependent on generating sufficient future taxable income in the appropriate jurisdiction and/or entity. We have recorded a full valuation allowance on our net deferred tax assets as of December 31, 2025, based on all available evidence, it is considered more likely than not that all the recorded deferred tax assets will not be realized in a future period. Additionally, most of our deferred tax assets are determined by reference to applicable corporate income tax rates in Denmark. Accordingly, in the event of a reduction of any such corporate income tax rates, the carrying value of certain of our deferred tax assets would decrease.

Moreover, our ability to use our NOLs and other deferred tax assets to offset future taxable income in Denmark and the United States may be limited if we experience an ownership change. For Danish income tax purposes, an ownership change will generally occur when one, or several shareholders together, at once or successively, acquire shares representing more than 50% of the share capital or voting power. Although such an ownership change entails no reduction of the amount of NOLs to be carried forward, the utilization is restricted to exclude offsetting against positive net capital income (e.g. income from interest, dividend and royalty) on NOLs incurred in a previous income year, where the ownership has changed by more than by 50% (under section 12D of the Danish Corporate Tax Act). In the United States, in general, under Section 382 of the Internal Revenue Code of 1986, as amended, and corresponding provisions of state law, a corporation that undergoes an “ownership change,” generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders over a three-year period, is subject to limitations on its ability to utilize its pre-change NOLs and research and development tax credit carryforwards to offset future taxable income. We have not conducted a study to assess whether any such ownership changes have occurred. We may have experienced such ownership changes in the past and may experience such ownership changes in the future through subsequent changes in our stock ownership (which may be outside our control). As a result, if, and to the extent that, we earn net taxable income, our ability to use our pre-change NOLs and research and development tax credit carryforwards to offset such taxable income may be subject to limitations.

There is also a risk that due to regulatory changes, such as suspensions on the use of NOLs, or other unforeseen reasons, our existing NOLs could expire or otherwise become unavailable to offset future income tax liabilities. Additionally, in the United States, state NOLs generated in one state cannot be used to offset income generated in another state. For these reasons, even if we attain profitability, we may be unable to use a material portion of our NOLs and other tax attributes.

The tax authorities in the jurisdictions in which we operate may challenge our transfer pricing procedures.

We are a multinational business that has operations in Denmark and other tax jurisdictions, and the tax laws of those jurisdictions generally require that royalty and other payments between affiliated companies in different jurisdictions be the same as those between unrelated companies dealing at arm’s length, and that such prices are supported by contemporaneous documentation. While we believe that we operate in compliance with applicable transfer pricing laws and intend to continue to do so, our transfer pricing procedures are not binding on applicable tax authorities. If tax authorities in any of these jurisdictions were to successfully challenge our transfer prices as not reflecting arm’s length transactions, they could require us to adjust our transfer prices and thereby reallocate our income or deductions to reflect these revised transfer prices, which could result in a higher overall tax liability to us and possibly interest and penalties.

Additionally, tax authorities in the jurisdictions in which we operate may challenge our treatment of our corporate reorganization. No assets (either physical or intangible) were transferred from Denmark to the United States pursuant to our corporate reorganization, nor were any existing business functions or units operating from Denmark transferred from Hemab ApS to Hemab Therapeutics Holdings, Inc. as part of our corporate reorganization to form part of our U.S. operations. Accordingly, we have not treated and do not intend to treat our corporate reorganization as a deemed sale of all or part of our business by Hemab ApS to Hemab Therapeutics Holdings, Inc. If Danish tax authorities were to disagree with our position and treat our corporate reorganization or any of our activities thereafter as a deemed sale, in whole or in part, of intellectual property rights and/or other assets owned by Hemab ApS to Hemab Therapeutics Holdings, Inc., we could be subject to a Danish tax, the current rate of which is 22%, on the gain realized calculated as the difference between the fair market value and the tax value of the assets, at the time of the deemed sale of the assets from Denmark as determined by the Danish tax authorities.

Finally, the nature of our operations can produce conflicting claims from tax authorities in different countries as to the profits to be taxed in the individual countries. The jurisdictions in which we operate have double tax treaties with other jurisdictions, which provide a framework for mitigating the impact of double taxation on our revenues and capital gains. However, mechanisms developed to resolve such conflicting claims are largely untested, can be expected to be very lengthy, and do not always contain a mandatory dispute resolution clause. In recent years, tax authorities around the world have increased their scrutiny of company tax filings and have become more rigid in exercising any discretion they may have.

In general, tax reform efforts, including with respect to transfer pricing, will require us to continually assess our organizational structure and could lead to an increased risk of international tax disputes, an increase in our effective tax rate and an adverse effect on our financial condition.

Risks Related to the Discovery, Development and Commercialization of Our Product Candidates

We are heavily dependent on the success of sutacimig and HMB-002, which are our only clinical-stage product candidates.

We currently have no products that are approved for commercial sale and may never be able to develop marketable products. We expect that a substantial portion of our efforts and expenditures over the next several years will be devoted to sutacimig and HMB-002, which are currently our only clinical-stage product candidates. Accordingly, our business currently depends heavily on the successful development, marketing approval and commercialization of these product candidates. We cannot be certain that sutacimig or HMB-002 will receive marketing approval, be approved for the indications that we may seek or be successfully commercialized even if we receive marketing approvals. If we were required to discontinue development of sutacimig or HMB-002, or if any of these product candidates do not receive marketing approvals or fail to achieve significant market acceptance, we would be delayed by many years in our ability to achieve profitability, if ever, and may not be able to generate sufficient revenue to continue our business.

If we are unable to successfully complete clinical development, obtain marketing approval for, and ultimately commercialize our product candidates, or experience significant delays in doing so, our business will be materially harmed.

To date, we have invested a majority of our efforts and financial resources in the preclinical and clinical development of our product candidates, including our ongoing Phase 1/2 clinical trial of sutacimig in patients Glanzmann thrombasthenia, Phase 2 clinical trial of sutacimig in patients with Factor VII deficiency and our ongoing Phase 1/2 clinical trial of HMB-002 in patients with Von Willebrand Disease. We have not yet initiated a Phase 3 trial of any product candidate. Our future success is heavily dependent on our ability to successfully develop, obtain marketing approval for and ultimately commercialize our product candidates. We cannot be certain that our product candidates will be successful in clinical trials or receive marketing approval.

The success of our product candidates will depend on several factors, including the following:

- successfully completing clinical trials;
- acceptance by the FDA or other regulatory agencies of regulatory filings for our product candidates;
- expanding and maintaining a workforce of experienced scientists and others to continue to develop our product candidates;
- obtaining and maintaining intellectual property protection and regulatory exclusivity for our product candidates;
- making arrangements with third-party manufacturers for, or establishing, commercial manufacturing capabilities;
- establishing sales, marketing and distribution capabilities and successfully launching commercial sales, if and when approved, whether alone or in collaboration with others;
- acceptance of the products, if and when approved, by patients, the medical community and third-party payors;
- further chemistry, manufacturing and controls, manufacturing or development and optimization of the formulation and presentation of our product candidates;
- effectively competing or successfully being administered with other approved therapies;
- obtaining and maintaining coverage, adequate pricing and adequate reimbursement from third-party payors, including government payors;
- patients' willingness to pay out of pocket for our products in the absence of coverage and/or adequate reimbursement from third-party payors;
- maintaining, enforcing, defending and protecting our rights in our intellectual property portfolio;

- not infringing, misappropriating or otherwise violating others' intellectual property or proprietary rights; and
- maintaining a continued acceptable safety and tolerability profile following receipt of any marketing approvals.

Although we are planning to conduct a multinational, multicenter, Phase 3, single-arm, open-label clinical trial evaluating sutacimig as a prophylactic therapy in adults with Glanzmann thrombasthenia, the FDA may determine that a randomized controlled clinical trial is necessary to support filing and approval of our Biologics License Application, or BLA. We intend to schedule a Type D meeting with the FDA in the coming months to obtain the FDA's feedback on, and seek alignment regarding, our proposed Phase 3 trial design. A Type D meeting is intended to facilitate focused discussion on a limited number of specific issues, but there can be no assurance that the FDA will agree with our proposed approach. If the FDA requires us to conduct a randomized controlled Phase 3 clinical trial, we could incur additional costs and delays, to the extent any such trial is more complex, time-consuming and/or expensive to design, initiate and complete. A randomized trial may require a larger number of patients, longer enrollment and follow-up periods, and additional clinical sites, which could delay the timing of any regulatory submission and potential approval. In addition, the use of a control arm may introduce ethical, operational and recruitment challenges, particularly if patients or investigators are reluctant to participate in a study where treatment assignment is randomized. There is also a risk that a randomized trial could fail to meet its primary or secondary endpoints, even if a single-arm study might have demonstrated favorable results, which could materially and adversely affect our ability to obtain regulatory review and approval and commercialize our product candidate.

Many of these factors are beyond our control, including clinical outcomes, the regulatory review process, potential threats to our intellectual property rights and the manufacturing, marketing and sales efforts of any future collaborators. If we are unable to develop, receive marketing approval for and successfully commercialize our product candidates, or if we experience delays as a result of any of these factors or otherwise, we may need to spend significant additional time and resources to identify other product candidates, advance them through preclinical and clinical development, and apply for marketing approvals, which would adversely affect our business, prospects, financial condition and results of operations.

Clinical drug development involves a lengthy and expensive process, with an uncertain outcome. We will be required to incur substantial costs and may experience delays in completing, or ultimately be unable to complete, the development and commercialization of any product candidates.

The risk of failure for our product candidates and any other product candidates we may develop is high. It is impossible to predict when or if our product candidates and any other product candidates we may develop will prove effective or safe in humans or will receive marketing approval. The time required to obtain approval from the FDA, EMA or other comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of regulatory authorities. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of such product candidate in humans. We have not yet initiated a pivotal clinical trial for any of our product candidates. Clinical trials may fail to demonstrate that our current or future product candidates are safe for humans and effective for indicated uses. Even if initial clinical trials in any of our product candidates we may develop are successful, these product candidates may fail to show the desired safety and efficacy in later stages of clinical development despite having successfully advanced through preclinical studies and initial clinical trials. There is a high failure rate for drugs proceeding through clinical trials. A number of companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in later-stage clinical trials even after achieving promising results in earlier-stage clinical trials.

Furthermore, clinical trials for blood disorders present unique challenges:

- The small patient populations in the indications we are pursuing, such as Glanzmann thrombasthenia and Factor VII deficiency (which we estimate to be approximately 10,000 patients in the aggregate in the geographies where we intend to commercialize sutacimig, including the United States, the European Union, Japan, the Gulf Cooperation Council, or GCC, countries and other select regions), may make it challenging to enroll a sufficient number of patients in our clinical trials.
- The variability in bleeding phenotypes and disease severity in these conditions can make it difficult to demonstrate statistical significance in clinical endpoints.
- The lack of validated biomarkers and endpoints in blood disorders requires us to develop novel endpoints, which may not be accepted by regulatory authorities.
- Patients with coagulation disorders may be geographically dispersed, requiring multi-national clinical trials with associated regulatory complexity.
- Recruitment of patients for our clinical trials may be slower than anticipated due to the low prevalence of these conditions, competition for patients from other clinical trials and the burden of our clinical trials on patients, including due to the duration of our clinical trials, the need for a higher degree of oversight by principal investigators, and the requirement of patient adherence to strict electronic bleed diary protocol requirements.

- The potential that rare and severe side effects of our product candidates may be uncovered in the later stages of clinical development due to accelerated development, which could result in disruptions and delays or a need for increased sample sizes for our clinical trials.
- As with most procoagulant drugs, our product candidates have the potential for adverse effects, including thrombotic events, which can occur at any active dose level due to sporadic or patient-specific factors that are hard to identify.
- The patient populations in coagulation disorders are not as accustomed to participation in clinical trials, as in other indications, which may impact the ability to recruit and maintain patients in our clinical trials.

Even if the clinical trials are successful, changes in marketing approval policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted product application may cause delays in the approval or rejection of an application.

Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support investigational new drug applications, or INDs, and other regulatory filings in the United States, marketing applications in the European Union and other applications and filings in other jurisdictions. We cannot be certain of the timely completion or outcome of preclinical testing and studies and cannot predict if the FDA or other regulatory agencies will accept any proposed clinical programs or if the outcome of any preclinical testing and studies will ultimately support the further development of any product candidates. As a result, we cannot be sure that we will be able to submit INDs or similar applications for any preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin. Furthermore, product candidates are subject to continued preclinical safety studies, which may be conducted concurrently with clinical testing. The outcomes of these safety studies may delay the launch of, or enrollment in, future clinical trials and could impact our ability to continue to conduct our clinical trials.

Clinical testing is expensive and is difficult to design and implement, can take many years to complete, and is uncertain as to outcome. We cannot guarantee that any of our clinical trials will be conducted as planned or completed on schedule, or at all. A failure of one or more clinical trials can occur at any stage of testing, which may result from a multitude of factors, including, but not limited to, flaws in study design, dose selection issues, placebo effects, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits.

Preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Furthermore, the failure of any of our product candidates to demonstrate safety and efficacy in any clinical trial could negatively impact the perception of our other product candidates and/or cause the FDA, EMA or other regulatory authorities to require additional testing before approving any of our product candidates.

We may incur unexpected costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

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

- regulators or institutional review boards, or IRBs, or independent ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- regulators may decide that longer follow-up data are needed before they will consider our marketing applications, which would delay our ability to obtain marketing approval;
- regulators may decide the design of our clinical trials is flawed, for example, if our trial protocol does not evaluate treatment effects in trial subjects for a sufficient length of time;
- clinical trials of our product candidates and any other product candidates we may develop may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon product development programs;
- we may be unable to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful, or, if we seek accelerated approval, biomarker efficacy endpoints that applicable regulatory authorities would consider likely to predict clinical benefit;

- preclinical testing may produce results based on which we may decide, or regulators may require us, to conduct additional preclinical studies before we proceed with certain clinical trials, limit the scope of our clinical trials, halt ongoing clinical trials or abandon product development programs;
- the number of patients required for clinical trials of our product candidates and any other product candidates we may develop may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate, or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may decide, or regulators or IRBs may require us, to suspend or terminate clinical trials of our product candidates and any other product candidates we may develop for various reasons, including non-compliance with regulatory requirements or a finding that the participants are being exposed to unacceptable health risks;
- regulators may require us to perform additional or unanticipated clinical trials to obtain approval or we may be subject to additional post-marketing testing requirements to maintain marketing approval;
- regulators may revise the requirements for approving our product candidates and any other product candidates we may develop, or such requirements may not be as we anticipate;
- the cost of clinical trials of our product candidates and any other product candidates we may develop may be greater than we anticipate;
- the supply or quality of our product candidates and any other product candidates we may develop or other materials necessary to conduct clinical trials of such product candidates may be insufficient or inadequate;
- our product candidates and any other product candidates we may develop may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs or ethics committees to suspend or terminate the trials; and
- regulators may withdraw their approval of a product or impose restrictions on its distribution, such as in the form of a risk evaluation and mitigation strategy, or REMS.

We could encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are conducted or their ethics committees, by the data review committee or data safety monitoring board for such trial or by the FDA, EMA or other foreign regulatory authorities. Such authorities may suspend or terminate a clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA, EMA or other foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, including those relating to the class of products to which our product candidates belong.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials or other testing of our product candidates or any other product candidates we may develop, if the results of these trials or tests are not positive or are only modestly positive, or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for any product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling or a REMS that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in preclinical studies or clinical trials or in obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. We may also determine to change the design or protocol of one or more of our clinical trials, including to add additional patients or arms, which could result in increased costs and expenses and/or delays. Significant preclinical study or clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize any product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize any product candidates and may harm our business and results of operations.

The outcome of preclinical studies and earlier-stage clinical trials may not be predictive of the success of later-stage clinical trials.

The outcome of preclinical testing and earlier-stage clinical trials may not be predictive of the success of later-stage clinical trials. Our product candidates and any other product candidates we may develop may fail to show the desired safety, potency and purity in clinical development despite positive results in preclinical studies or having successfully advanced through initial clinical trials. For example, we are currently planning our Phase 3 clinical trial of sutacimig in patients with Glanzmann thrombasthenia, based off the positive results of our Phase 1/2 dose-finding study in patients with Glanzmann thrombasthenia. However, we cannot provide assurances that the evidence of activity we observed in our Phase 1/2 trial of sutacimig will translate to our planned Phase 3 clinical trial. Additionally, any positive results generated in our ongoing and planned clinical trials do not ensure that we will achieve similar results in later-stage clinical trials of these product candidates, and we cannot provide assurances that we will be able to seek or obtain marketing approval for any of our product candidates even if our clinical trials are successful.

Many companies in the pharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving promising results in preclinical testing and earlier-stage clinical trials, and we cannot be certain that we will not face similar setbacks. In addition, while the animal models used in preclinical studies are designed to be representative of disease states in humans, these preclinical models may not be able to accurately predict the way a product candidate will affect patients in clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products. Furthermore, the failure of any product candidate to demonstrate safety, potency and purity in any clinical trial could negatively impact the perception of any other product candidates we may developing at the time and/or cause the FDA or other regulatory authorities to require additional testing before approving any other product candidates.

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

From time to time, we may publish or report interim, top-line or preliminary results from our clinical trials. For example, we plan to report data for our Phase 2 clinical trial of sutacimig in Factor VII deficiency in late 2026 or early 2027, and data from our Phase 1/2 clinical trial of HMB-002 in patients with Von Willebrand Disease in late 2026 or early 2027. 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, interim 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 or interim data we previously published. As a result, interim, top-line and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could be material and could significantly harm our reputation and business prospects and may cause the trading price of our common stock to fluctuate significantly.

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

We will need to successfully complete pivotal clinical trials in order to obtain the approval of the FDA, the EMA, or other regulatory agencies to market our product candidates or any future product candidate. Carrying out later-stage clinical trials is a complicated process. As an organization, we have not previously conducted any pivotal clinical trials. In order to do so, we will need to significantly expand our clinical development and regulatory capabilities. In addition, we may be unable to recruit and train qualified personnel. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to approval of our product candidates or future product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining marketing approvals of product candidates that we develop.

Due to the complexity, expense, scale and size of clinical trials, we may have to find one or more collaborators to conduct such a trial, and there can be no assurance that we would be able to do so. Even if we are able to find a collaborator, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. See “—Risks Related to Our Dependence on Third Parties—We may enter into collaborations with third parties for the development or commercialization of product candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates and our business could be adversely affected.” Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in commercializing our product candidates.

If we do not achieve our projected development and commercialization goals in the timeframes we announce and expect, the development and commercialization of our product candidates may be delayed, and our business and results of operations may be harmed.

For planning purposes, we sometimes estimate the timing of the accomplishment of various scientific, clinical, regulatory and other product development objectives. These milestones may include our expectations regarding the commencement or completion of scientific studies and clinical trials, the submission of regulatory filings or commercialization objectives. From time to time, we may publicly announce the expected timing of some of these milestones, such as the completion of an ongoing clinical trial, the initiation of other clinical programs, receipt of marketing approval or a commercial launch of a product. The achievement of many of these milestones may be outside of our control. All of these milestones are based on a variety of assumptions which, if not realized as expected, may cause the timing of achievement of the milestones to vary considerably from our estimates, including:

- our available capital resources or capital constraints we experience;
- the rate of progress, costs and results of our clinical trials and research and development activities, including the extent of scheduling conflicts with participating clinicians and collaborators;
- our ability to identify and enroll patients who meet clinical trial eligibility criteria;
- our receipt of approvals by the FDA, EMA, and other comparable regulatory authorities and the timing thereof;
- other actions, decisions or rules issued by regulators;
- our ability to access sufficient, reliable and affordable supplies of materials used to manufacture our product candidates;
- the efforts of our collaborators with respect to the commercialization of our product candidates; and
- the securing of, costs related to, and timing issues associated with, product manufacturing as well as sales and marketing activities.

If we fail to achieve announced milestones in the timeframes we expect, the development and commercialization of our product candidates may be delayed, and our business and results of operations may be harmed.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our receipt of necessary marketing approvals could be delayed or prevented.

Identifying and qualifying patients to participate in clinical trials for our product candidates and any other product candidates we may develop is critical to our success. Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients, as required by the FDA, EMA or similar regulatory authorities in other jurisdictions, who remain in the trial until its conclusion. Additionally, the prevalence of patients in our target indications is estimated to be low, and we estimate that there are approximately an aggregate of 10,000 patients with Glanzmann thrombasthenia and Factor VII deficiency and an aggregate of 120,000 patients with Von Willebrand Disease in the geographies where we intend to commercialize, including the United States, the European Union, Japan, the GCC countries and other select regions. We may not be able to identify, recruit, and enroll a sufficient number of patients to complete our clinical trials of our product candidates because of the perceived risks and benefits of our product candidates, the availability of competing therapies and clinical trials, the proximity and availability of clinical trial sites for prospective subjects and the subject referral practices of physicians, among other factors. Patient enrollment is affected by a variety of other factors, including:

- the prevalence and severity of the disease under investigation;
- the eligibility and the discontinuation criteria for the trial in question;
- the perceived risks and benefits of the product candidate under trial;
- the requirements of the trial protocols;
- the availability of existing commercially available treatments for the targeted indications;
- the ability to recruit clinical trial investigators with the appropriate competencies and experience;
- efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- the proximity and availability of clinical trial sites for prospective patients;
- the conduct of clinical trials by competitors for product candidates that treat the targeted indications;
- the ability to identify specific patient populations for biomarker-defined trial cohort(s); and
- the cost to, or lack of adequate compensation for, prospective patients.

Our inability to locate and enroll a sufficient number of patients for our clinical trials would result in significant delays, could require us to abandon one or more clinical trials altogether and could delay or prevent our receipt of necessary marketing approvals, any of which would have an adverse effect on our business, financial condition, results of operations and prospects. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and any other product candidates we may develop, which would cause the value of our company to decline and limit our ability to obtain additional financing.

Even if we are able to enroll a sufficient number of patients for our future clinical trials, we may have difficulty maintaining patients in our clinical trials, including that patients may drop out of our clinical trials. If we have difficulty enrolling or maintaining a sufficient number of patients to conduct our clinical trials, we may need to delay, limit or terminate clinical trials, any of which would harm our business, financial condition, results of operations and prospects.

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

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered over the course of development in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue.

Serious adverse events of thrombosis have been identified in the development of sutacimig, and if additional serious adverse events or unacceptable side effects are identified during the development of our product candidates and any other product candidates we may develop, we may need to abandon or limit our development of those product candidates.

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 our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. For example, our Phase 1/2 clinical trial of sutacimig for the treatment of Glanzmann thrombasthenia has included only 34 patients.

In addition, as we continue to evaluate our product candidates, rare and severe side effects of our product candidates may be uncovered in the later stages of our current and future clinical development. For example, in our Phase 1/2 clinical trial of sutacimig in Glanzmann thrombasthenia, several patients have experienced events of thrombosis. In particular, one patient experienced a grade 2 proximal deep vein thrombotic event at the highest exposure level (0.9 mg/kg) and one patient at the 0.3 mg/kg dose level (whose dose had been reduced from 0.6 mg/kg) experienced grade 2 subsegmental pulmonary embolism. These events were reported to the FDA on an expedited reporting basis as an event of a type referred to as a Suspected Unexpected Serious Adverse Reaction (SUSAR). While we expect to select a lower dose than 0.6 mg/kg for purposes of our planned Phase 3 clinical trial, thrombotic events have been reported at the 0.3 mg/kg dose level, and there is no guarantee that thrombotic events or other serious adverse events will not occur even at lower doses. In addition, sutacimig's mechanism of action inherently carries the risk of thrombotic complications if the drug achieves excessive systemic exposure or if patients have concurrent prothrombotic conditions or other risk factors. HMB-002's intended mechanism of increasing von Willebrand factor, or VWF, and Factor VIII levels could also increase thrombotic risk, particularly in patients with concurrent conditions that increase VWF levels, such as pregnancy, acute illness, or hormonal contraception use, or result in other adverse events.

Furthermore, many product candidates that initially showed promise in early-stage testing have later been found to cause side effects that prevented their further development. If our product candidates and any other product candidates we may develop are associated with undesirable side effects in clinical trials or have characteristics that are unexpected in clinical trials or preclinical testing, we may need to abandon their development or limit development to more narrow uses or subpopulations in which the side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. In biopharmaceutical development, many compounds that initially show promise in early-stage or clinical testing are later found to cause side effects that delay or prevent further development of the compound.

Additionally, if results of our clinical trials reveal unacceptable side effects, we, the FDA or the IRBs at the institutions in which our studies are conducted could suspend or terminate our clinical trials, or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of our product candidates and any other product candidates we may develop for any or all targeted indications. Furthermore, we expect that our clinical trial protocol for our planned Phase 3 trial may require us to pause or stop enrollment in the trial if one or more thrombotic events occur in order to assess whether it is safe to proceed with further enrollment and dosing. Any such event could cause significant delays in the execution and completion of the trial, or lead to discontinuation altogether. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete any of our clinical trials. In addition, these side effects may not be appropriately recognized or managed by the treating medical staff. We may need to train medical personnel using our product candidates to understand the side effect profiles for our clinical trials and upon any commercialization of any of our product candidates. Inadequate training in recognizing or managing the potential side effects of our product candidates could result in harm to patients that are administered our product candidates. Any of these occurrences may adversely affect our business, financial condition and prospects significantly.

If any product candidate receives marketing approval and we, or others, later discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability to market the drug could be compromised.

We conduct, and intend to conduct in the future, clinical trials of product candidates in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If any product candidate receives marketing approval, and we, or others, later discover that it is less effective than previously believed, or causes undesirable side effects, a number of potentially significant negative consequences could result, including:

- withdrawal or limitation by regulatory authorities of approvals of such product;
- seizure of the product by regulatory authorities;
- recall of the product;
- restrictions on the marketing of the product or the manufacturing process for any component thereof;
- requirement by regulatory authorities of additional warnings on the label, such as a “black box” warning or contraindication;
- requirement that we implement a REMS or create a medication guide outlining the risks of such side effects for distribution to patients;
- commitment to expensive post-marketing studies as a prerequisite of approval by regulatory authorities of such product;
- the product may become less competitive;
- initiation of regulatory investigations and government enforcement actions;
- initiation of legal action against us to hold us liable for harm caused to patients; and
- harm to our reputation and resulting harm to physician or patient acceptance of our products.

Any of these events could prevent us from achieving or maintaining market acceptance of a particular product candidate, if approved, and could significantly harm our business, financial condition, and results of operations.

Some data for our product candidates comes from clinical trials conducted outside the United States or European Union. The FDA, EMA, or other comparable regulatory authorities, may not accept data from trials conducted in such locations, which could subject us to additional delays and expense.

We may conduct one or more of our clinical trials with one or more trial sites that are located outside the United States or European Union. The acceptance of data from clinical trials conducted outside the United States or another jurisdiction by the FDA may be subject to certain conditions or may not be accepted at all. Similarly, the EMA, and other equivalent foreign regulatory authorities may not accept data from trials conducted outside their jurisdiction. For example, we are currently conducting our ongoing Phase 2 clinical trial of sutacimig in patients with Factor VII deficiency at sites in the United Kingdom, and our ongoing Phase 1/2 trial of HMB-002 in patients with Von Willebrand Disease at sites in United Kingdom, Australia, and the United States. We plan to conduct our Phase 3 clinical trial of sutacimig in patients with Glanzmann thrombasthenia in the United States, Europe and potentially other jurisdictions. In cases where data from clinical trials outside of the United States are intended to serve as the basis for marketing approval in the United States, acceptance of these data is subject to conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and be performed by qualified investigators in accordance with ethical principles. The FDA must be able to validate the data from the trial through an onsite inspection, if necessary. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In addition, while these clinical trials are subject to the applicable local laws, whether the FDA accepts the data will depend on its determination that the trials also complied with all applicable U.S. laws and regulations. Additionally, recent policy proposals in the United States, if enacted in the future, may make acceptance by the FDA or inclusion in a marketing application of non-U.S. data more difficult or costly. There can be no assurance that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from any trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and could delay or permanently halt our development of the applicable product candidates.

We may not be successful in our efforts to identify or discover additional product candidates and may fail to capitalize on programs or product candidates that may present a greater commercial opportunity or for which there is a greater likelihood of success.

If we do not successfully develop and eventually commercialize products, we will not generate product revenue in future periods, resulting in significant harm to our financial position and adversely affecting our share price. Research programs to identify new product candidates require substantial technical, financial and human resources.

Although our product candidates are currently in clinical development, we may fail to identify other potential product candidates for clinical development. Our focus on blood coagulation disorders limits our opportunities to a specific therapeutic area. If there are fewer than anticipated viable product targets in this area, or if competitors develop superior products for these indications, our business may suffer.

Additionally, because we have limited resources, we may forego or delay pursuit of opportunities with certain programs or product candidates or for indications that later prove to have greater commercial potential. For example, we currently intend to focus our capital resources primarily on the development of our product candidates. We have prioritized the development of sutacimig for Glanzmann thrombasthenia and Factor VII deficiency, which are both blood disorders with small patient populations, instead of potentially expanding into larger platelet disorder indications, which may have larger markets and potentially greater commercial returns. The development of our product candidates may ultimately prove to be unsuccessful or less successful than another potential product candidate in our pipeline that we might have chosen to pursue on a more aggressive basis with our capital resources. If we do not accurately evaluate the commercial potential for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic collaborations, licensing or other arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate. Alternatively, we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

If we engage in future acquisitions, this may increase our capital requirements, dilute our stockholders, cause us to incur debt or assume contingent liabilities, and subject us to other risks.

From time to time, we evaluate various acquisition opportunities, including licensing or acquiring complementary products, product candidates, intellectual property rights, technologies or businesses. Any potential acquisition may entail numerous risks, including:

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

We do not know if we will be able to identify acquisitions or strategic relationships we deem suitable, whether we will be able to successfully complete any such transactions on favorable terms, if at all, or whether we will be able to successfully integrate any acquired business, product or technology into our business or retain any key personnel or suppliers. Our ability to successfully grow through strategic transactions depends upon our ability to identify, negotiate, complete and integrate suitable target businesses, technologies or products and to obtain any necessary financing. These efforts could be expensive and time-consuming and may disrupt our ongoing business and prevent management from focusing on our operations.

To finance any acquisitions, investments or strategic alliances, we may choose to issue shares of our common stock as consideration, which could dilute the ownership of our stockholders. If the price of our common stock is low or volatile, we may be unable to consummate any acquisitions, investments or strategic alliances using our common stock as consideration. Additional funds may not be available on terms that are favorable to us, or at all.

Even if any product candidate receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If any product candidate receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. Sales of medical products depend in part on the willingness of physicians to prescribe the treatment, which is likely to be based on a determination by these physicians that the products are safe, therapeutically effective and cost-effective. In addition, the inclusion or exclusion of products from treatment guidelines established by various physician groups and the viewpoints of influential physicians can affect the willingness of other physicians to prescribe the treatment. We cannot predict whether physicians, physicians' organizations, hospitals, other healthcare providers, government agencies or private insurers will determine that our product is safe, therapeutically effective and cost-effective as compared with competing treatments. Efforts to educate the medical community and third-party payors on the benefits of our product candidates and any other product candidates we may develop may require significant resources, including management time and financial resources, and may not be successful. If our product candidates and any other product candidates we may develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable. The degree of market acceptance of our product candidates and any other product candidates we may develop, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy, safety and potential advantages of our product candidates compared to the advantages and relative risks of alternative treatments;
- the effectiveness of sales and marketing efforts;
- the cost of treatment in relation to alternative treatments, including any similar generic or biosimilar treatments;
- whether the product is designated under physician treatment guidelines as a first-, second- or third-line therapy;
- limitations or warnings, including distribution or use restrictions contained in the product's approved labeling;
- the clinical indications for which the product is approved;
- the convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try new therapies and to continue treatment over time and of physicians to prescribe these therapies;
- the strength of marketing and distribution support;
- the timing of market introduction of competitive products;
- the availability of third-party coverage and adequate reimbursement, and patients' willingness to pay out of pocket for required co-payments or in the absence of third-party coverage or adequate reimbursement;
- the prevalence and severity of any side effects;
- any restrictions on the use of our products, if approved, together with other medications; and
- any failure by one or more of our product candidates that obtains regulatory approval to achieve market acceptance or commercial success would adversely affect our business prospects.

If the market opportunities for any product candidates we develop are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer.

We focus our research and product development on treatments for bleeding disorders. Given the small number of patients who have certain of the diseases that we are targeting, it is critical to our ability to grow and become profitable that we continue to successfully identify patients with these diseases. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with any product candidates we may develop, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including scientific literature, surveys of clinics, patient foundations or market research, and "360" natural history studies that we conducted, and may prove to be incorrect or contain errors. New studies may change the estimated incidence or prevalence of these diseases. The number of patients may turn out to be lower than expected. The effort to identify patients with diseases we seek to treat is in early stages, and we cannot accurately predict the number of patients for whom treatment might be possible. Additionally, the potentially addressable patient population for each of our product candidates may be limited or may not be amenable to treatment with our product candidates, and new patients may become increasingly difficult to identify or gain access to, which would adversely affect our results of operations and our business. Further, even if we obtain significant market share for our product candidates, because the potential target populations are very small, we may never achieve profitability despite obtaining such significant market share. Additionally, if the actual market for any product candidates we may develop is smaller than we estimate, our revenues, if any, may be limited and it may be more difficult for us to achieve or maintain profitability.

Even with high penetration rates and premium pricing typical of orphan drugs, the revenue potential for sutacimig for the treatment of Glanzmann thrombasthenia and Factor VII deficiency may be limited due to the small patient populations. The pricing and reimbursement of any product candidates we may develop, if approved, is uncertain, and it may not be adequate to support commercial infrastructure. If we are unable to obtain adequate levels of pricing or reimbursement, our ability to successfully market and sell product candidates will be adversely affected.

If we are unable to establish sales, marketing and distribution capabilities or enter into sales, marketing and distribution agreements with third parties, we may not be successful in commercializing any product candidates if and when they are approved.

We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any product for which we have obtained marketing approval, we will need to establish a sales, marketing and distribution organization, either ourselves or through collaborations or other arrangements with third parties.

In the future, we expect to build a sales and marketing infrastructure to market our product candidates and any other product candidates we may develop in the United States, Europe and potentially other jurisdictions, if and when approved by the respective regulatory authority.

There are risks involved with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. These efforts may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to commercialize our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales, marketing, coverage or reimbursement, customer service, medical affairs and other support personnel;
- the inability of sales personnel to educate adequate numbers of physicians on the benefits of any future products;
- the inability of reimbursement professionals to negotiate arrangements for formulary access, reimbursement and other acceptance by payors;
- the inability to price our products at a sufficient price point to ensure an adequate and attractive level of profitability;
- restricted or closed distribution channels that make it difficult to distribute our products to segments of the patient population;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we are unable to establish our own sales, marketing and distribution capabilities and we enter into arrangements with third parties to perform these services, our product revenues and our profitability, if any, are likely to be lower than if we were to market, sell and distribute any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell, market and distribute any product candidates or may be unable to do so on terms that are acceptable to us. We likely will have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales, marketing and distribution capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing any product candidates.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The development and commercialization of new drug products is highly competitive. We face competition with respect to our product candidates, and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. There are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for the treatment of the same disease indications we are pursuing. Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization. Any product candidates that we successfully develop and commercialize will compete with existing products and new products that may become available in the future.

There are currently no subcutaneous prophylactic therapies for Glanzmann thrombasthenia or Factor VII deficiency that are in development or approved. However, companies could develop new therapies or repurpose existing therapies for Glanzmann thrombasthenia or Factor VII deficiency, such as emicizumab (Hemlibra), which was developed for hemophilia A, but could potentially be studied in other bleeding disorders, potentially including our target indications.

For Von Willebrand Disease, the competitive landscape includes currently available therapies and products in development. The current standard of care includes desmopressin and VWF replacement products, including both plasma-derived products (Humate-P, Wilate, Alphanate) and recombinant VWF (Vonvendi). These products have established positions in the market and physician familiarity. In addition, Star Therapeutics Inc. is currently developing VGA-039, an investigational monoclonal antibody that inhibits protein S, which is currently in Phase 3 clinical development for Von Willebrand Disease.

Our commercial opportunity 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 more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other marketing approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic and/or biosimilar products. If any product candidates achieve marketing approval, we expect that they would be priced at a significant premium over competitive generic or biosimilar products.

Many of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining marketing approvals and marketing approved products than we do. If we successfully obtain approval for any product candidate, we will face competition based on many different factors, including the safety, tolerability and effectiveness of our products, the ease with which our products can be administered, the timing and scope of regulatory approvals for these products, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, tolerable or convenient, safer, less expensive or marketed and sold more effectively than any products we may develop. Competing products may render any product candidates we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our product candidates. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected.

Mergers and acquisitions in the pharmaceutical, biopharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other 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, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Even if we are able to commercialize any product candidates, the products may become subject to unfavorable pricing regulations, third-party coverage or reimbursement practices or healthcare reform initiatives, which could harm our business.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drug products vary widely from country to country. Current and future legislation may significantly change the approval requirements in ways that could involve additional costs and cause delays in obtaining approvals. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing 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 in a particular country but then be subject to price regulations that delay our commercial launch of the product, possibly for lengthy time periods, and negatively impact the revenues we are able to generate from the sale of the product in that country. Adverse pricing limitations may hinder our ability to recoup our investment in one or more product candidates, even if any product candidates obtain marketing approval.

Our ability to commercialize any product candidates successfully will depend in part on the extent to which coverage and adequate reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Government authorities and other third- party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug

companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. Coverage and reimbursement may not be available for any product that we commercialize and, even if these are available, the level of reimbursement may not be satisfactory. Reimbursement may affect the demand for, or the price of, any product candidate for which we obtain marketing approval. Obtaining and maintaining adequate reimbursement for our products may be difficult. There can be no assurance that any product candidates, even if they are approved for sale in the United States, Europe or in other jurisdictions, will be considered medically reasonable and necessary for a specific indication or cost-effective by third-party payors. We may be required to conduct expensive pharmacoeconomic studies to justify coverage and reimbursement or the level of reimbursement relative to other therapies. If coverage and adequate reimbursement are not available, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval.

There may be significant delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which the drug is approved by the FDA, European Commission or similar regulatory authorities in other jurisdictions. Moreover, eligibility for coverage and reimbursement does not imply that a drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution expenses. Interim reimbursement levels for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement rates may vary according to the use of the drug and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost drugs and may be incorporated into existing payments for other services. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Further, no uniform policy for coverage and reimbursement exists in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies, but also have their own methods and processes apart from Medicare determinations. As a result, obtaining and maintaining coverage and adequate reimbursement is often time-consuming and costly. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for any approved products that we develop could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Our future growth depends, in part, on our ability to penetrate markets outside the United States and the European Union, where we would be subject to additional regulatory burdens and other risks and uncertainties that, if they materialize, could harm our business.

Our future profitability will depend, in part, on our ability to commercialize our product candidates and any other product candidates we may develop in markets outside of the United States and the European Union. We are not permitted to market or promote any product candidate before we receive regulatory approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for any product candidates. If we commercialize our product candidates and any other product candidates we may develop in foreign markets, we will be subject to additional risks and uncertainties, including:

- economic weakness, including inflation, or political instability in particular economies and markets;
- the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements, many of which vary between countries;
- different medical practices and customs in foreign countries affecting acceptance in the marketplace;
- tariffs and trade barriers, as well as other governmental controls and trade restrictions;
- other trade protection measures, import or export licensing requirements or other restrictive actions by governments in the jurisdictions in which we operate or plan to operate;
- longer accounts receivable collection times;
- longer lead times for shipping;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is common;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries, and related prevalence of generic alternatives to therapeutics;
- foreign currency exchange rate fluctuations and currency controls;
- differing foreign reimbursement landscapes;
- uncertain and potentially inadequate reimbursement of our products; and
- the interpretation of contractual provisions governed by foreign laws in the event of a contract dispute.

If risks related to any of these uncertainties materialize, it could have a material adverse effect on our business.

Clinical trial and product liability lawsuits against us could divert our resources, could cause us to incur substantial liabilities and could limit commercialization of any products that we may develop.

We face an inherent risk of clinical trial and product liability exposure related to the testing of our product candidates and any other product candidates we may develop in clinical trials, and we will face an even greater risk if we commercially sell any products that we may develop. While we currently have no products that have been approved for commercial sale, the current and future use of product candidates by us in clinical trials, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, healthcare providers, pharmaceutical companies or others selling such products. If we cannot successfully defend ourselves against claims that our product candidates and any other product candidates or products we may develop caused injuries, we will incur substantial liabilities. Even a successful defense would require significant financial and management resources. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our product candidates and any other product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend any related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

Although we currently hold clinical trial liability insurance coverage in amounts we believe to be adequate, the coverage limits may be inadequate to cover all liabilities we may incur, and we may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of any product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If a successful clinical trial or product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

If any product candidate receives marketing approval, we will be required to report to regulatory authorities if the product causes or contributes to adverse medical events, and any failure to do so would result in sanctions that would materially harm our business.

If we are successful in commercializing any product candidate, the FDA and foreign regulatory authorities would require that we report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events within the prescribed timeframe. If we fail to comply with such reporting obligations, the FDA or a foreign regulatory authority could take action, including criminal prosecution, the imposition of civil monetary penalties, seizure of our products or delay in approval or clearance of future products.

Risks Related to Our Dependence on Third Parties

We rely, and expect to continue to rely, on third parties to conduct our clinical trials, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, which may harm our business.

We currently rely on third-party clinical research organizations, or CROs, to conduct our planned and ongoing clinical trials. We do not plan to independently conduct clinical trials of our product candidates. We expect to continue to rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our clinical trials.

These third parties are not our employees, and except for remedies available to us under our agreements with such third parties, we have limited ability to control the amount or timing of resources that any such third party will devote to our preclinical studies or our clinical trials. The third parties we rely on for these services may also have relationships with other entities, some of which may be our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could affect their performance on our behalf. Some of these third parties may terminate their engagements with us at any time. We also have to negotiate budgets and contracts with CROs and clinical trial sites

and we may not be able to do so on favorable terms, which may result in delays to our development timelines and increased costs. If we need to enter into alternative arrangements with, or replace or add any such third parties, it would involve substantial cost and require extensive management time and focus, or involve a transition period, and may delay our drug development activities, as well as materially impact our ability to meet our desired clinical development timelines.

In addition, while our reliance on these third parties for research and development activities will reduce our control over these activities, it will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with standards, commonly referred to as good clinical practices, or GCPs, for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Our failure or the failure of third parties to comply with the applicable protocol, legal and regulatory requirements and scientific standards can result in rejection of our clinical trial data or other sanctions. Additionally, if we or our third-party contractors fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA may require us to perform additional clinical trials before approving our product candidates, which would delay the regulatory approval process. We cannot be certain that, upon inspection, the FDA will determine that any of our clinical trials comply with GCPs. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

We also rely on other third parties to store and distribute drug supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or regulatory approval of our product candidates or commercialization of any resulting products, producing additional losses and depriving us of potential product revenue.

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 any product candidates and will not be able to, or may be delayed in our efforts to, successfully develop and commercialize any product candidates.

Manufacturing biologics is complex, and we may experience manufacturing problems that result in delays in our development or future commercialization programs.

The manufacturing of biologics is complex and difficult and we, or our CMOs, may experience production issues or interruptions for sutacimig, HMB-002 or any other product candidate we may develop, including raw material or starting material variability in terms of quality, cell line viability, productivity or stability issues, shortages of any kind, shipping, distribution, storage and supply chain failures, growth media contamination, equipment malfunctions, operator errors, facility contamination, labor problems, natural disasters, disruption in utility services, terrorist activities, or acts of god that are beyond our control or the control of our third party manufacturers.

Given the nature of biologics manufacturing, there is a risk of contamination during manufacturing. Any contamination could materially harm our or our third party manufacturers' ability to produce sutacimig, HMB-002 or any other product candidate we may develop on schedule and could harm our results of operations and cause reputational damage. Some of the raw materials that we require in our manufacturing process are derived from biologic sources. Such raw materials may be difficult to procure and may be subject to contamination or recall.

Problems with the manufacturing process, even minor deviations from the normal process, could result in product defects or manufacturing failures that result in lot failures, product recalls, product liability claims, insufficient inventory or potentially delay progression of our preclinical or clinical development of sutacimig, HMB-002 and any other product candidate we may develop. If we successfully develop sutacimig, HMB-002 and any other product candidate, we may encounter problems achieving adequate quantities and quality that meet FDA, EMA or other comparable applicable foreign standards or specifications with consistent and acceptable production yields and costs. The ability to scale our manufacturing through manufacturers of drug substance for our product candidates and for finished drug product and maintain the manufacturing process at the same levels of quality and efficiency is yet to be tested. If we or our third party manufacturers are unable to scale our manufacturing at the same levels of quality and efficiency, we may not be able to supply the required number of doses for clinical trials or commercial supply. A material shortage, contamination or manufacturing failure in the manufacture of sutacimig, HMB-002 and any other product candidate we may develop or other adverse impact or disruption in the commercial manufacturing or the production of clinical material could materially harm our development timelines and our business, financial condition, results of operations and prospects.

We contract with third parties for the manufacture of our product candidates, plan to contract with third parties for any other product candidates we may develop for preclinical and clinical testing and expect to continue to do so for commercialization. This reliance on third parties entails risks, including that such third parties may not be able to comply with applicable regulatory requirements. Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval.

We do not have any manufacturing facilities. We currently rely on a small number of manufacturers of drug substance for our product candidates and for finished drug product, and we expect to continue to rely on third parties to manufacture clinical supplies of our product candidates and any other product candidates we may develop and commercial supplies of our products, if and when approved for marketing by applicable regulatory authorities, as well as for packaging, sterilization, storage, distribution and other production logistics.

Reliance on third-party manufacturers may expose us to different risks than if we were to manufacture product candidates ourselves. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or manufacture any product candidates in accordance with regulatory requirements, if there are disagreements between us and such parties or if such parties are unable to expand capacities to support commercialization of any product candidates for which we obtain marketing approval, we may not be able to fulfill, or may be delayed in producing sufficient product candidates to meet, our supply requirements. These facilities may also be affected by natural disasters, such as floods or fire, or geopolitical developments, or such facilities could face manufacturing issues, such as contamination or regulatory concerns following a regulatory inspection of such facility. In such instances, we may need to locate an appropriate replacement third-party facility and establish a contractual relationship, which may not be readily available or on acceptable terms, which would cause additional delay and increased expense, and may have a material adverse effect on our business.

Third-party manufacturers may not be able to comply with current good manufacturing practices, or cGMP, regulations or similar regulatory requirements outside of the United States. 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 products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

Our product candidates and any other product candidates or products that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us.

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

Any performance failure on the part of our existing or future manufacturers could delay clinical development or marketing approval. We do not have long-term supply agreements in place for drug product or drug substance for our product candidates. If any of our future contract manufacturers cannot perform as agreed, or decline to continue to supply us, we may be required to replace such manufacturers. Although we believe that there are several potential alternative manufacturers who could manufacture our product candidates and any other product candidates we may develop, we may incur added costs and delays in identifying and qualifying any such replacement.

Our current and anticipated future dependence upon others for the manufacture of our product candidates and any other product candidates or products we may develop may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

We may from time to time be dependent on single-source suppliers for some of the components and materials used in the product candidates we may develop.

We may from time to time depend on single-source suppliers for some of the components and materials used in any product candidate we may develop. We cannot ensure that these suppliers or service providers will remain in business, have sufficient capacity or supply to meet our needs or that they will not be purchased by one of our competitors or another company that is not interested in continuing to work with us. Our use of single-source suppliers of raw materials, components, key processes and finished goods could expose us to several risks, including disruptions in supply, price increases or late deliveries. There are, in general, relatively few alternative sources of supply for substitute components. These vendors may be unable or unwilling to meet our future demands for our clinical trials or commercial sale. Establishing additional or replacement suppliers for these components, materials and processes could take a substantial amount of time and it may be difficult to establish replacement suppliers who meet regulatory requirements. Any disruption in supply from any single-source supplier or service provider could lead to supply delays or interruptions which would damage our business, financial condition, results of operations and prospects.

If we have to switch to a replacement supplier, the manufacture and delivery of any product candidates we may develop could be interrupted for an extended period, which could adversely affect our business. Establishing additional or replacement suppliers, if required, may not be accomplished quickly. If we are able to find a replacement supplier, the replacement supplier would need to be qualified and may require additional regulatory authority approval, which could result in further delay. While we seek to maintain adequate inventory of the single source components and materials used in our products, any interruption or delay in the supply of components or materials, or our inability to obtain components or materials from alternate sources at acceptable prices in a timely manner, could impair our ability to meet the demand for our investigational medicines.

We may enter into collaborations with third parties for the development or commercialization of product candidates. If our collaborations are not successful, we may not be able to capitalize on the market potential of these product candidates and our business could be adversely affected.

We may utilize collaboration, distribution and other marketing arrangements with third parties to develop our product candidates or any future product candidates of ours or to commercialize any product for which we obtain marketing approval. Our likely collaborators for any sales, marketing, distribution, development, licensing or broader collaboration arrangements include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We are not currently party to any such arrangement.

We face significant competition in seeking appropriate collaborators, and a number of more established companies may also be pursuing strategies to license or acquire third-party intellectual property rights that we consider attractive. These established companies may have a competitive advantage over us due to their size, financial resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical and biotechnology companies that have resulted in a reduced number of potential future collaborators. As a result, we may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all.

If we are unable to reach agreements with suitable collaborators on a timely basis, on acceptable terms or at all, we may have to curtail the development of a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to fund and undertake development or commercialization activities on our own, we may need to obtain additional expertise and additional capital, which may not be available to us on acceptable terms or at all. If we fail to enter into collaborations and do not have sufficient funds or expertise to undertake the necessary development and commercialization activities, we may not be able to further develop any product candidates or bring them to market.

If we are able to enter into collaborations with any third parties in the future, we will likely have limited control over the amount and timing of resources that any future collaborators of ours dedicate to the development or commercialization of our product candidates and any future product candidates of ours. Our ability to generate revenues from these arrangements will depend on any future collaborators of ours abilities and efforts to successfully perform the functions assigned to them in these arrangements. We cannot be certain that, following a collaboration, license or strategic transaction, we will achieve an economic benefit that justifies such transaction.

Collaborations that we enter into may not be successful, and any success will depend heavily on the efforts and activities of such collaborators. Collaborations pose a number of risks, including the following:

- collaborators have significant discretion in determining the amount and timing of efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development of our product candidates and any future product candidates of ours or may elect not to continue or renew development programs based on results of clinical trials or other studies, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- we may not have access to, or may be restricted from disclosing, certain information regarding product candidates being developed or commercialized under a collaboration and, consequently, may have limited ability to inform our stockholders about the status of such product candidates;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with any product candidates and products if the collaborators believe that the competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- product candidates discovered in collaboration with us may be viewed by any future collaborators of ours as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of any product candidates;
- a collaborator may fail to comply with applicable regulatory requirements regarding the development, manufacture, distribution or marketing of a product candidate or product;
- a collaborator with marketing and distribution rights to one or more of any product candidates that achieves marketing approval may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over intellectual property or proprietary rights, contract interpretation or the preferred course of development, might cause delays or terminations of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly obtain, maintain, enforce, defend or protect our intellectual property or proprietary rights or may use our proprietary information in such a way as to potentially lead to disputes or legal proceedings that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- disputes may arise with respect to the ownership of intellectual property developed pursuant to our collaborations;
- collaborators may infringe, misappropriate or otherwise violate the intellectual property or proprietary rights of third parties, which may expose us to litigation and potential liability;
- we may be required to invest resources and attention into collaborations, which could distract from other business objectives; and
- collaborations may be terminated by the collaborator (including for convenience), and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner, or at all. If any collaborations that we enter into do not result in the successful development and commercialization of products or if one of our future collaborators terminates its agreement with us, we may not receive any future research funding or milestone or royalty payments under the collaboration. If we do not receive the funding we expect under these agreements, our development of any product candidates could be delayed and we may need additional resources to develop any product candidates. All of the risks relating to product development, marketing approval and commercialization described in this "Risk Factors" section also apply to the activities of any future collaborators of ours.

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

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

We employ individuals who were previously employed at other biotechnology or biopharmaceutical companies. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information, trade secrets or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

Risks Related to Our Intellectual Property

If we fail to comply with our obligations under our existing license agreements with Novo Nordisk and Genmab, or under any future intellectual property licenses, or otherwise experience disruptions to our business relationships with our current or any future licensors, we could lose intellectual property rights that are important to our business.

We are party to existing license agreements with each of Novo Nordisk and Genmab with respect to sutacimig. Termination of either of these agreements or a reduction or elimination of our licensed rights could lead to the loss of our ability to develop and commercialize sutacimig. Under the Novo Nordisk Agreement, we have been granted an exclusive (even as to Novo Nordisk), worldwide and sublicensable license under specified patent rights, and a non-exclusive, worldwide and sublicensable license under specified know-how, to research, develop, make, have made, use, offer for sale, sell, import, export or otherwise exploit, or transfer possession of or title in, products containing bispecific IgG antibodies targeting TLT-1 and Factor VII, including sutacimig, for the treatment of bleeding conditions, including hemophilia. Under the Genmab Agreement, we have been granted an exclusive (even as to Genmab and its affiliates), worldwide and sublicensable license under platform technology patent rights and know-how relating to Genmab's proprietary DuoBody® platform to research, develop, make, have made, use, manufacture, import, export and commercialize products containing bispecific IgG antibodies targeting TLT-1 and Factor VII, including sutacimig, for the treatment of bleeding conditions, including hemophilia. For further information regarding our license agreements with Novo Nordisk and Genmab see "Business—License Agreements."

We may enter into additional license agreements in the future. Our future license agreements may not provide us with exclusive rights to use the licensed intellectual property and technology or may not provide us with exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our product candidates and technology in the future. Additionally, future agreements may impose various development, diligence, commercialization and other obligations on us and require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses.

Our license agreements with Novo Nordisk and Genmab impose, and we expect that future licenses may impose, specified diligence, milestone payments, royalties and other obligations on us. Furthermore, Novo Nordisk and Genmab each has the right to terminate their respective license agreement if we materially breach such agreement and fail to cure such breach within a specified period or in the event of insolvency. In spite of our best efforts, our current or any future licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize product candidates and technology covered by these license agreements. As a result, we may be required to cease our development and commercialization of our product candidates and use of our proprietary technologies covered by the patent rights owned by such licensors. If these in-licenses are terminated, or if the in-licensed intellectual property fails to provide the intended exclusivity, competitors may have the freedom to seek regulatory approval of, and to market, products identical to ours. This could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

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

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;

- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our current or future licensors, and us and our partners; and
- the priority of invention of patented technology.

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

If we are unable to obtain licenses from third parties on commercially reasonable terms or fail to comply with our obligations under such agreements, our business could be harmed.

We currently have rights to intellectual property, through licenses from third parties, to identify and develop certain product candidates, and we may enter into additional licenses in the future as we expand our product candidate pipeline. Although we have succeeded in licensing intellectual property from third-party licensors, including Genmab and Novo Nordisk, in the past, we cannot assure our stockholders that we will be able to in-license or acquire the rights to any potential product candidates from third parties on acceptable terms or at all.

In addition, our license agreements may provide that our fields of use exclude particular fields. If we determine that rights to such fields are necessary to commercialize our product candidates or maintain our competitive advantage, we may need to obtain additional license rights in order to continue developing, manufacturing or marketing our product candidates. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses.

Various third parties practice in competitive areas and may have issued patents or patent applications that will issue as patents in the future, which could impede or preclude our ability to commercialize our product candidates. For any third-party patents that could be relevant to our product candidates, we rely in part on the “safe harbor” or research exemption under 35 U.S.C. § 271(e)(1), which exempts activities related to pursuing FDA approval for a drug product from patent infringement. However, while U.S. patent law provides such a “safe harbor” to our clinical product candidates under this provision, that exemption may expire when a BLA is submitted. Given the uncertainty of clinical trials, we cannot be certain of the timing of their completion and it is possible that we may submit a BLA for one of our future product candidates at a time when one or more relevant third-party patents is in force. It may therefore be necessary for us to use the patented or proprietary intellectual property of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. If we are unable to license such intellectual property, or if we are forced to license such intellectual property on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, we may be unable to develop or commercialize the affected product candidates, which could materially harm our business and the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales or an obligation on our part to pay royalties and/or other forms of compensation. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same intellectual property licensed to us.

Additionally, we may collaborate with academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution’s rights in intellectual property resulting from the collaboration. Even if we hold such an option, we may be unable to negotiate a license from the institution within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program.

In addition, the licensing or acquisition of third-party intellectual property rights is a highly competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be

unable to license or acquire third party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the applicable product candidate, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our product candidates, or the methods for manufacturing them or to develop or license replacement intellectual property, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly.

Additionally, if we fail to comply with our obligations under license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market, or may be forced to cease developing, manufacturing or marketing, any product that is covered by these agreements or may face other penalties under such agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements, or current and future restrictions on our ability to freely assign or sublicense our rights under such agreements when it is in the interest of our business to do so, may result in our having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or impede, or delay or prohibit the further development or commercialization of one or more potential product candidates that rely on such agreements.

If we are unable to obtain, maintain, enforce, defend and otherwise protect the intellectual property relating to our technology and product candidates, and if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize technology and products similar or identical to ours, and our ability to successfully develop and commercialize our technology and product candidates may be adversely affected.

Our success depends in large part on our ability to obtain and maintain protection of the intellectual property we may own solely and jointly with others or may license from others, particularly patents with respect to any proprietary technology and product candidates we develop. We seek to protect our proprietary position by filing patent applications in the United States, Europe and other jurisdictions in which we plan to market any products, if approved, related to our product candidates and any other product candidates we may develop that are important to our business and by in-licensing intellectual property related to our technologies and product candidates. If we, or our licensors, are unable to obtain or maintain patent protection with respect to any proprietary technology or product candidates, our business, financial condition, results of operations and prospects could be materially harmed.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute, maintain, defend or license all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Therefore, these in-licensed patents and applications may not be prepared, filed, prosecuted, maintained, defended and enforced in a manner consistent with the best interests of our business.

The patent position of pharmaceutical and biotechnology companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. With respect to both owned and in-licensed patent rights, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors. Further, we may not be aware of all third-party intellectual property rights potentially relating to our product candidates and any other product candidates we may develop. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications are typically not published until 18 months after filing of the priority application, or in some cases not published at all. Therefore, neither we nor our licensors can know with certainty whether either we or our licensors were the first to make the inventions claimed in the patents and patent applications we own or in-license now or in the future, or that either we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our owned and in-licensed patent rights are highly uncertain. Moreover, our owned and in-licensed pending and future patent applications may not result in patents being issued that protect our technology and product candidates, in whole or in part, or that effectively prevent others from commercializing competitive technologies and products. Changes in either the patent laws or interpretation of the patent laws in the United States, the European Union and other countries may diminish the value of our patents and our ability to obtain, protect, maintain, defend and enforce our patent rights, narrow the scope of our patent protection and, more generally, could affect the value of, or narrow the scope of, our patent rights.

As of March 31, 2026, we own, co-own, or hold exclusive license rights to approximately 11 issued patents and 71 pending patent applications related to our product candidates. In order to continue to pursue protection based on provisional patent applications, we will need to file Patent Cooperation Treaty applications, non-U.S. applications and/or U.S. non-provisional patent applications prior to applicable deadlines. Even then, as highlighted above, patents may never issue from our patent applications, or the scope of any patent may not be sufficient to provide a competitive advantage. With respect to sutacimig, our foundational composition of matter patent application was filed in April 2020 (and claims priority to April 2019) with an expected expiration in April 2040, potentially extending to 2045 with patent term extension. The foundational sutacimig composition of matter patent family is exclusively licensed to us from Novo Nordisk. For HMB-002, our initial composition of matter patent application was filed in February 2023 (and claims priority to February 2022) with an expected expiration in February 2043. We solely own the initial HMB-002 composition of matter patent family. A second composition of matter patent application covering HMB-002 was filed in August 2024 (and claims priority to August 2023), with an expected expiration in August 2044. We also solely own the second HMB-002 composition of matter patent family.

Moreover, we or our licensors may be subject to a third-party preissuance submission of prior art to the United States Patent and Trademark Office, or USPTO, or become involved in opposition, derivation, revocation, re-examination, inter partes review, post-grant review, interference or other similar proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize technology and product candidates that are identical or similar to ours and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights. If the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Additionally, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance, including as a result of challenges brought in patent offices or court proceedings. Even if our owned and in-licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and in-licensed patents may be challenged in the courts or patent offices in the United States, the European Union and other jurisdictions. Such challenges may result in loss of exclusivity or freedom to operate, or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and product candidates. Such proceedings also may result in substantial cost and require significant time from our management and employees, even if the eventual outcome is favorable to us. 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. Moreover, some of our owned and in-licensed patents and patent applications may in the future be, and certain of our current patent applications are, co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. Furthermore, our competitors may be able to circumvent our owned or in-licensed patents by developing similar or alternative technologies or products in a non-infringing manner. As a result, our owned and in-licensed patent portfolio may not provide us with sufficient rights to exclude others from using or commercializing technology and products similar or identical to any of our technology and product candidates.

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. The patent term of a U.S. patent may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier-filed patent.

Notwithstanding these and other extensions that may be available, the life of a patent, and the protection it affords, is limited. Even if patents covering any product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. 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. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Given the expected expiration date of these patents, and the fact that safe harbor protections in many jurisdictions permit third parties to engage in development, including clinical trials, prior to patent expiry, these patents may not provide us with a meaningful competitive advantage.

If we are unable to obtain licenses from third parties on commercially reasonable terms, or fail to comply with our obligations under such agreements, our business could be harmed.

It may be necessary for us to use the patented or proprietary technology of one or more third parties to develop or commercialize our current and future product candidates, in which case we would be required to obtain a license from these third parties.

If we are unable to license such technology, or if we are forced to license such technology on unfavorable terms, our business could be materially harmed. If we are unable to obtain a necessary license, or to otherwise acquire the relevant intellectual property rights, we may be unable to develop or commercialize the affected product candidates, or such development and commercialization may be delayed, which could materially harm our business. In addition, the third parties owning such intellectual property rights could seek either an injunction prohibiting our sales or an obligation on our part to pay royalties and/or other forms of compensation. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us.

If we are unable to obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected technology and product candidates, which could materially harm our business, financial condition, results of operations and prospects significantly.

Additionally, if we fail to comply with our obligations under our current and future license agreements, our counterparties may have the right to terminate these agreements, in which event we might not be able to develop, manufacture or market, or may be forced to cease developing, manufacturing or marketing, any product that is covered by these agreements or may face other penalties under such agreements. Such an occurrence could materially adversely affect the value of the product candidate being developed under any such agreement. Termination of these agreements or reduction or elimination of our rights under these agreements, or restrictions on our ability to freely assign or sublicense our rights under such agreements when it is in the interest of our business to do so, may result in our having to negotiate new or reinstated agreements with less favorable terms, cause us to lose our rights under these agreements, including our rights to important intellectual property or technology or impede, or delay or prohibit the further development or commercialization of one or more product candidates that rely on such agreements.

We may not have the right to control the prosecution, maintenance, enforcement or defense of patents and patent applications that we license from third parties. In such cases, we would be reliant on the licensor to take any necessary actions. We cannot be certain that such licensor would act with our best interests in mind, or in compliance with applicable laws and regulations, or that their actions would result in valid and enforceable patents. For example, it is possible that a licensor's actions in enforcing and/or defending a patent licensed by use may be less vigorous than had we conducted them ourselves. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we do not obtain patent term extensions in the United States under the Hatch-Waxman Act and in non-U.S. countries under similar legislation, thereby potentially limiting the term of our marketing exclusivity for any product candidates we may develop, our business may be materially harmed.

In the United States, the patent term of a patent that covers an FDA-approved drug may be eligible for limited patent term extension, which permits patent term restoration as compensation for the patent term lost during the FDA regulatory review process. The Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, permits a patent term extension of up to five years beyond the expiration of the patent. The length of the patent term extension is related to the length of time the drug is under regulatory review. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, and only one patent applicable to an approved drug may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. Similar provisions are available in the European Union and certain other non-U.S. jurisdictions to extend the term of a patent that covers an approved drug. While, in the future, if and when any product candidates receive FDA approval or equivalent approvals in foreign jurisdictions, if available, we expect to

apply for patent term extensions on patents covering those product candidates, there is no guarantee that the applicable authorities will agree with our assessment of whether such extensions should be granted, and even if granted, the length of such extensions. We may not be granted patent term extensions either in the United States or in any non-U.S. country because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than we request. If we are unable to obtain any patent term extension or the term of any such extension is less than we request, our competitors may obtain approval of competing products earlier than if such extension was granted as requested by us, and our business, financial condition, results of operations and prospects could be materially harmed.

It is possible that we will not obtain patent term extension under the Hatch-Waxman Act for a U.S. patent covering any of any product candidates that we may identify even where that patent is eligible for patent term extension, or if we obtain such an extension, it may be for a shorter period than we had sought. Further, for our licensed patents, we may not have the right to control prosecution, including filing with the USPTO a petition for patent term extension under the Hatch-Waxman Act. Thus, if one of our licensed patents is eligible for patent term extension under the Hatch-Waxman Act, we may not be able to control whether a petition to obtain a patent term extension is filed, or obtained, from the USPTO.

Also, there are detailed rules and requirements regarding the patents that may be submitted to the FDA for listing in the Approved Drug Products with Therapeutic Equivalence Evaluations, or the Orange Book. We may be unable to obtain patents covering any product candidates that contain one or more claims that satisfy the requirements for listing in the Orange Book. Even if we submit a patent for listing in the Orange Book, the FDA may decline to list the patent, or a manufacturer of generic drugs may challenge the listing. If a product candidate is approved and a patent covering that product candidate is not listed in the Orange Book, a manufacturer of generic drugs would not have to provide advance notice to us of any abbreviated new drug application, or ANDA, filed with the FDA to obtain permission to sell a generic version of such product candidate.

Changes to patent laws in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of patent laws in the United States, including patent reform legislation such as the Leahy-Smith America Invents Act, or the Leahy-Smith Act, could increase the uncertainties and costs surrounding the prosecution of our owned and in-licensed patent applications and the maintenance, enforcement or defense of our owned and in-licensed issued patents. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These changes include provisions that affect the way patent applications are prosecuted, redefine prior art, provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, and enable third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent at USPTO-administered post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith Act, the United States transitioned to a first-to-file system in which, assuming that the other statutory requirements for patentability 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. As such, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents once obtained. Depending on future actions by Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our patent rights and our ability to protect, defend and enforce our patent rights in the future.

Further, a new court system recently became operational in the European Union. The Unified Patent Court, or UPC, began accepting patent cases on June 1, 2023. The UPC is a common patent court with jurisdiction over patent infringement and revocation proceedings effective for multiple European Union member states. The broad geographic reach of the UPC could enable third parties to seek revocation of any of our European patents in a single proceeding at the UPC rather than through multiple proceedings in each of the individual European Union member states in which the

European patent is validated. Under the UPC, a successful revocation proceeding for a European Patent under the UPC would result in loss of patent protection in those European Union countries. Accordingly, a single proceeding under the UPC could result in the partial or complete loss of patent protection in numerous European Union countries. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates and, resultantly, on our business, financial condition, prospects and results of operations. Moreover, the controlling laws and regulations of the UPC will develop over time and we cannot predict what the outcomes of cases tried before the UPC will be. The case law of the UPC may adversely affect our ability to enforce or defend the validity of our European patents. Patent owners have the option to opt-out their European Patents from the jurisdiction of the UPC, defaulting to pre-UPC enforcement mechanisms. We have decided to opt out certain European patents and patent applications from the UPC. However, if certain formalities and requirements are not met, our European patents and patent applications could be subject to the jurisdiction of the UPC. We cannot be certain that our European patents and patent applications will avoid falling under the jurisdiction of the UPC, if we decide to opt out of the UPC.

We and our licensors, and any future licensors, may become involved in lawsuits to protect or enforce our patent or other intellectual property rights, which could be expensive, time-consuming and unsuccessful, and which may result in our patents being found invalid or unenforceable.

Competitors and other third parties may infringe, misappropriate or otherwise violate our or our current and future licensors' issued patents or other intellectual property. As a result, we or any current or future licensors may need to file infringement, misappropriation or other intellectual property related claims, which can be expensive and time- consuming. Any claims we assert against perceived infringers could provoke such parties to assert counterclaims against us alleging that we infringe, misappropriate or otherwise violate their intellectual property. In addition, in a patent infringement proceeding, such parties could counterclaim that the patents we or our licensors have asserted are invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may institute such claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in non-U.S. jurisdictions (e.g., opposition proceedings). The outcome following legal assertions of invalidity and unenforceability is unpredictable, and the outcome of any intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance, including the demeanor and credibility of witnesses and the identity of any adverse party. This is especially true in intellectual property cases that may turn on the testimony of experts as to technical facts upon which experts may reasonably disagree.

An adverse result in any such proceeding could put one or more of our owned or in-licensed patents at risk of being invalidated or interpreted narrowly and could put any of our owned or in-licensed patent applications at risk of not yielding an issued patent. A court may also refuse to stop the third party from using the technology at issue in a proceeding on the grounds that our owned or in-licensed patents do not cover such technology. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information or trade secrets could be compromised by disclosure during this type of litigation. Any of the foregoing could allow such third parties to develop and commercialize competing technologies and products and have a material adverse impact on our business, financial condition, results of operations and prospects.

Interference or derivation proceedings provoked by third parties, or brought by us or by our licensors, or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome in such proceedings could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference or derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees.

In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring any product candidates to market.

Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could have a material adverse effect on the success of our business.

Our commercial success depends upon our ability and the ability of any future collaborators of ours to develop, manufacture, market and sell any product candidates we may develop and use our proprietary technologies without infringing, misappropriating or otherwise violating the intellectual property and proprietary rights of third parties. There is considerable patent and other intellectual property litigation in the pharmaceutical and biotechnology industries. We may become party to, or threatened with, adversarial proceedings or litigation regarding intellectual property rights with respect to our technology and product candidates, including interference proceedings, post-grant review, inter partes review, and derivation proceedings before the USPTO and similar proceedings in non-U.S. jurisdictions, such as oppositions before the European Patent Office. Numerous U.S. and non-U.S. issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our technologies or product candidates that we may identify may be subject to claims of infringement of the patent rights of third parties.

The legal threshold for initiating litigation or contested proceedings is low, so that even lawsuits or proceedings with a low probability of success might be initiated and require significant resources to defend. Litigation and contested proceedings can also be expensive and time-consuming, and our adversaries in these proceedings may have the ability to dedicate substantially greater resources to prosecuting these legal actions than we can. The risks of being involved in such litigation and proceedings may increase if and as any product candidates near commercialization and as we gain the greater visibility associated with being a public company. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future, regardless of merit. We may not be aware of all such intellectual property rights potentially relating to our technology and product candidates and their uses, or we may incorrectly conclude that third-party intellectual property is invalid or that our activities and product candidates do not infringe such intellectual property. Thus, we do not know with certainty that our technology and product candidates, or our development and commercialization thereof, do not and will not infringe, misappropriate or otherwise violate any third party's intellectual property.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations or methods, such as methods of manufacture or methods for treatment, related to the discovery, use or manufacture of the product candidates that we may identify or related to our technologies. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that the product candidates that we may identify may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, as noted above, there may be existing patents that we are not aware of or that we have incorrectly concluded are invalid or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover, for example, the manufacturing process of the product candidates that we may identify, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize the product candidates that we may identify. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products, be forced to indemnify our customers or collaborators or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure.

We may choose to take a license or, if we are found to infringe, misappropriate or otherwise violate a third party's intellectual property rights, we could also be required to obtain a license from such third party to continue developing, manufacturing and marketing our technology and product candidates. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors and other third parties access to the same technologies licensed to us and could require us to make substantial licensing and royalty payments. We could be forced, including by court order, to cease developing, manufacturing and commercializing the infringing technology or product. A finding of infringement could prevent us from commercializing any product candidates or force us to cease some of our business operations, which could materially harm our business. In addition, we may be forced to redesign any product candidates, seek new marketing approvals and indemnify third parties pursuant to contractual agreements. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar material adverse effect on our business, financial condition, results of operations and prospects.

Intellectual property litigation or other legal proceedings relating to intellectual property could cause us to spend substantial resources and distract our personnel from their normal responsibilities.

Litigation or other legal proceedings relating to intellectual property claims, with or without merit, are unpredictable and generally expensive and time-consuming. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and may also have an advantage in such proceedings due to their more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of intellectual property litigation or other proceedings could compromise our ability to compete in the marketplace.

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

Periodic maintenance, renewal and annuity fees and various other government fees on any issued patent and pending patent application must be paid to the USPTO and non-U.S. patent agencies in several stages or annually over the lifetime of our owned and in-licensed patents and patent applications. The USPTO and various non-U.S. patent agencies also require compliance with a number of procedural, documentary and other similar provisions during the patent application process. With respect to our patents, we rely on an annuity service, outside firms and outside counsel to remind us of the due dates and to make payment after we instruct them to do so. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which non-compliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, potential competitors might be able to enter the market with similar or identical products or technology. If we or our current or future licensors fail to maintain the patents and patent applications covering any product candidates, it may have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and the laws of non-U.S. countries may not protect our rights to the same extent as the laws of the United States. In addition, the laws of some non-U.S. countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, and even where such protection is nominally available, judicial and governmental enforcement of such intellectual property rights may be lacking. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection or licenses but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our current or future licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

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

We or our licensors may be subject to claims that former employees, collaborators or other third parties have an interest in our owned or in-licensed patents, trade secrets or other intellectual property as an inventor or co-inventor. For example, we or our licensors may have inventorship disputes arise from conflicting obligations of employees, consultants or others who are involved in developing any product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our or our licensors' ownership of our owned or in-licensed patents, trade secrets or other intellectual property. If we or our licensors 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, intellectual property that is important to any product candidates. 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. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims by third parties asserting that our employees, consultants or contractors have wrongfully used or disclosed confidential information of third parties, or we have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting we have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Certain of our employees, consultants and contractors were previously employed at universities or other pharmaceutical or biotechnology companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims.

In addition, while it is our policy to require that our employees, consultants and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. In addition, even when we obtain agreements assigning intellectual property to us, such intellectual property assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property. Furthermore, individuals executing agreements with us may have preexisting or competing obligations to a third party, such as an academic institution, and thus an agreement with us may be ineffective in perfecting ownership of inventions developed by that individual. Such claims could have a material adverse effect on our business, financial conditions, results of operations and prospects.

In addition, we or our licensors may in the future be subject to claims by former employees, consultants or other third parties asserting an ownership right in our owned or licensed patents or patent applications. An adverse determination in any such claim or proceeding may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar technology and product candidates. Such challenges may also result in our inability to develop, manufacture or commercialize technology and product candidates infringing third-party patent rights. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could have a material adverse effect on our competitive business position and prospects. Such intellectual property rights could be awarded to a third party, and we could be required to obtain a license from such third party to commercialize our technology or products, which license may not be available on commercially reasonable terms, or at all, or such license may be non-exclusive. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our management and employees.

If we are unable to protect the confidentiality of our proprietary information, our business and competitive position may be harmed.

In addition to seeking patents for any product candidates, we also rely on confidentiality agreements to protect our unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect our proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants, but we cannot guarantee that we have entered into such agreements with each party that may have or has had access to our proprietary technology. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information and we may not be able to obtain adequate remedies for such breaches. We may also rely on trade secrets to maintain our competitive position. Detecting the disclosure or misappropriation of a trade secret and enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside of the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them, or those to whom they communicate it, from using that technology or information to compete with us. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position may be materially and adversely harmed.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest.

Our future trademark applications in the United States and in foreign jurisdictions may not be allowed or may subsequently be opposed. Once filed and registered, our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. As a means to enforce our trademark rights and prevent infringement, we may be required to file trademark claims against third parties or initiate trademark opposition proceedings. This can be expensive and time-consuming. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make product candidates that are similar to ours but that are not covered by the claims of the patents that we own or license;
- we, or our licensors or current or future collaborators, might not have been the first to make the inventions covered by the issued patent or pending patent applications that we own or license;
- we, or our licensors or current or future collaborators, might not have been the first to file patent applications covering certain of our or their inventions;
- others may independently develop similar or alternative technologies or duplicate our technologies without infringing our owned or in-licensed intellectual property rights;
- others may circumvent our regulatory exclusivities, such as by pursuing approval of a competitive product via the traditional approval pathway based on their own clinical data, rather than relying on the abbreviated pathway provided for biosimilar or generic applicants;
- it is possible that our owned and in-licensed pending patent applications or those we may own or in-license in the future will not lead to issued patents;
- issued patents that we hold rights to now or in the future may be held invalid or unenforceable, including as a result of legal challenges by our competitors;

- our competitors might conduct research and development activities in countries where we do not have patent rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly and time consuming regardless of outcome;
- the patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business;
- we cannot ensure that any of our patents, or any of our pending patent applications, if issued, or those of our licensors, will include claims having a scope sufficient to protect any product candidates;
- we cannot ensure that any patents issued to us or our current or future licensors will provide a basis for an exclusive market for our commercially viable product candidates or will provide us with any competitive advantages;
- we cannot ensure that our commercial activities or product candidates will not infringe upon the patents of others;
- we cannot ensure that we will be able to successfully commercialize any product candidates on a substantial scale, if approved, before the relevant patents that we own or license expire;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may harm our business; and
- we may choose not to file a patent in order to maintain certain technology as trade secrets or know-how, and a third party may subsequently file a patent application covering such technology.

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

Risks Related to Marketing Approval of Our Product Candidates and Other Legal Compliance Matters

Even if we complete the necessary preclinical studies and clinical trials, the marketing approval process is expensive, time-consuming and uncertain and may prevent us from obtaining approvals for the commercialization of some or all of our product candidates. As a result, we cannot predict when or if, and in which territories, we will obtain marketing approval to commercialize a product candidate.

The research, testing, manufacturing, labeling, approval, selling, marketing, promotion and distribution of products are subject to extensive regulation by the FDA, EMA and comparable regulatory authorities in other jurisdictions. We are not permitted to market our product candidates in the United States, the European Union or in other jurisdictions until we receive approval of a BLA from the FDA or marketing approval from the European Union or other applicable regulatory authorities. Our product candidates are in various stages of development and are subject to the risks of failure inherent in development. We have not submitted an application for or received marketing approval for any of our product candidates in the United States, the European Union or in any other jurisdiction. Additionally, we have no experience as a company in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third-party CROs to assist us in this process.

The process of obtaining marketing approvals, both in the United States, the European Union and in other jurisdictions, is lengthy, expensive and uncertain. It may take many years, if approval is obtained at all, and can vary substantially based upon a variety of factors, including the type, complexity and novelty of the product candidates involved. Securing marketing approval requires the submission of extensive preclinical and clinical data and supporting information, including manufacturing information, to regulatory authorities for each therapeutic indication to establish the product candidate's safety, potency and purity. The FDA or other regulatory authorities may determine that our product candidates are not safe, potent or pure, only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or a comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the clinical trial. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as applicable, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

Further, under the Pediatric Research Equity Act of 2003, or PREA, a BLA or supplement thereto must contain data that are adequate to assess the safety, potency and purity of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe, potent or pure, unless granted a deferral or waiver. A deferral may be granted for several reasons, including a finding that the product or therapeutic candidate is ready for approval for use in adults before pediatric trials are complete or that additional data needs to be collected before the pediatric trials begin. The applicable legislation in the European Union also requires sponsors to either conduct clinical trials in a pediatric population in accordance with a Pediatric Investigation Plan approved by the Pediatric Committee of the EMA or to obtain a waiver or deferral from the conduct of these studies by this Pediatric Committee. For any of our product candidates for which we are seeking marketing approval in the United States or the European Union, we cannot guarantee that we will be able to obtain a waiver or alternatively complete any required studies and other requirements in a timely manner, or at all, which could result in associated reputational harm and subject us to enforcement action.

In addition, changes in marketing approval policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted product application, may cause delays in the approval or rejection of an application. For example, in December 2022, with the passage of the Food and Drug Omnibus Reform Act, or FDORA, Congress required sponsors to develop and submit a diversity action plan, or DAP, for each Phase 3 clinical trial or any other "pivotal study" of a new drug product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. In June 2024, as mandated by FDORA, the FDA issued draft guidance outlining the general requirements for DAPs. Unlike most guidance documents issued by the FDA, the DAP guidance, when finalized, will have the force of law because FDORA specifically dictates that the form and manner for submission of DAPs are specified in FDA guidance.

On January 27, 2025, in response to an Executive Order issued by President Trump on January 21, 2025, relating to Diversity, Equity and Inclusion programs, the FDA removed the draft DAP guidance from its website. That action, along with similar actions by the Trump Administration to remove many other healthcare webpages, is currently the subject of ongoing litigation. In late July 2025, pursuant to a court order, the FDA restored the draft DAP guidance to its website with a statement that "information on this page may be modified and/or removed in the future subject to the terms of the court's order and implemented consistent with applicable law." Accordingly, in light of these ongoing actions, there is considerable uncertainty surrounding the draft DAP guidance and how the FDA will consider diversity action plans in connection with its review of BLAs.

Further, in January 2022, the new Clinical Trials Regulation (EU) No 536/2014, or CTR, became effective in the European Union and replaced the prior Clinical Trials Directive 2001/20/EC. This regulation aims at simplifying and streamlining the authorization, conduct and transparency of clinical trials in the European Union. Under the coordinated procedure for the approval of clinical trials, the sponsor of a clinical trial to be conducted in more than one European Union member state is only required to submit a single application for approval by each applicable European Union member state. The submission will be made through the Clinical Trials Information System, a clinical trials portal overseen by the EMA and available to clinical trial sponsors, competent authorities of the European Union member states and the public. While the CTR has been in place for several years, and applied to all clinical studies in the European Union as of January 31, 2025, we will need to carefully navigate our compliance with the CTR to ensure that it does not delay our ability to commence and conduct clinical studies in the European Union.

In addition, the FDA may determine that we must provide additional evidence and data before approving a BLA for any of our product candidates. For example, the novel nature of our product candidates may create further challenges in obtaining regulatory approval. That may be because: sutacimig is a bispecific antibody with a novel mechanism targeting Factor VII to activated platelets via TLT-1, which has not been previously exploited therapeutically, and regulatory authorities may have limited experience reviewing similar mechanisms and may require additional data to support approval; our product candidates target bleeding disorders where traditional clinical trial designs and endpoints used in more common bleeding disorders (such as hemophilia A and B) may not be fully applicable or validated; for Glanzmann thrombasthenia and Factor VII deficiency, there are no approved prophylactic therapies, so we cannot rely on precedent for endpoint selection, trial design, or benefit-risk assessment; and for Von Willebrand Disease, we will need to demonstrate that increasing endogenous VWF and Factor VIII levels translates to clinically meaningful bleeding reduction, which may require longer-term trials with bleed rate endpoints.

The FDA reviews an application to determine whether there is "substantial evidence" to support a finding of effectiveness for the proposed product for its intended use(s). The FDA has interpreted this evidentiary standard to generally require two adequate and well-controlled clinical trials to establish effectiveness of a new product. Under certain circumstances, however, the FDA has indicated that a single trial with certain characteristics and additional information may satisfy this standard. The FDA issued draft guidance in September 2023 that outlines considerations for relying on confirmatory evidence in lieu of a second clinical trial to demonstrate efficacy. The FDA has not yet finalized such guidance but, in February 2026, the Commissioner of the FDA and the Director of the FDA's Center for Biologics Evaluation and Research published an editorial in the New England Journal of Medicine in which they declared that, in

most cases, the new default requirement for FDA approval of a new product will be one robust pivotal clinical trial plus confirmatory evidence, rather than two pivotal clinical trials. In determining whether to rely on one trial, the FDA will focus on the single trial's quality, including magnitude of effect, appropriateness of control arms, endpoint selection, statistical power, blinding, handling of missing data, biological plausibility and alignment with intermediate biomarkers. While the FDA has long had authority to approve new products in this manner and, in recent years, has exercised that authority with respect to certain types of products, the publication declares that this will be the new official default standard for most new products. This approach will reportedly be implemented as the FDA places a greater emphasis on collecting robust post-marketing data on all pharmaceutical products. At this point, it is unclear how this new policy will be implemented by the FDA and how, if at all, it will affect our clinical development programs. Moreover, although we are planning to conduct a multinational, multicenter, Phase 3, single-arm, open-label clinical trial evaluating sutacimig as a prophylactic therapy in adults with Glanzmann thrombasthenia, the FDA may determine that a randomized controlled clinical trial is necessary to support filing and approval of our BLA. We intend to schedule a Type D meeting with the FDA in the coming months to obtain the FDA's feedback on, and seek alignment regarding, our proposed Phase 3 trial design. A Type D meeting is intended to facilitate focused discussion on a limited number of specific issues, but there can be no assurance that the FDA will agree with our proposed approach. Our failure to timely agree with the FDA on the design of our planned Phase 3 clinical trial may lead to delays in its initiation and completion.

Regulatory authorities have substantial discretion in the approval process and varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable. Regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

We could also be adversely affected by several significant administrative law cases decided by the U.S. Supreme Court in 2024. In *Loper Bright Enterprises v. Raimondo*, for example, the court overruled *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, which for 40 years required federal courts to defer to permissible agency interpretations of statutes that are silent or ambiguous on a particular topic. The U.S. Supreme Court stripped federal agencies of this presumptive deference and held that courts must exercise their independent judgment when deciding whether an agency such as the FDA acted within its statutory authority under the Administrative Procedure Act, or APA. Additionally, in *Corner Post, Inc. v. Board of Governors of the Federal Reserve System*, the U.S. Supreme Court held that actions to challenge a federal regulation under the APA can be initiated within six years of the date of injury to the plaintiff, rather than the date the rule is finalized. The decision appears to give prospective plaintiffs a personal statute of limitations to challenge longstanding agency regulations. Another decision, *Securities and Exchange Commission v. Jarkesy*, overturned regulatory agencies' ability to impose civil penalties in administrative proceedings. These decisions could introduce additional uncertainty into the regulatory process and may result in additional legal challenges to actions taken by federal regulatory agencies, including the FDA and the Center for Medicare & Medicaid Services, or CMS, on which we rely. In addition to potential changes to regulations as a result of legal challenges, these decisions may result in increased regulatory uncertainty and delays and other impacts, any of which could adversely impact our business and operations.

Finally, our ability to develop and market new drug products may be impacted if litigation challenging the FDA's approval of another company's drug product continues. In April 2023, the U.S. District Court for the Northern District of Texas invalidated the approval by the FDA of mifepristone, a drug product which was originally approved in 2000 and whose distribution is governed by various measures adopted under a REMS. The Court of Appeals for the Fifth Circuit declined to order the removal of mifepristone from the market but did hold that plaintiffs were likely to prevail in their claim that changes allowing for expanded access of mifepristone, which the FDA authorized in 2016 and 2021, were arbitrary and capricious. In June 2024, the U.S. Supreme Court reversed that decision after unanimously finding that the plaintiffs did not have standing to bring this legal action against the FDA. On October 11, 2024, the Attorneys General of three states filed an amended complaint in the district court in Texas challenging the FDA's actions. On January 16, 2025, the district court in Texas agreed to allow these states to file an amended complaint and continue to pursue this challenge. Thereafter, on September 30, 2025, the district court in Texas declined to dismiss the case and, instead, transferred it to the federal district court in the Eastern District of Missouri. Depending on the outcome of this litigation, our ability to develop new product candidates and to maintain approval of any then-existing drug products could be at risk and could be delayed, undermined or subject to protracted litigation.

Failure to obtain marketing approval in the European Union or other jurisdictions outside the United States would prevent our product candidates from being marketed in those jurisdictions. Any approval we may be granted for our product candidates in the United States would not ensure approval of our product candidates in the European Union or any other jurisdictions and any of our product candidates that may be approved for marketing in the European Union or another jurisdiction will be subject to risks associated with operation in such jurisdiction.

We intend to market our current product candidates, if approved, in the European Union and other markets outside of the United States either directly or through collaborations. In order to market and sell our products in the European Union and other non-U.S. jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The marketing approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. We may not obtain approvals from the European Union and regulatory authorities outside the United States on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one regulatory authority outside the United States does not ensure approval by regulatory authorities in other countries or jurisdictions or by the FDA. We may file for marketing approvals but not receive necessary approvals to commercialize our product candidates in any market.

In many countries outside the United States, a product candidate must also be approved for reimbursement before it can be sold in that country. In some cases, the price that we intend to charge for our products, if approved, is also subject to approval. Obtaining non-U.S. marketing approvals and compliance with non-U.S. regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our product candidates in certain countries. In addition, if we fail to obtain the non-U.S. approvals required to market our product candidates outside the United States or if we fail to comply with applicable non-U.S. regulatory requirements, our target markets will be reduced and our ability to realize the full market potential of our product candidates will be harmed and our business, financial condition, results of operations and prospects may be adversely affected.

Additionally, we could face heightened risks with respect to obtaining marketing authorization in the United Kingdom as a result of the withdrawal of the United Kingdom from the European Union, commonly referred to as Brexit. The United Kingdom is no longer part of the European Single Market and EU Customs Union. As of January 1, 2025, the Medicines and Healthcare products Regulatory Agency, or MHRA, is responsible for approving all medicinal products destined for the U.K. market (i.e., Great Britain and Northern Ireland). On April 28, 2025, the U.K. Parliament adopted amendments to improve and strengthen the United Kingdom's clinical trials regulatory regime, which will take effect on April 28, 2026. Since the United Kingdom left the European Union prior to the date on which the EU Clinical Trials Regulation (Regulation EU No 536/2014) took effect, the U.K. legal framework (which was based upon the now-repealed EU Clinical Trials Directive (2001/20/EC)) did not benefit from the same revisions as occurred in the European Union. In anticipation of these new requirements, on October 1, 2025, the MHRA updated its guidance for clinical trials to address, among other things, research transparency requirements for clinical trials, the approvals process, the Research Ethics Committee review of clinical trials, simplified arrangements for consent in clinical trials and pharmacovigilance. We will need to ensure that we comply with the new U.K. regulatory regime for any clinical trials we conduct in the United Kingdom, which could add time and expense to our conduct of such trials.

At the same time, the United Kingdom has introduced a new international recognition procedure, or IRP, which is intended to facilitate approval of pharmaceutical products in the United Kingdom. The IRP is open to applicants that have already received an authorization for the same product from one of the MHRA's specified Reference Regulators, or RRs. The RRs notably include the EMA and regulators in the European Union/European Economic Area, or EEA, member states for approvals in the European Union centralized procedure and mutual recognition procedure as well as the FDA (for product approvals granted in the United States). However, the IRP does not guarantee that a marketing authorization will be granted in the United Kingdom for all products with an approval from the EMA, and the MHRA retains the authority to reject applications if the evidence provided is considered insufficiently robust. Any delay in obtaining, or an inability to obtain, any marketing approvals may force us or any of our future collaborators to restrict or delay efforts to seek regulatory approval in the United Kingdom for our product candidates, which could significantly and materially harm our business.

In addition, the EU pharmaceutical legislation is currently undergoing a complete review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products, which may reduce the duration of regulatory data protection and exclusivity periods for orphan drugs, and revise the eligibility for expedited pathways in addition to other changes, was published on April 26, 2023. On June 4, 2025, after almost two years of negotiations among the European Union member states, the Council of the European Union adopted its position on the proposed overhaul of the EU general pharmaceutical legislative framework, which is known as the new Pharma Package. On December 11, 2025, the European Parliament and European Council reached a provisional political agreement on the legislation. The revisions may have a significant impact on the pharmaceutical industry and our

business. The new Pharma Package would, among other things, set a baseline period of eight years of data exclusivity and one year of market exclusivity with possible extensions for new indications up to a maximum of 11 years total. The new framework is expected to be adopted by mid-2026 and there will likely be a transition period of 24 months, with the changes taking effect in mid-2028.

We expect that we will be subject to additional risks in commercializing any of our product candidates that receive marketing approval outside the United States, including tariffs, trade barriers and regulatory requirements; economic weakness, including inflation or political instability in particular foreign economies and markets; compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; and workforce uncertainty in countries where labor unrest is more common than in the United States.

Any marketing approval to market our products will be limited by indication. If we fail to comply or are found to be in violation of FDA regulations restricting the promotion of our products for unapproved uses, we could be subject to criminal penalties, substantial fines or other sanctions and damage awards.

The regulations relating to the promotion of products for unapproved uses are complex and subject to substantial interpretation by the FDA, EMA, MHRA and other government agencies. In September 2021, the FDA published final regulations which describe the types of evidence that the FDA will consider in determining the intended use of a drug product. Moreover, with the passage of the Pre-Approval Information Exchange Act in December 2022, sponsors of products that have not been approved may proactively communicate to payors certain information about products in development to help expedite patient access upon product approval. Physicians may nevertheless prescribe our products off-label to their patients in a manner that is inconsistent with the approved label. The use of our product candidates for indications other than those approved by the FDA may not effectively treat such conditions. Any such off-label use of our product candidates could harm our reputation in the marketplace among physicians and patients. There may also be increased risk of injury to patients if physicians attempt to use our product candidates for these uses for which they are not approved, which could lead to product liability suits that might require significant financial and management resources and that could harm our reputation.

In January 2025, the FDA published final guidance outlining its policies governing the distribution of scientific information to healthcare providers about unapproved uses of approved products. The final guidance calls for such communications to be truthful, non-misleading and scientifically sound and to include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about the unapproved use of the approved product. Notwithstanding these programs, the FDA or other government agencies may allege or find that our practices constitute prohibited promotion of our products for unapproved uses. We also cannot be sure that our employees will comply with company policies and applicable regulations regarding the promotion of products for unapproved uses.

In addition, companies may also communicate information that is consistent with the prescribing information and may proactively speak to payors, formulary committees, and similar entities regarding healthcare economic information data for an unapproved drug or unapproved uses of an approved drug. We may engage in these discussions and communicate with healthcare providers, payors and other constituencies in compliance with all applicable laws, regulatory guidance and industry best practices. We will need to carefully navigate the FDA's various regulations, guidance and policies, along with recently enacted legislation, to ensure compliance with restrictions governing promotion of our products.

In recent years, a significant number of pharmaceutical and biotechnology companies have been the target of inquiries and investigations by various federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice and various U.S. Attorneys' Offices, the Office of Inspector General of the Department of Health and Human Services, the FDA, the Federal Trade Commission, or the FTC, and various state Attorneys General offices. These investigations have alleged violations of various federal and state laws and regulations, including claims asserting antitrust violations, violations of the Federal Food, Drug and Cosmetic Act, or FDCA, the False Claims Act, the Prescription Drug Marketing Act and anti-kickback laws and other alleged violations in connection with the promotion of products for unapproved uses, pricing and Medicare and/or Medicaid reimbursement. Many of these investigations originate as "*qui tam*" actions under the False Claims Act. Under the False Claims Act, any individual can bring a claim on behalf of the government alleging that a person or entity has presented a false claim or caused a false claim to be submitted to the government for payment. The person bringing a *qui tam* suit is entitled to a share of any recovery or settlement. *Qui tam* suits, also commonly referred to as "whistleblower suits," are often brought by current or former employees. In a *qui tam* suit, the government must decide whether to intervene and prosecute the case. If it declines, the individual may pursue the case alone.

For example, in September 2025, President Trump issued a Memorandum directing the U.S. Department of Health and Human Services, or HHS, to "ensure transparency and accuracy in direct-to-consumer prescription drug advertising, including by increasing the amount of information regarding any risks associated with the use of any such prescription drug required to be provided in prescription drug advertisements." To that end, the FDA announced that it is initiating a rulemaking process "to eliminate the 'adequate provision' loophole that allows pharmaceutical advertisements to hide safety information by placing it in another format or location." In this context, the FDA declared that it will no longer tolerate what it characterized as "deceptive practices" in prescription drug advertising and that the FDA would "aggressively deploy" its available enforcement tools, with "heightened scrutiny" of fair balance and disclosures in social media promotions. The FDA also issued a generic "notice letter" directing companies to "remove any noncompliant advertising and bring all promotional communications into compliance." The FDA has subsequently increased its enforcement scrutiny over prescription drug advertising, particularly direct-to-consumer product promotion and advertising. If the FDA finds any of our promotional communications or advertising to be violative, we may receive an untitled or warning letter, requests for corrective advertising, or fines, amongst other enforcement tools available to the FDA.

If the FDA or any other governmental agency initiates an enforcement action against us or if we are the subject of a *qui tam* suit and it is determined that we violated prohibitions relating to the promotion of products for unapproved uses, we could be subject to substantial civil or criminal fines or damage awards and other sanctions such as consent decrees and corporate integrity agreements pursuant to which our activities would be subject to ongoing scrutiny and monitoring to ensure compliance with applicable laws and regulations. Any such fines, awards or other sanctions would have an adverse effect on our revenue, business, financial prospects and reputation.

Any product for which we obtain marketing approval in the future could be subject to post-marketing restrictions or withdrawal from the market, and we may be subject to substantial penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with any such product following approval.

Any product for which we obtain marketing approval, as well as the manufacturing processes, post-approval studies and measures, labeling, advertising and promotional activities for such product, among other things, will be subject to ongoing requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents, requirements regarding the distribution of samples to physicians and recordkeeping. Manufacturers of approved products and their facilities are subject to continual review and periodic and unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. Even if marketing approval of a product is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, including the requirement to implement a REMS.

The FDA may also impose requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of a product. The FDA and other agencies, including the Department of Justice, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are manufactured, marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we market any product for an indication that is not approved, we may be subject to warnings or enforcement action for off-label marketing. Violation of the FDCA and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription drugs may lead to investigations or allegations of violations of federal and state healthcare fraud and abuse laws and state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with any product for which we may obtain marketing approval and its manufacturers or manufacturing processes or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such product, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of the product;
- restrictions on product distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the product from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of the product;
- restrictions on coverage by third-party payors;
- fines, restitution or disgorgement of profits or revenues;

- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of the product;
- product seizure; or
- injunctions or the imposition of civil or criminal penalties.

Similar restrictions apply to the authorization and post-authorization supervision of our products in the European Union. The holder of a marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. These include: compliance with the European Union's stringent pharmacovigilance or safety reporting rules, which can impose post-authorization studies and additional monitoring obligations; the manufacturing of authorized medicinal products, for which a separate manufacturer's license is mandatory; and the marketing and promotion of authorized drugs, which are strictly regulated in the European Union and are also subject to European Union member state laws. The failure to comply with these and other EU requirements can also lead to significant penalties and sanctions.

Accordingly, assuming we, or any future collaborators of ours, receive marketing approval for one or more of our product candidates, we, and any future collaborators of ours, and our and their contract manufacturers will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we, and any future collaborators of ours, are not able to comply with post-approval regulatory requirements, our or any future collaborators of ours ability to market any future products could be limited, which could adversely affect our ability to achieve or sustain profitability. Further, the cost of compliance with post-approval regulations may have a negative effect on our operating results and financial condition.

If approved, our product candidates that are licensed and regulated as biologics may face competition from biosimilars approved through an abbreviated regulatory pathway.

The Biologics Price Competition and Innovation Act of 2009, or the BPCIA, was enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Amendment, or ACA, to establish an abbreviated pathway for the approval of biosimilar and interchangeable biological products. The regulatory pathway establishes legal authority for the FDA to review and approve biosimilar biologics, including the possible designation of a biosimilar as "interchangeable" based on its similarity to an approved biologic.

Under the BPCIA, a reference biological product is granted 12 years of data exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. In addition, the licensure of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still develop and receive licensure of a competing biologic, so long as its BLA does not rely on the reference product, sponsor's data or submit the application as a biosimilar application.

We believe that any of the product candidates we develop as a biological product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to U.S. congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Further, the FDA may revise the standards governing the approval of biosimilars so as to bring such products to the market more quickly. For example, in October 2025, the FDA issued draft guidance which proposes to eliminate the need for sponsors of biosimilar products to conduct comparative human clinical efficacy studies in many circumstances, allowing them to rely instead on analytical testing to assess product differences from a reference product.

Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of the reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors that are still developing. There have been recent government proposals to reduce the 12-year reference product exclusivity period, but none has been enacted to date. At the same time, since passage of the BPCIA, many states have passed laws or amendments to laws, which address pharmacy practices involving biosimilar products. The approval of a biosimilar to our product candidates would have a material adverse impact on our business due to increased competition and pricing pressure.

We have sought and received Fast Track designation, Breakthrough Therapy designation and ILAP designation in the United Kingdom and may in the future seek additional designations for our product candidates, including but not limited to Priority Review designation in the United States, and PRIority Medicines, or PRIME, Designation in the European Union, but we might not receive such designations, and even if we do, such designations may not lead to a faster development or regulatory review or approval process.

We have received and may in the future seek certain designations for one or more of our product candidates that could expedite review and approval by the FDA. A Breakthrough Therapy product is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For products that have been designated as Breakthrough Therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens.

The FDA may also designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For Fast Track products, sponsors may have greater interactions with the FDA, and the FDA may initiate review of sections of a Fast Track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product may be effective.

We have received Fast Track and Breakthrough Therapy designations for sutacimig for the treatment of Glanzmann thrombasthenia and may seek Fast Track and Breakthrough Therapy designations for sutacimig in other indications or for other of our product candidates, but such designation may not lead to a faster development or regulatory review and approval process or increase the likelihood that such product candidate will receive regulatory approval.

We may also seek a Priority Review designation for one or more of our product candidates. If the FDA determines that a product candidate is intended to treat a serious condition and, if approved, offers a significant improvement in safety or effectiveness, the FDA may designate the product candidate for priority review. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A Priority Review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months.

These designations are within the discretion of the FDA. Accordingly, even if we believe that one of our product candidates meets the criteria for these designations, the FDA may disagree and instead determine not to make such designation. Further, even if we receive a designation, the receipt of such designation for a product candidate may not result in a faster development or regulatory review or approval process compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualifies for these designations, the FDA may later decide that the product candidates no longer meet the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

In September 2025, the FDA introduced a framework intended to streamline the approval of new therapies for ultrarare diseases. The Rare Disease Evidence Principles framework is intended to allow sponsors to rely on a single-arm trial in support of approval of biologics that treat rare diseases with very small patient populations and where the disease is linked to a known genetic defect and characterized by progressive functional deterioration leading to disability or death in a short period of time. The targeted diseases should also lack adequate alternative therapies.

In the European Union, we may seek PRIME designation for our product candidates in the future. PRIME is a voluntary program aimed at enhancing the EMA's role to reinforce scientific and regulatory support in order to optimize development and enable accelerated assessment of new medicines that are of major public health interest with the potential to address unmet medical needs. The program focuses on medicines that target conditions for which there exists no satisfactory method of treatment in the European Union or, if such a method exists, the medicine offers a major therapeutic advantage over existing treatments. PRIME is limited to medicines under development and not authorized in the European Union, where the applicant intends to apply for an initial marketing authorization application through the centralized procedure. To be accepted for PRIME, a product candidate must meet the eligibility criteria in respect of its major public health interest and therapeutic innovation based on information that is capable of substantiating the claims.

The benefits of a PRIME designation include the appointment of a Committee for Medicinal Products for Human Use, or CHMP, rapporteur to provide continued support and help to build knowledge ahead of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review, meaning reduction in the review time for an opinion on approvability to be issued earlier in the application process. PRIME enables an applicant to request parallel EMA scientific advice and health technology

assessment advice to facilitate timely market access. Even if we receive PRIME designation for any of our product candidates, the designation may not result in a materially faster development process, review or approval compared to conventional EMA procedures. Further, obtaining PRIME designation does not assure or increase the likelihood of the European Commission's grant of a marketing authorization.

In the United Kingdom, sutacimig has received innovative licensing and access pathway, or ILAP. designation from the MHRA for the treatment of Glanzmann thrombasthenia. The ILAP is open to sponsors of potentially transformative medicines or drug-device combination products that address unmet medical needs. It supports products with evidence of safe use in humans but before confirmatory trials have started. It is designed to reduce the end-to-end timeline for research and development, regulatory approval and timely adoption of new technologies to benefit patients and the healthcare system in the United Kingdom. To these ends, the ILAP comprises an Innovation Passport designation, a Target Development profile and a toolkit to support all stages of the design, development and approval process. As with expedited review and approval programs in other jurisdictions, the designation of sutacimig under the ILAP does not guarantee approval of this candidate product in the United Kingdom by the MHRA. Further, we will need to carefully navigate the requirements of the ILAP to ensure that we benefit from this accelerated pathway to approval.

We have received orphan drug designation for sutacimig for the treatment of Glanzmann thrombasthenia, but we may be unable to maintain this designation or realize the benefits associated with orphan drug designation, including exclusivity.

We sought and obtained orphan drug designation for sutacimig from the FDA and the EMA for the treatment of Glanzmann thrombasthenia, however, we may not be able to maintain these designations. We also may seek orphan drug designation for sutacimig in other specific orphan indications, or for HMB-002 or any future product candidates, but we may never receive such designations. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition. A similar regulatory scheme governs orphan designation by the European Commission, following a recommendation from the EMA's Committee for Orphan Medicinal Products in the European Union.

Generally, if a product candidate with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or EMA from approving another marketing authorization application for the same product (or a similar medicinal product in the European Union) for the same approved use indication for that time period, subject to limited exceptions. The applicable period is seven years in the United States and ten years in the European Union. The exclusivity period in the European Union can be reduced to six years if a product no longer meets the criteria for orphan drug designation, including if the product is sufficiently profitable so that market exclusivity is no longer justified.

In order for the FDA to grant orphan drug exclusivity, the FDA must find that the product is indicated for the treatment of a condition or disease with a patient population of fewer than 200,000 individuals annually in the United States. The FDA may conclude that the condition or disease for which we seek orphan drug exclusivity does not meet this standard. Even if orphan drug exclusivity is obtained for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same approved use or indication. In addition, even after an orphan drug is approved, the FDA can subsequently approve the same product for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. Orphan drug exclusivity may also be lost if the FDA or EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of the patients with the rare disease or condition.

The FDA and Congress may further reevaluate and revise the Orphan Drug Act and its regulations and policies. For example, in September 2021, the Court of Appeals for the 11th Circuit held that, for the purpose of determining the scope of orphan drug exclusivity, the term "same disease or condition" means the designated "rare disease or condition" and not the "indication or use" for which the product is approved. Subsequently, in another case, a federal district court in Washington, D.C. followed the reasoning of the 11th Circuit decision, and that decision was appealed to the U.S. Court of Appeals for the D.C. Circuit. On February 3, 2026, the Consolidated Appropriations Act of 2026 was enacted into law. It overruled these court decisions and codified the FDA's longstanding interpretation of the scope of orphan drug exclusivity to apply to "the same drug for the same approved use or indication within such designated rare disease or condition." This change, which applies retroactively, expressly authorizes the FDA to approve multiple versions of the same orphan drug for different sub-indications and subpopulations, such as adult and pediatric patients or multiple variations of the same disease that are caused by different genetic variants.

We do not know if, when, or how the FDA or Congress 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.

In addition, obtaining orphan drug designation in the European Union requires demonstrating that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the European Union or, if such method exists, the medicinal product will be of significant benefit to those affected by that condition. There is no assurance that we would be able to meet that standard for sutacimig in indications other than Glanzmann thrombasthenia or for any of our product candidates. Further, orphan drug designation for a product candidate in the European Union cannot be maintained at the time of a marketing authorization application without a showing, to the satisfaction of the EU regulatory authorities, that the product candidate is of significant benefit to patients over available commercial products for the indication in the European Union and any additional products that are ahead of our product candidate in clinical development for the indication.

Disruptions at the FDA and other government agencies from funding cuts, personnel losses, regulatory reform, government shutdowns and other developments could hinder our ability to obtain guidance from the FDA regarding our clinical development programs and develop and secure approval of our product candidates in a timely manner, which would negatively impact our business.

The FDA and comparable regulatory agencies in foreign jurisdictions, such as the EMA and CHMP, play a critical role in the development of our product candidates by providing guidance on our clinical development programs and reviewing and approving our regulatory submissions, including INDs, requests for special designations and marketing applications. If these oversight and review activities are disrupted or delayed, then correspondingly our ability to develop and secure timely approval of our product candidates could be impacted in a negative manner.

For example, the loss of FDA leadership and personnel could lead to disruptions and delays in FDA guidance, review and potential approval of our product candidates. In November 2025, a Congressional Continuing Resolution ended the government shutdown, which began on October 1, 2025, providing full-year funding of the FDA for the 2026 federal fiscal year of approximately $7 billion with a slight increase in user fees for drug and device companies.

While the FDA's review of marketing applications and other activities for new drugs and biologics is largely funded through the user fee program established under the Prescription Drug User Fee Act, or PDUFA, it remains unclear how the FDA's 2025 reduction in force and budget cuts will impact this program and the ability of the FDA to provide guidance and review our product candidates in a timely manner. For example, while the FDA's 2025 reduction in force did not reportedly specifically target FDA reviewers, many operations, administrative and policy staff that help support such reviews were affected and those losses could lead to delays in PDUFA reviews and related activities. There has been at least one report in which the FDA failed to meet a PDUFA goal date for approval of an NDA or BLA due to heavy workload and limited resources.

There is also substantial uncertainty as to how regulatory reform measures being implemented by the Trump Administration across the government will impact the FDA and other federal agencies with jurisdiction over our activities. For example, since taking office, the President has issued a number of executive orders that could have a significant impact on the manner in which the FDA conducts its operations and engages in regulatory and oversight activities. These include E.O. 14192, "Unleashing Prosperity Through Deregulation," January 31, 2025; E.O. 14212, "Establishing the President's Make America Healthy Again Commission," February 13, 2025; and E.O. 14219, "Ensuring Lawful Governance and Implementing the President's 'Department of Government Efficiency" Deregulatory Initiative," February 21, 2025. If these or other orders or executive actions impose constraints on the FDA's ability to engage in oversight and implementation activities in the normal course, our business may be negatively impacted.

Similarly, actions by the U.S. government have significantly disrupted the operations of U.S. government agencies such as the National Institutes of Health, National Science Foundation, Centers for Disease Control and Prevention, and the FDA, which have traditionally provided funding for basic research, research and development, and clinical testing. These U.S. government actions have included, among other things, suspending, terminating and withholding of disbursements of funds owed under ongoing contracts, grants, and other financial assistance agreements; declining to continue multi-year research projects for additional annual budget periods; canceling or delaying solicitations for new contract, grant and other financial assistance awards; canceling or delaying proposal evaluation processes and issuance of such new awards; substantially reducing federal agency staff responsible for managing contract and financial assistance programs; eliminating agency information and resources for facilitating research activity; delaying or terminating federal agency procedures for authorizing international transactions; initiating aggressive enforcement actions that may disrupt the operations of major research universities that are significant contributors to life sciences research in the United States, and threatening access to federal agency contracts and other funding awards based on companies'

otherwise lawful corporate policies and choice of counsel. These U.S. government actions could, directly or indirectly, significantly disrupt, delay, prevent, or increase the costs of our research and product commercialization programs, including our ability to develop new product candidates, conduct clinical trials, implement research collaborations with other companies or institutions, and obtain approvals to market and sell new products.

In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions and could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

For example, the federal government shut down on October 1, 2025, and reopened on November 13, 2025. At the outset of that shutdown, the FDA issued a public notice stating that FDA operations would continue to the extent permitted by law, such as activities necessary to address imminent threats to the safety of human life and activities funded by carryover user fee funds. The FDA declared that, during the shutdown period, it does not have legal authority to accept user fees assessed for fiscal year 2026 until a fiscal year 2026 appropriation or Continuing Resolution for the FDA is enacted. As a result, during the government shutdown, the FDA did not accept any regulatory submissions for fiscal year 2026 that require a fee payment.

At the same time, disruptions at the FDA and other government agencies may result from public health events similar to the COVID-19 pandemic. For example, during the pandemic, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. In the event of a similar public health emergency in the future, the FDA may not be able to continue its current pace and review timelines could be extended. Regulatory authorities outside the United States facing similar circumstances may adopt similar restrictions or other policy measures in response to a similar public health emergency and may also experience delays in their regulatory activities.

Accordingly, if any of the foregoing developments and others impact the ability of the FDA to provide us with guidance regarding our clinical development programs or delay the FDA's review and processing of our regulatory submissions, including INDs and BLAs, our business would be negatively impacted. Further, any future government shutdown could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

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

In the future, we may seek approval of our product candidates using the FDA's accelerated approval pathway. A product candidate may be eligible for accelerated approval if it treats a serious or life-threatening condition, generally provides a meaningful advantage over available therapies, and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA or other applicable regulatory agency makes the determination regarding whether a surrogate endpoint is reasonably likely to predict long-term clinical benefit.

Prior to seeking such accelerated approval, we will seek feedback from the FDA and otherwise evaluate our ability to seek and receive such accelerated approval. As a condition of approval, the FDA requires that a sponsor of a product receiving accelerated approval perform an adequate and well-controlled post-marketing confirmatory clinical trial or trials. These confirmatory trials must be completed with due diligence and we may be required to evaluate different or additional endpoints in these post-marketing confirmatory trials. These confirmatory trials may require enrollment of more patients than we currently anticipate and will result in additional costs, which may be greater than the estimated costs we currently anticipate. In addition, the FDA currently requires as a condition for accelerated approval preapproval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

There can be no assurance that the FDA will agree with any proposed surrogate endpoints or that we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval for any of our current or future product candidates. Similarly, there can be no assurance that, after feedback from FDA, we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or under another expedited regulatory designation, there can be no assurance that such submission or application will be accepted or that any expedited review or approval will be granted on a timely basis, or at all.

The FDA may withdraw approval of a product candidate approved under the accelerated approval pathway if, for example, the trial required to verify the predicted clinical benefit of our product candidate fails to verify such benefit or does not demonstrate sufficient clinical benefit to justify the risks associated with the drug. The FDA may also withdraw approval if other evidence demonstrates that our product candidate is not shown to be safe or effective under the conditions of use, we fail to conduct any required post approval trial of our product candidate with due diligence or we disseminate false or misleading promotional materials relating to our product candidate. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidates, or withdrawal of a product candidate, would result in a longer time period for commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

Further, there can be no assurance that we will satisfy all FDA requirements, including new provisions, that govern accelerated approval. For example, with the passage of FDORA in December 2022, Congress modified certain provisions governing accelerated approval of products. Specifically, the legislation authorized the FDA to require a sponsor to have its confirmatory clinical trial underway before accelerated approval is awarded and to submit progress reports on its post-approval studies to FDA every six months until the study is completed. Moreover, FDORA established expedited procedures authorizing FDA to withdraw an accelerated approval if certain conditions are met, including where a required confirmatory study fails to verify and describe the predicted clinical benefit or where evidence demonstrates the product is not shown to be safe or effective under the conditions of use. The FDA may also use such procedures to withdraw an accelerated approval if a sponsor fails to conduct any required post-approval study of the product with due diligence, including with respect to "conditions specified by the Secretary." The new procedures include the provision of due notice and an explanation for a proposed withdrawal, and opportunities for a meeting with the Commissioner of the FDA or the designee of the Commissioner of the FDA and a written appeal, among other things. We will need to fully comply with these and other requirements in connection with the development and approval of any product candidate that qualifies for accelerated approval.

In March 2023, the FDA issued draft guidance that outlines its views and approach to accelerated approval. The FDA indicated that the accelerated approval pathway is commonly used for approval of oncology drugs due to the serious and life-threatening nature of cancer. Although single-arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach as it provides a more robust efficacy and safety assessment and allows for direct comparisons to an available therapy. To that end, the FDA outlined considerations for designing, conducting, and analyzing data for trials intended to support accelerated approvals of oncology therapeutics. Subsequently, in December 2024 and January 2025, the FDA issued additional draft guidances relating to accelerated approval. These guidances describe the FDA's views on what it means to conduct a confirmatory trial with due diligence and how the FDA plans to interpret whether such a study needs to be underway at the time of approval. While these guidances are currently only in draft form and will ultimately not be legally binding even when finalized, sponsors typically observe the FDA's guidance closely to ensure that their investigational products qualify for accelerated approval.

In the European Union, a conditional marketing authorization may be granted for certain medicines on less comprehensive clinical data than normally required, where the benefit of immediate availability of the medicine outweighs the risk inherent in the fact that additional data are still required. A conditional marketing authorization is subject to conditions to be fulfilled for generating missing data or ensuring increased safety measures. A conditional marketing authorization is valid for one year and has to be renewed annually until fulfillment of all relevant conditions. Once the applicable pending studies are provided, a conditional marketing authorization can be converted to a standard marketing authorization. However, if the conditions are not fulfilled within the timeframe set by the EMA, the marketing authorization will cease to be renewed.

Our activities, including our interactions with healthcare providers, third party payors, patients and government officials, are, and will continue to be, subject to extensive regulation involving healthcare, anti-corruption, data privacy and security and consumer protection laws. Failure to comply with applicable laws could result in substantial penalties, contractual damages, reputational harm, diminished revenues and curtailment or restructuring of our operations.

Our activities may now or in the future be directly or indirectly subject to various federal and state laws related to healthcare, anti-corruption, data privacy and security consumer protection. If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws include, but are not limited to:

- federal false claims, false statements and civil monetary penalties laws prohibiting, among other things, any person from knowingly presenting, or causing to be presented, a false claim for payment of government funds or knowingly making, or causing to be made, a false statement to get a false claim paid;

- the federal anti-kickback law, which prohibits, among other things, persons from offering, soliciting, receiving or providing any remuneration, directly or indirectly, to induce, either the referral of an individual for, or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;
- the federal anti-kickback prohibition known as Eliminating Kickbacks in Recovery Act, enacted in 2018, which prohibits certain payments related to referrals of patients to certain providers (recovery homes, clinical treatment facilities and laboratories) and applies to services reimbursed by private health plans as well as government healthcare programs;
- the federal law known as Health Insurance Portability and Accountability Act of 1996, or HIPAA, which, in addition to privacy protections to healthcare providers and other entities, prohibits executing a scheme to defraud any healthcare benefit program (which may include private health plans) or making false statements relating to healthcare matters;
- the FDCA, which among other things, strictly regulates drug marketing, prohibits manufacturers from marketing such products for off-label use and regulates the distribution of samples;
- federal laws that 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 teaching hospitals, physicians and certain non-physician practitioners to the federal government for re-disclosure to the public;
- the privacy, security and breach provisions of HIPAA, which impose obligations on certain “covered entities” (healthcare providers, health plans and healthcare clearinghouses) and certain of their “business associate” contractors with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- federal and state laws and regulations, including state security breach notification laws, state comprehensive privacy laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, disclosure and protection of health-related and other personal information;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the Foreign Corrupt Practices Act, or FCPA, a United States law which regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals); and
- state law analogues of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including private health plans, state privacy laws, state consumer protection laws, and state laws regulating interactions between pharmaceutical manufacturers and healthcare providers, requiring disclosure of such financial interactions or mandating adoption of certain compliance standards, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts.

Companies that violate these laws can be subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. Further, lack of knowledge (anti-kickback laws, HIPAA) or lack of intent (false claims laws) may not be valid defenses to violating such laws.

In addition, the marketing approval and commercialization of any of our product candidates in the European Union and other jurisdictions outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including, without limitation, civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations.

Current and future legislation may increase the difficulty and cost for us to obtain reimbursement for our product candidates.

In the United States and some foreign jurisdictions, there have been and continue to be a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could, among other things, prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to

profitably sell any products for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and additional downward pressure on the price that we may receive for any approved products. If reimbursement of our products is unavailable or limited in scope, our business could be materially harmed.

The ACA was enacted in March 2010, and other legislative changes have been proposed and adopted since its enactment. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2031 under the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act.

The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our products or product candidates for which we may obtain marketing approval or the frequency with which any such product is prescribed or used.

Since enactment of the ACA, there have been and continue to be numerous legal challenges and U.S. congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act, or the Tax Act, in 2017, Congress repealed the "individual mandate." The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. On June 17, 2021, the U.S. Supreme Court dismissed a challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

In the European Union, on December 13, 2021, Regulation (EU) 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted. While the Regulation entered into force in January 2022, it only began to apply from January 2025 onwards and has a phased implementation depending on the concerned products. The Regulation intends to boost cooperation among European Union member states in assessing health technologies, including new medicinal products as well as certain high-risk medical devices, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It permits European Union member states to use common HTA tools, methodologies, and procedures across the European Union, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual European Union member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology and making decisions on pricing and reimbursement.

We expect that these healthcare reforms, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product and/or the level of reimbursement physicians receive for administering any approved product we might bring to market. Reductions in reimbursement levels may negatively impact the prices we receive or the frequency with which our products are prescribed or administered. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. Accordingly, such reforms, if enacted, could have an adverse effect on anticipated revenue from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop or commercialize product candidates.

The prices of prescription pharmaceuticals in the United States and foreign jurisdictions are subject to considerable legislative and executive actions and could impact the prices we obtain for our products, if and when licensed.

The prices of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. There have been U.S. congressional inquiries, as well as proposed and enacted state and federal legislation designed to, among other things, bring more transparency to pharmaceutical pricing, review the relationship between pricing and manufacturer patient programs, and reduce the costs of pharmaceuticals under Medicare and Medicaid.

For example, in October 2020, HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program, or SIP, to import certain prescription drugs from Canada into the United States. That regulation was challenged in a lawsuit by the Pharmaceutical Research and Manufacturers of America, or PhRMA, but the case was dismissed by a federal district court in February 2023 after the court found that PhRMA did not have standing to sue HHS. Several states have passed laws allowing for the importation of drugs from Canada. On January 5, 2024, the FDA approved Florida's plan for Canadian drug importation. That state now has authority to import certain drugs from Canada for a period of two years once certain conditions are met. Florida will first need to submit a pre-import request for each drug selected for importation, which must be approved by the FDA. The state will also need to relabel the drugs and perform quality testing of the products to meet FDA standards. On May 21, 2025, the FDA announced that it would offer individual states the opportunity to submit a draft proposal for pre-review and meet with the FDA to obtain initial feedback from FDA prior to formally submitting their SIP proposals. The intent of these meetings is to assist states in developing their proposals by further clarifying requirements, enhancing the quality of proposals submitted to the FDA and ultimately shortening the review timeline.

In August 2022, the Inflation Reduction Act, or IRA, was signed into law by President Biden. The legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap, and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). In addition, the IRA established inflation rebate programs under Medicare Part B and Part D. These programs require manufacturers to pay rebates to Medicare if they raise their prices for certain Part B and Part D drugs faster than the rate of inflation. On December 9, 2024, with issuance of its 2025 Physician Fee Schedule final regulation, CMS finalized its rules governing the IRA inflation rebate programs. The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Further, the IRA subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated "maximum fair price" under the law or for taking price increases that exceed inflation. The legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The law also capped Medicare out-of-pocket drug costs at an estimated $4,000 a year in 2024 and at $2,000 a year in 2025 and onwards. In addition, the IRA potentially raises legal risks with respect to individuals participating in a Medicare Part D prescription drug plan who may experience a gap in coverage if they required coverage above their initial annual coverage limit before they reached the higher threshold, or "catastrophic period" of the plan. Individuals requiring services exceeding the initial annual coverage limit and below the catastrophic period, must pay 100% of the cost of their prescriptions until they reach the catastrophic period. Among other things, the IRA contains many provisions aimed at reducing this financial burden on individuals by reducing the co-insurance and co-payment costs, expanding eligibility for lower income subsidy plans, and price caps on annual out-of-pocket expenses, each of which could have potential pricing and reporting implications. Accordingly, while it is currently unclear how the IRA will be effectuated, we cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, any of which could adversely affect our business, results of operations and financial condition.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 additional Medicare Part D drugs in 2027, 15 additional Medicare Part B or Part D drugs in 2028, and 20 additional Medicare Part B or Part D drugs per year in 2029 and beyond. This provision applies to drug products that have been approved for at least nine years. Drugs that have been approved for a single rare disease or condition were originally categorically excluded from price negotiation. With the passage of the One Big Beautiful Bill Act, or OBBBA, on July 3, 2025, which was signed into law on July 4, 2025, Congress extended this exemption to drugs with multiple orphan drug designations. Nonetheless, since CMS may establish a maximum price for these products in price negotiations, we would be fully at risk of government action if our products are the subject of Medicare price negotiations. Moreover, given the risk that could be the case, these provisions of the IRA may also further heighten the risk that we would not be able to achieve the expected return on any of our product candidates, if approved, or the full value of our patents protecting any such approved drug products if prices are set after any such approved products have been on the market for nine years.

The first cycle of negotiations for the Medicare Drug Price Negotiation Program commenced in the summer of 2023 with the negotiated prices for ten selected drug products becoming effective on January 1, 2026. The second cycle of negotiations with participating drug companies occurred during 2025, and the negotiated prices for this second set of 15 drugs will become effective on January 1, 2027. On January 27, 2026, CMS published the list of 15 drugs selected for the third cycle of negotiations. These negotiated prices will become effective on January 1, 2028.

On June 6, 2023, Merck & Co. filed a lawsuit against HHS and CMS asserting that, among other things, the IRA's Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the U.S. Constitution. Subsequently, a number of other parties also filed lawsuits in various courts with similar constitutional claims. HHS has generally won the substantive disputes in these cases or succeeded in getting claims dismissed for lack of standing or on the merits. For example, on May 8, 2025, the U.S. Court of Appeals for the Third Circuit rejected AstraZeneca L.P.'s challenge to the Medicare price negotiation program, finding that the program did not violate the company's due process rights under the U.S. Constitution. Litigation involving these and other provisions of the IRA will continue with unpredictable and uncertain results.

We expect that litigation involving these and other provisions of the IRA will continue, with unpredictable and uncertain results. Accordingly, while it is currently unclear how the IRA will be effectuated, we cannot predict with certainty what impact any federal or state health reforms will have on us, but such changes could impose new or more stringent regulatory requirements on our activities or result in reduced reimbursement for our products, if approved, any of which could adversely affect our business, results of operations and financial condition.

In addition, the Trump Administration has taken a number of actions to reduce the costs of pharmaceutical products. For example, on April 15, 2025, President Trump issued an Executive Order which directs HHS to take steps to reduce the prices of pharmaceutical products. Such measures include streamlining the state drug importation program and modifying provisions of the 340B program. Further, on May 12, 2025, President Trump issued an additional Executive Order calling on pharmaceutical manufacturers to voluntarily reduce the prices of medicines in the United States. The Executive Order provides that if such actions do not lower the costs of pharmaceuticals, the Secretary of HHS would pursue other actions, including proposing a rulemaking that imposes most-favored nation, or MFN, pricing in the United States. Thereafter, on July 31, 2025, President Trump issued letters to 17 pharmaceutical companies reiterating the requirements of the May 12, 2025 Executive Order and demanding that such companies extend MFN pricing to Medicaid patients, guarantee MFN pricing for newly-launched drug products, return increased revenues abroad to American patients and provide for direct purchasing at MFN pricing. Since that time, virtually all of these pharmaceutical companies have entered into agreements with the Trump Administration to provide for lower prices on certain pharmaceuticals. On February 5, 2026, President Trump launched TrumpRx.gov, a website that directs individuals to pharmaceutical manufacturer websites that are offering price discounts based on the administration's pricing agreements with pharmaceutical manufacturers.

On December 23, 2025, CMS, through its Center for Medicare and Medicaid Innovation, proposed two five-year pilot programs to implement a "reference pricing" regime for drugs paid for under Medicare for 25% of covered beneficiaries. The programs are referred to as the Global Benchmark for Efficient Drug Pricing Model for Medicare Part B drugs, referred to as GLOBE, and the Guarding U.S. Medicare Against Rising Drug Costs for Medicare Part D drugs, referred to as GUARD. Under the proposed pilot programs, a manufacturer would owe rebates to Medicare if prices for their drugs exceeded the prices paid by other economically comparable reference countries, defined in the proposed regulations as Organisation for Economic Co-operation and Development countries with a gross domestic product of $400 billion and a per capita gross domestic product that is at least 60% of the U.S. per capita gross domestic product (an initial list of 19 reference countries is included in the proposed rule). The pilot programs are proposed to go into effect beginning October 1, 2026.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. This is increasingly true with respect to products approved pursuant to the accelerated approval pathway. States, including through their Medicaid programs and regulatory agencies, as well as other payers are developing strategies and implementing significant coverage barriers, or refusing to cover these products outright, arguing that accelerated approval products have insufficient or limited evidence despite meeting the FDA's standards for accelerated approval. Certain states are also pursuing cost containment efforts through Prescription Drug Affordability Boards, or PDABs, and similar entities. While many PDABs have been granted authority to promote drug price transparency and reporting, some states have granted PDABs more expansive authority, including to set Upper Payment Limits, or UPLs, on select, high price drugs. The adoption and implementation of UPLs may put downward pressure on drug prices and impact our company's future revenues. In addition, regional healthcare organizations and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for our products, if approved, or put pressure on our product pricing.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. This is increasingly true with respect to products approved pursuant to the accelerated approval pathway. State Medicaid programs and other payers are developing strategies and implementing significant coverage barriers, or refusing to cover these products outright, arguing that accelerated approval drugs have insufficient or limited evidence despite meeting the FDA's standards for accelerated approval.

In the European Union, similar political, economic and regulatory developments may affect our ability to profitably commercialize our product candidates, if approved. In markets outside of the United States and the European Union, reimbursement and healthcare payment systems vary significantly by country and many countries have instituted price ceilings on specific products and therapies. In many countries, including those of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control and access. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or any future collaborators of ours may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels, our business could be materially harmed.

We are subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security, and a failure to comply with such requirements could subject us to significant fines and penalties, which may have a material adverse effect on our business, financial condition or results of operations.

We are subject to data privacy and protection laws and regulations that apply to the collection, transmission, storage, use, disclosure and other processing of sensitive, confidential and personally identifying information, which among other things, impose certain requirements relating to the privacy, security and transmission of such information, including comprehensive regulatory systems in the United States, European Union and United Kingdom. The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with any of these laws and regulations could result in enforcement action against us, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

There are numerous U.S. federal and state laws and regulations related to the privacy and security of personal information. At the federal level, regulations promulgated pursuant to HIPAA establish privacy and security standards 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. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. These obligations may be applicable to some or all of our business activities now or in the future.

If we are unable to properly protect the privacy and security of protected health information, we could be found to have breached our contracts. Further, if we fail to comply with applicable privacy laws, including applicable HIPAA privacy and security standards, we could face civil and criminal penalties. HHS enforcement activity under HIPAA can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy or security of the personal information of state residents, including pursuant to the state privacy laws discussed below. We cannot be sure how these regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

We make public statements about our use, collection, disclosure and other processing of personal information through our privacy policies and information provided on our website. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be alleged to have failed to do so. The publication of our privacy policies and other statements that provide promises and assurances about data privacy and security can subject us to potential government or legal action if they are found to be deceptive, unfair or misrepresentative of our actual practices.

In addition to potential enforcement by HHS, we are also potentially subject to privacy enforcement from the FTC. The FTC has been particularly focused on the unpermitted processing of health and genetic data through its recent enforcement actions and is expanding the types of privacy violations that it interprets to be "unfair" under Section 5 of the Federal Trade Commission Act of 1914, as well as the types of activities it views to trigger the Health Breach Notification Rule (which the FTC also has the authority to enforce). We will need to account for the FTC's evolving rules and guidance for proper privacy and data security practices in order to mitigate our risk for a potential enforcement action, which may be costly. If we are subject to a potential FTC enforcement action, we may be subject to a settlement order that requires us to adhere to very specific privacy and security practices (depending on the nature of the alleged violations). If we violate any consent order that we reach with the FTC, we may be subject to additional fines and compliance requirements.

There are also increased restrictions at the federal level relating to transferring sensitive data outside of the United States to certain foreign countries. For example, the Department of Justice's January 8, 2025, rule on "Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons," prohibits data brokerage transactions involving certain sensitive personal data categories, including health data, genetic data, and biospecimens, to countries of concern, including China. The regulations also restrict certain investment agreements, employment agreements and vendor agreements involving such data and countries of concern, absent specified cybersecurity controls. Actual or alleged violations of these regulations may be punishable by criminal and/or civil sanctions and may result in exclusion from participation in federal and state programs.

Numerous states have also created comprehensive privacy laws which govern the processing of personal information. For example, the California Consumer Privacy Act, or the CCPA, took effect on January 1, 2020 and imposed many requirements on businesses that process the personal information of California residents. Many of the CCPA's requirements are similar to those found in the EU General Data Protection Regulation, or the EU GDPR, which is further described below, including requiring businesses to provide notice to data subjects regarding the information collected about them and how such information is used and shared, and providing data subjects the right to request access to such personal information and, in certain cases, request the erasure of such personal information. The CCPA also affords California residents the right to opt out of "sales" of their personal information. The CCPA contains significant penalties for companies that violate its requirements. The California Privacy Rights Act, or the CPRA, went into effect on January 1, 2023 and significantly expanded the CCPA to incorporate additional EU GDPR-like provisions including requiring that the use, retention and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. The CPRA also created an enforcement agency—the California Privacy Protection Agency—the sole responsibility of which is to enforce the CPRA and other California privacy laws, which will further increase compliance risk. The provisions in the CPRA may apply to some of our business activities.

In addition to California, a number of other states have passed similarly comprehensive privacy laws. Like the CCPA, these laws create obligations related to the processing of personal information, as well as special obligations for the processing of "sensitive" data (which includes health data in some cases). Some of the provisions of these laws may apply to our business activities. There are also states that are specifically regulating specific categories of personal information, such as health information that may affect our business. For example, the State of Washington recently passed a health privacy law that will regulate the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk. Additionally, a small number of states, such as Illinois and Texas, have enacted laws that specifically target the collection and use of biometric information. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

Additionally, laws in all 50 states require businesses to provide notice to customers whose personal information has been disclosed as a result of a data breach. These laws are not consistent, and compliance in the event of a widespread data breach is difficult and may be costly. Moreover, states have been frequently amending existing laws, requiring attention to changing regulatory requirements. We also may be contractually required to notify affected individuals or other counterparties of a cybersecurity incident, data breach, or other compromise. Although we may have contractual protections with our vendors, any actual or perceived security breach, incident, or compromise could harm our reputation and brand, expose us to potential liability or require us to expend significant resources on data security and in responding to any such actual or perceived cybersecurity incident, data breach, or other compromise. Any contractual protections we may have from our vendors may not be sufficient to adequately protect us from any such liabilities and losses, and we may be unable to enforce any such contractual protections. In addition to government regulation, privacy advocates and industry groups have and may in the future propose self-regulatory standards from time to time. These and other industry standards may legally or contractually apply to us, or we may elect to comply.

Plaintiffs' lawyers are also increasingly using privacy-related statutes at both the state and federal level to bring lawsuits against companies for their data-related practices. In particular, there have been a significant number of cases filed against companies for their use of pixels and other web trackers. These cases often allege violations of the California Invasion of Privacy Act and other state laws regulating wiretapping, as well as the federal Video Privacy Protection Act. The rise in these types of lawsuits creates potential risk for our business.

Similar to the laws in the United States, there are significant and evolving privacy and data security laws that apply in Europe and other countries. The collection, use, disclosure, transfer or other processing of personal data, including personal health data, regarding individuals who are located in the EEA and the United Kingdom and the processing of personal data that takes place in the EEA and the United Kingdom, is regulated by the EU GDPR with respect to the EEA, and the U.K. General Data Protection Regulation, or U.K. GDPR, with respect to the United Kingdom, and collectively with the EU GDPR referred to as the "GDPR" in this report unless specified otherwise. The GDPR applies to all organizations processing or holding personal data of EEA and/or U.K. data subjects (regardless of the organization's location) as well as to organizations outside these jurisdictions that offer goods or services in the EEA and United Kingdom, or that monitor the behavior of EEA and/or U.K. data subjects. The GDPR imposes extensive obligations on companies that process personal data, including requirements relating to lawful bases for processing, transparency, consent where required, security safeguards, data processing agreements, data subject rights, breach notification, record-keeping, data protection impact assessments and, in some cases, appointment of a data protection officer. It also restricts transfers of personal data outside the EEA and United Kingdom (including to the United States). Breaches can result in significant penalties (up to €20 million / £17.5 million or 4% of global annual turnover, whichever is higher), and data subjects have rights to lodge complaints and seek compensation.

The GDPR imposes strict rules on the transfer of personal data out of the EEA/United Kingdom to countries not regarded by the European Commission and the U.K. government as providing adequate protection, or third countries, including the United States. These transfers are prohibited unless an appropriate safeguard specified by data protection laws is implemented, such as the Standard Contractual Clauses, or SCCs, approved by the European Commission, or a derogation applies. Transfers made pursuant to the SCCs need to be assessed on a case-by-case basis to ensure the law in the recipient country provides "essentially equivalent" protections to safeguard the transferred data. If the standard is not met, businesses will be required to adopt supplementary measures. Further, the European Union and United States have adopted its adequacy decision for the EU-U.S. Data Privacy Framework, or the Framework, which entered into force on July 11, 2023. This Framework provides that the protection of personal data transferred between the European Union and the United States is comparable to that offered in the European Union. This provides a further avenue to ensuring transfers to the United States are carried out in line with the GDPR. The United Kingdom is not subject to the European Commission's SCCs but the U.K. Information Commissioner's Office has published the United Kingdom's own transfer mechanisms for personal data originating from the United Kingdom (the International Data Transfer Agreement and International Data Transfer Addendum, or, each, an IDTA), which have been in force since March 21, 2022. The IDTA requires the same case-by-case risk assessment of the transfer. In addition, there has been an extension to the Framework to cover U.K. transfers to the United States. The Framework could be challenged like its predecessor frameworks. The international transfer obligations under the EEA and U.K. data protection regimes will require significant effort and cost, and may result in us needing to make strategic considerations around where EEA/U.K. personal data is located and which service providers we can utilize for the processing of EEA/U.K. personal data, particularly as the enforcement around GDPR international transfer compliance obligations is currently unclear. The above transfer requirements and other future developments regarding the flow of data across borders could increase the cost and complexity of delivering our services in some markets and may lead to governmental enforcement actions, litigation, fines, and penalties or adverse publicity, which could adversely affect our business and financial position.

Although the United Kingdom is regarded as a third country under the EU GDPR, the European Commission has now issued a decision recognizing the United Kingdom as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the European Union to the United Kingdom remain unrestricted. In December 2025, the European Commission adopted a decision to extend the validity of the U.K. adequacy decision for six years until December 2031, determining that the United Kingdom continues to offer a level of data protection that is "essentially equivalent" to the EU standards. This follows the United Kingdom's adoption of the Data (Use and Access) Act 2025 on June 19, 2025. Like the EU GDPR, the U.K. GDPR restricts personal data transfers outside the United Kingdom to countries not regarded by the United Kingdom as providing adequate protection. The U.K. government has confirmed that personal data transfers from the United Kingdom to the EEA remain free flowing. The respective provisions and enforcement of the EU GDPR and U.K. GDPR may further diverge in the future and create additional regulatory challenges and uncertainties. This lack of clarity on future U.K. laws and regulations and their interaction with EU laws and regulations could add legal risk, complexity and cost to our handling of personal data and our privacy and data security compliance programs and could require us to implement different compliance measures for the United Kingdom and the EEA.

Beyond GDPR, there are privacy and data security laws in a growing number of countries around the world. While many loosely follow GDPR as a model, other laws contain different or conflicting provisions. These laws will impact our ability to conduct our business activities, including both our clinical trials and the sale and distribution of commercial products, if approved, through increased compliance costs, costs associated with contracting and potential enforcement actions.

While we continue to address the implications of the recent changes to data privacy regulations, data privacy remains an evolving landscape at both the domestic and international level, with new regulations coming into effect and continued legal challenges, and our efforts to comply with such evolving data protection laws, rules and regulations may be unsuccessful. These laws are not consistent, and compliance in the event of a widespread data breach is costly and time-consuming. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices, which could adversely affect our business. We must devote significant resources to understanding and complying with this changing landscape. Failure by us or our third-party vendors to comply with federal, state and international laws regarding privacy and security of personal information could expose us to the risk of enforcement actions taken by data protection authorities and can carry with it the potential for significant fines and penalties under such laws if we are found to be non-compliant. Even if we are not determined to have violated these laws, rules or regulations, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business, financial condition, results of operations or prospects.

Laws and regulations governing international operations may preclude us from developing, manufacturing and selling certain products outside of the United States and require us to develop and implement costly compliance programs.

We have operations in Denmark and are required to dedicate additional resources to comply with U.S. laws regarding international operations and the laws and regulations in Denmark and any additional jurisdiction in which we operate.

The FCPA prohibits any U.S. individual or business from paying, offering or authorizing payment or offering of anything of value, directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision of the foreign entity in order to assist the individual or business in obtaining or retaining business. The FCPA also obligates companies whose securities are listed in the United States to comply with certain accounting provisions requiring the company to maintain books and records that accurately and fairly reflect all transactions of the company, including international subsidiaries and to devise and maintain an adequate system of internal accounting controls for international operations.

Compliance with the FCPA is expensive and difficult, particularly in countries in which corruption is a recognized problem. In addition, the FCPA presents particular challenges in the pharmaceutical industry because in many countries, hospitals are operated by the government and doctors and other hospital employees are considered foreign officials. Certain payments to hospitals in connection with clinical trials and other work have been deemed to be improper payments to government officials and have led to FCPA enforcement actions.

Various laws, regulations and executive orders also restrict the use and dissemination outside of the United States or the sharing with certain non-U.S. nationals, of information classified for national security purposes, as well as certain products and technical data relating to those products. Further, the provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the European Union. The provision of benefits or advantages to physicians is also governed by the national anti-bribery laws of European Union member states, such as the U.K. Bribery Act 2010. Infringement of these laws could result in substantial fines and imprisonment. Payments made to physicians in certain European Union member states must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual European Union member states. These requirements are provided in the national laws, industry codes or professional codes of conduct applicable in the European Union member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

If we expand our international presence beyond Denmark, it will require us to dedicate additional resources to comply with these laws and these laws may preclude us from developing, manufacturing or selling certain products and product candidates outside of the United States, which could limit our growth potential and increase our development costs. The creation, implementation and maintenance of international business practices compliance programs may be necessary and costly, and such programs are difficult to enforce, particularly where reliance on third parties is required. The failure to comply with laws governing international business practices may result in substantial civil and criminal penalties and suspension or debarment from government contracting. The SEC also may suspend or bar issuers from trading securities on U.S. exchanges for violations of the FCPA's accounting provisions.

We and our third-party contract manufacturers must comply with environmental, health and safety laws and regulations, and failure to comply with these laws and regulations could expose us to significant costs or liabilities.

We and our third-party manufacturers are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the use, generation, manufacture, distribution, storage, handling, treatment, remediation and disposal of hazardous materials and wastes. Hazardous chemicals, including flammable and biological materials, are involved in certain aspects of our business, and we cannot eliminate the risk of injury or contamination from the use, generation, manufacture, distribution, storage, handling, treatment or disposal of hazardous materials and wastes. In the event of contamination or injury, or failure to comply with environmental, health and safety laws and regulations, we could be held liable for any resulting damages and any such liability could exceed our assets and resources. We could also incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations. 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.

Environmental, health and safety laws and regulations are becoming increasingly more stringent. We may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Our failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or business disruption, any of which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Further, with respect to the operations of our third-party contract manufacturers, it is possible that if they fail to operate in compliance with applicable environmental, health and safety laws and regulations or properly dispose of wastes associated with our products, we could be held liable for any resulting damages, suffer reputational harm or experience a disruption in the manufacture and supply of our product candidates or products.

Our employees, consultants and business partners may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, consultants and business partners. Misconduct by these parties could include intentional failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations, to comply with state and federal securities laws, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and serious harm to our reputation. We are also exposed to risks in connection with any insider trading violations by employees or others affiliated with us. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Changes in and uncertainty surrounding U.S. and international trade policies, particularly with respect to China, may adversely impact our business and operating results.

In the spring of 2025, the U.S. government initiated a series of tariff-related actions against U.S. trading partners. On April 2, 2025, an Executive Order announced a "baseline" reciprocal tariff of 10% on all U.S. trading partners effective April 5, 2025, and higher individualized reciprocal tariffs on 57 countries (with certain product exemptions for

pharmaceutical-related products, among others). Previously, the U.S. government had imposed a 25% tariff on Canada and Mexico for goods not covered by the United States-Mexico-Canada Agreement, and tariffs due to drug trafficking equaling 20% on imports from China. In response, several countries threatened retaliatory measures, including Canada and China, which then imposed retaliatory tariffs. Prior to when the country-specific reciprocal tariffs were scheduled to take effect, the U.S. delayed the effective date of such tariffs for all countries except China to August 1, 2025. Later, the United States and China reached a framework agreement that ultimately resulted in the suspension of the higher reciprocal tariffs on China until November 10, 2025. Shortly before that expiration date, the United States and China reached a one-year agreement with an expiration of November 10, 2026, that includes the continued suspension of the heightened reciprocal tariffs on China and delayed enforcement of new U.S. export rules targeting affiliates of blacklisted firms.

Since the April 2025 reciprocal tariffs announcement, the European Union, Japan, South Korea, Switzerland and the United Kingdom, among others, have reached deals with the United States that include reduced tariff rates to varying levels and other measures. On July 31, 2025, the Trump Administration issued an Executive Order detailing new reciprocal tariff rates for individual countries that took effect on August 7, 2025. The deals with the European Union, Japan, South Korea, Switzerland (and Liechtenstein), the United Kingdom and others cap pharmaceutical tariffs at 15%. In addition, an agreement with Malaysia provides a zero percent tariff exemption for pharmaceutical products that are not patented in the United States and are used in pharmaceutical applications and an agreement with Switzerland and Lichenstein caps tariffs on pharmaceuticals imported from those two countries at 15%. Finally, an agreement with Taiwan concluded on January 15, 2026 eliminates tariffs on generic pharmaceuticals and their active ingredients imported from Taiwan.

The reciprocal tariffs and the fentanyl tariffs were imposed pursuant to the International Emergency Economic Powers Act, or the IEEPA. These tariffs were found to be unconstitutional by multiple federal courts in the spring and summer of 2025. On February 20, 2026, the U.S. Supreme Court held that the IEEPA does not authorize the U.S. President to impose tariffs, invalidating both the reciprocal tariffs and the drug trafficking tariffs. Shortly thereafter, President Trump issued a new Executive Order revoking the IEEPA tariffs and Customs and Border Protection ceased collecting the tariffs on February 24, 2026. At the same time, however, the Trump Administration imposed a new 10% global tariff under Section 122 of the Trade Act of 1974, effective February 24, 2026. Pursuant to the statute, absent an extension by Congress, these tariffs will expire in 150 days on July 24, 2026. For those countries that have concluded trade deals with the United States, the tariff rates agreed to, including with regard to pharmaceuticals and pharmaceutical ingredients, have now reverted to 10% until July 24, 2026. Like the IEEPA tariffs, pharmaceuticals and pharmaceutical ingredients are exempt from the Section 122 tariffs along with a list of other products. The Trump Administration has announced that it also plans to initiate new investigations on “most major trading partners” under Section 301 of the same act, which will likely lead to additional tariffs.

Neither the U.S. Supreme Court’s decision nor the Executive Order revoking the IEEPA tariffs addressed refunds, leaving the issue to renewed proceedings before the U.S. Court of International Trade, where importers may need to pursue administrative remedies and/or litigation amid continued uncertainty. Sustained uncertainty about, or the further escalation of, trade and political tensions between the United States and China could result in a disadvantageous research and manufacturing environment in China, particularly for U.S.-based companies, including retaliatory restrictions that hinder or potentially inhibit our ability to rely on CMOs and other service providers that operate in China.

Separately, in April 2025, the Department of Commerce announced an investigation under Section 232 of the Trade Expansion Act of 1962, or Section 232, into imports of pharmaceuticals and pharmaceutical ingredients, including finished products, medical countermeasures, critical inputs such as active pharmaceutical ingredients, and key starting materials, and derivative products of those items. On September 25, 2025, via a post on Truth Social, President Trump announced that, beginning October 1, 2025, all branded or patented drugs imported in the United States would face a 100% tariff. At the same time, President Trump indicated that these tariffs could be avoided by building pharmaceutical manufacturing facilities in the United States. Thereafter, President Trump delayed the October 1, 2025 effective date of the tariffs on branded or patented pharmaceutical products announcing that the Trump Administration had now “begun preparing” tariffs on manufacturers that do not build in the United States or enter into a most-favored-nation drug pricing agreement with the Trump Administration. A host of other U.S. tariff actions remain possible, including additional 25% tariffs on products from countries that do certain business with Iran or Cuba.

On April 2, 2026, President Trump issued a proclamation invoking Section 232 to impose tariffs on imports of certain patented pharmaceuticals, biologics, and associated ingredients into the United States, or the Proclamation. The Proclamation affects pharmaceutical manufacturers, importers, and supply chain participants. Specifically, beginning September 29, 2026, tariffs ranging from 10% to 100% will apply to pharmaceutical articles that are subject to a valid, unexpired U.S. patent and are listed either in the Orange Book or are listed in the FDA’s Lists of Licensed Biological Products, or the Purple Book. These tariffs apply to active pharmaceutical ingredients and key starting materials for such

articles. Certain categories of products are exempt from these tariffs, including generic pharmaceuticals and biosimilars; U.S.-origin pharmaceutical products, active pharmaceutical ingredients and key starting materials; products classified in certain 10-digit tariff codes, listed in Annex IV of the Proclamation; drugs and associated ingredients for all approved indications that are designated as orphan pursuant to the Orphan Drug Act; drugs for certain specific uses, including nuclear medicines; plasma-derived therapies; fertility treatments; cell and gene therapies; antibody drug conjugates; medical countermeasures related to chemical, biological, radiological, and nuclear threats; animal health; and other specialty pharmaceutical products to be later identified by the Secretary of Commerce; and goods that qualify as "prototypes to be used exclusively for development, testing, product evaluation, or quality control purposes," may be excluded from the additional tariffs.

As a result of changes in tariffs that have been announced and/or implemented, and the underlying uncertainty currently surrounding international trade, we could experience a negative impact to our costs of materials and production processes, and supply chain disruptions and delays as a result of any new tariff policies or trade restrictions. If we are unable to obtain necessary raw materials or product components in sufficient quantity and in a timely manner due to disruptions in the global supply chain caused by macroeconomic events and conditions, the development, testing and clinical trials of our product candidates may be delayed or infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. We cannot yet predict the effect of the recently imposed U.S. tariffs on imports, or the extent to which other countries will impose quotas, duties, tariffs, taxes or other similar restrictions upon imports or exports in the future, nor can we predict future trade policy or the terms of any renegotiated trade agreements and their impact on our business.

Further, some of our manufacturers and suppliers are located in China. Trade tensions and conflicts between the United States and China have been escalated in recent years and, as such, we are exposed to the possibility of product supply disruption and increased costs and expenses in the event of changes to the laws, rules, regulations and policies of the governments of the United States or China, or due to geopolitical unrest and unstable economic conditions. Certain Chinese biotechnology companies may become subject to trade restrictions, sanctions, other regulatory requirements or proposed legislation by the U.S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting their supply of material to us. For example, in February 2024, U.S. lawmakers called for investigations into and the imposition of possible economic sanctions against Chinese biotechnology companies WuXi AppTec and WuXi Biologics, or collectively WuXi, over alleged ties to the Chinese military.

Subsequently, in December 2025, as part of the Fiscal Year 2026 National Defense Authorization Act, President Trump signed into law the BIOSECURE Act. Under the BIOSECURE Act, U.S. government agencies cannot (1) buy or obtain biotechnology equipment or services provided by biotechnology companies of concern, or BCCs, (2) enter into, extend, or renew a contract with any entity using biotechnology equipment or services provided by a BCC to perform a government contract, or (3) expend, loan or grant funds for biotechnology equipment or services provided by a BCC, whether directly or through a loan or grant recipient. The BIOSECURE Act does not name specific companies as BCCs but treats any company on the Department of Defense 1260H list of "Chinese military companies" as a BCC. On December 18, 2025, the Chairs of multiple Senate and House committees, including the House Select Committee on China, sent a letter to the Department of Defense recommending that WuXi be added to the 1260H list, which would make it a BCC. The 1260H list was updated by the Department of Defense in January 2024 and January 2025. On February 13, 2026, the Department published an updated list, which included WuXi, but then abruptly withdrew the list. The implications of this action remain unclear.

Risks Related to Employee Matters and Managing Growth

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

We are highly dependent on the research and development, clinical, regulatory, and business development expertise of Benny Sørensen, M.D., Ph.D., our president and chief executive officer, as well as the other principal members of our management, scientific and clinical teams. Although we have entered into employment agreements with our executive officers, each of them may terminate their employment with us at any time. We do not maintain "key person" insurance for any of our executives or other employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals. Recruiting and retaining qualified scientific, clinical, manufacturing, accounting, legal and sales and marketing personnel will also be critical to our success.

The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and

experience required to successfully develop, gain marketing approval of and commercialize products. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate these key personnel on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel. We also experience competition for the hiring of scientific and clinical personnel from universities and research institutions.

In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. Our success as a public company also depends on implementing and maintaining internal controls and the accuracy and timeliness of our financial reporting. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited.

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

We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, clinical, regulatory affairs, manufacturing and quality control and, if any product candidate receives marketing approval, sales, marketing and distribution. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. 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. The expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

Future acquisitions or strategic alliances could disrupt our business and harm our financial condition and results of operations.

We may acquire additional businesses, technologies or assets, form strategic alliances or create joint ventures with third parties that we believe will complement or augment our existing business. If we acquire businesses with promising markets or technologies, those markets or technologies may not achieve the outcomes that we expect. Acquiring new product candidates is inherently risky, and there can be no assurance that any acquired product candidates would prove to be successful. In addition, we may not be able to realize the benefit of acquiring such businesses if we are unable to successfully integrate them with our existing operations and company culture. We may encounter numerous difficulties in developing, manufacturing and marketing any new products or product candidates resulting from a strategic alliance or acquisition that may delay or prevent us from realizing their expected benefits or enhancing our business. We cannot assure our stockholders that, following any such acquisition, we will achieve the expected synergies to justify the transaction. The risks we face in connection with acquisitions include:

- diversion of management time and focus from operating our business to addressing acquisition integration challenges;
- coordination of research and development efforts;
- retention of key employees from the acquired company;
- changes in relationships with collaborators as a result of product acquisitions or strategic positioning resulting from the acquisition;
- cultural challenges associated with integrating employees from the acquired company into our organization;
- the need to implement or improve controls, procedures and policies at a business that prior to the acquisition may have lacked sufficiently effective controls, procedures and policies;
- liability for activities of the acquired company before the acquisition, including intellectual property infringement claims, violation of laws, commercial disputes, tax liabilities and other known liabilities unanticipated write-offs or charges; and
- litigation or other claims in connection with the acquired company, including claims from terminated employees, customers, former stockholders or other third parties.

The internal information technology systems, or those of any future collaborators of ours, vendors or other contractors or consultants, on which we depend have in the past and may in the future fail or suffer cybersecurity incidents, data breaches, loss of data and other disruptions, which could result in a material disruption of our product development programs, compromise sensitive information related to our business or prevent us from accessing critical information, trigger contractual and legal obligations, potentially exposing us to liability, reputational harm or otherwise adversely affect our business and financial results.

We are dependent upon information technology systems, infrastructure and data to operate our business. In the ordinary course of business, we collect, store and transmit confidential information, including but not limited to intellectual property, proprietary business information and personal information.

Despite the implementation of security measures, our internal information technology systems and those of any collaborators, vendors, contractors or consultants are vulnerable to breakdowns, damage or interruption from computer viruses, computer hackers, malicious code, ransomware, malware, malicious conduct or error by employees or other users, theft or misuse, denial-of-service attacks, sophisticated nation-state and nation-state-supported actors, unauthorized access, natural disasters, terrorism, wars or other armed conflict, telecommunication and electrical failures or other compromise. There could also be an increase in cybersecurity attacks generally as a result of ongoing military conflicts and the resulting sanctions imposed by the United States and European governments, together with any additional future sanctions or other actions by them.

Cyberattacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyberattacks could include the deployment of harmful malware, ransomware, business email compromises, denial-of-service attacks, unauthorized access to or deletion of files, social engineering (including phishing attacks) and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Cyberattacks also could include phishing attempts or e-mail fraud to cause payments or information to be transmitted to an unintended recipient. These attacks and activity are also being facilitated or enhanced by evolving technologies, including artificial intelligence. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies.

Like other companies in our industry, we, and our third-party vendors, have experienced threats and cybersecurity incidents relating to our information systems and infrastructure. We cannot guarantee that the measures we have taken to date, and actions we may take in the future, will be sufficient to prevent any future system failures, cyberattacks, accidents or cybersecurity incidents or data breaches with respect to our information technology systems, or the information technology systems of our vendors, collaborators or other contractors or consultants.

To the extent we or our vendors, collaborators or other contractors or consultants experience a material system failure, accident, cyberattack or security breach, it could result in a material disruption of our development programs and our business operations, whether due to a loss of our trade secrets or other proprietary or confidential information or other disruptions. For example, the loss of clinical trial data from our ongoing or planned clinical trials could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology and cybersecurity infrastructure, we could suffer significant business disruption (and may suffer such disruption notwithstanding the building and sustaining of such infrastructure), including transaction errors, supply chain or manufacturing interruptions, processing inefficiencies, data loss or the loss of or damage to intellectual property or other proprietary information.

To the extent that any disruption, cybersecurity incident or data breach were to result in a loss of, or damage to, our or our vendors', collaborators' or other contractors' or consultants' data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, including litigation exposure, penalties and fines, we could become the subject of regulatory action or investigation, our competitive position and reputation could be harmed and the further development and commercialization of our product candidates could be delayed. As a result of such an event, we may also be in breach of our contractual obligations. Due to applicable laws, rules, regulations and standards or contractual obligations, we may be held responsible for any system failure or security incident attributed to our third-party vendors as they relate to the information we share with them.

Furthermore, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our customers or employees, could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damage. Any of the above could have a material adverse effect on our business, financial condition, results of operations or prospects.

The financial exposure from the events referenced above could either not be insured against or not be fully covered through any insurance that we maintain and could have a material adverse effect on our business, financial condition, results of operations or prospects. In addition, we cannot be sure that our existing insurance coverage will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages as a result of the events referenced above.

While we do not currently use artificial intelligence, or AI, in a manner that is central to our operations, we may decide to do so, which may cause us to expend material resources in the future. Our current use of AI is limited, but we are still exposed to the inherent risks of the use of AI. The risks and challenges associated with the use of AI, whether in the more limited manner that we currently do so or the manner that we may do so in the future, include security and other risks to our confidential information, proprietary information and personal information, any of which may result in reputational harm and liability, "hallucinations" or other errors, and biases, among other potential adverse effects to our business.

We may use and integrate AI into our business processes both in our own development and implementation of AI and through the adoption of commercially available tools. The rapid evolution of AI will require the application of significant resources to design, develop, test and maintain such systems to help ensure that AI is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impact. Engaging appropriate resources (including computing power) to properly develop such technologies may require substantial expense and it may require substantial time to develop a properly functioning AI system, including because expertise in the use of AI for drug discovery or other life sciences applications is rare, and we may be unable to successfully integrate AI tools into our business or to do so efficiently. We may also need to license data from third-party sources or develop data internally, each of which may take substantial time and require substantial expense. If we enable or offer solutions that draw controversy due to perceived or actual negative societal impact, we may experience brand or reputational harm, competitive harm or legal liability.

Whether with our current, limited use of AI or a future, more fundamental use of AI, we are exposed to the risk related to the use and integration of AI. Use of this technology could pose cybersecurity, data privacy, IT, intellectual property, regulatory, legal, operational, competitive, reputational and other risks and challenges that could affect our business. Specifically, risks related to accuracy, bias, AI hallucinations, discrimination, harmful content, misinformation, fraud, scams, targeted attacks (including model poisoning or data poisoning), surveillance, data leakage, inequality, environmental harms, and other harms may flow from our development, use, or deployment of AI technologies.

No assurance can be provided that the use of AI will enhance our business or assist our business in becoming more efficient or profitable. The use of AI can give rise to intellectual property risks, including compromises to our proprietary intellectual property and risks of infringement or misappropriation of third party intellectual property, each of which may result in time-consuming and costly litigation and could require us to purchase a costly license or cease use of any material created using AI (and any intellectual property derived from such material). In addition, there is currently significant uncertainty around the extent to which we would be able to claim ownership in, or otherwise protect using intellectual property or similar proprietary rights, any inventions or other materials, which we develop through the use of AI. As a result, we could have no remedy if third parties reused those same materials, or similar materials also generated by AI. In addition, the use of AI by any of our personnel or our third-party providers could include the input of proprietary or confidential information (including material non-public information) into any AI systems, resulting in such proprietary or confidential information becoming part of a dataset that is accessible by other third-party AI users. Not all providers of AI tools may offer an option to opt-out of usage of such inputs or prompts to further train the tools, and, even where we do opt-out, we cannot guarantee that the opt-out will be fully effective.

AI is generally highly reliant on the collection and analysis of large amounts of data. The data we may use to train AI models may be inaccurate, such as if we do not generate the data in an accurate manner, we license third-party data that is inaccurate, or we use a third-party AI system trained on data that is inaccurate. As a result of this potential inaccuracy, we may have analyses, recommendations or other outputs that are deficient, inaccurate, incomplete, overbroad, or biased, which may in turn adversely affect our business, financial condition and results of operations. Another data-related risk of the use of AI, even if the underlying data is accurate, is that AI may be subject to data herding and interconnectedness (i.e., multiple market participants utilizing the same data to generate the same or similar results), and if those results are important to our business, that may adversely impact our financial or operational condition.

Additionally, we may see increasing government and supranational regulation and ethical concerns related to AI use which may also significantly increase the burden and cost of research, development and compliance in this area. For example, the European Union began implementing the Artificial Intelligence Act, or the AI Act, on August 1, 2024, with a significant part of the law scheduled to come into effect in August 2026. As currently enacted, the AI Act, which may be

amended as part of the EU's Digital Omnibus, imposes significant obligations on providers and deployers of high-risk artificial intelligence systems, and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles in their development and use of these systems. The scope of requirements depends on judicial interpretations and forthcoming legislative amendments, and non-compliance can lead to significant fines.

In the United States, the AI regulatory environment is complex and uncertain. Over the past year, states have advanced, and in some cases passed, dozens of laws focusing on AI governance and regulation, including on deployment of AI in healthcare settings. At the federal level, the Trump Administration has endorsed a federal moratorium on the enforcement of state AI laws, including through a December 11, 2025, Executive Order on "Ensuring a National Policy Framework for Artificial Intelligence." So far, these efforts have not been successful at curtailing state action on AI regulation, contributing to a complicated legislative patchwork, which may be litigated in state and federal courts. If we develop or use AI systems that are governed by the these laws or regulations, we will need to meet higher standards of data quality, transparency, and human oversight, and we would need to adhere to specific and potentially burdensome and costly ethical, accountability, and administrative requirements. Because of the interest in AI by many governmental authorities, there may be additional laws or regulations that limit our ability to use AI or apply novel liability frameworks to the use of AI, and these risks may cause adverse effects to our business, operations or financial condition.

We may collaborate with third parties, or source work from vendors, that use AI, with or without our knowledge that those third parties or vendors are using AI. As a result, we may face the risks associated with the use of AI without knowingly using AI. Bad actors around the world also use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, confidential information and intellectual property. In addition, the use of generative AI models in our internal or third-party systems may create new attack surfaces or methods for adversaries, which could impact us and our vendors. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

We may be exposed to significant foreign exchange risk.

Our consolidated financial statements are presented in U.S. dollars. We have operations in Denmark, and we incur portions of our expenses, and may in the future derive revenues, in a variety of currencies. As a result, we are exposed to foreign currency exchange risk as our results of operations and cash flows are subject to fluctuations in foreign currency exchange rates. Fluctuations in currency exchange rates have had, and will continue to have, an impact on our results as expressed in U.S. dollars. We currently do not engage in hedging transactions to protect against uncertainty in future exchange rates between particular foreign currencies and the U.S. dollar. 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.

Risks Related to Ownership of Our Common Stock and Operating as a Public Company

An active trading market for our common stock may not continue to develop or be sustained.

Our common stock began trading on the Nasdaq Global Select Market on May 1, 2026. Prior to May 1, 2026, there was no public market for our common stock, and we cannot assure our stockholders that an active trading market for our shares will continue to develop or be sustained. As a result, it may be difficult for our stockholders to sell their shares without depressing the market price for the shares, or at all.

We may not be able to maintain a listing of our common stock on Nasdaq.

We must meet certain financial and liquidity criteria to maintain the listing of our common stock on Nasdaq. If we violate Nasdaq's listing requirements, our common stock may be delisted. If we fail to meet any of Nasdaq's listing standards, our common stock may be delisted. In addition, our board of directors may determine that the cost of maintaining our listing on a national securities exchange outweighs the benefits of such listing. A delisting of our common stock from Nasdaq may materially impair our stockholders' ability to buy and sell our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock. The delisting of our common stock could significantly impair our ability to raise capital and the value of our stockholders' investment.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for our stockholders.

Our stock price is likely to be volatile. The stock market in general and the market for smaller biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, our stockholders may not be able to sell their common stock at or above the price they paid for their shares. The market price for our common stock may be influenced by many factors, including:

- results of or developments in preclinical studies and clinical trials of our product candidates and any other product candidates we may develop or those of our competitors or potential collaborators;
- the results of our preclinical studies and clinical trials of our competitors;
- our success in commercializing any product candidates, if and when approved;
- developments with respect to competitive products;
- regulatory or legal developments in the United States and other countries;
- announcements by us or our competitors of significant acquisitions, in-licensing arrangements, strategic partnerships, joint ventures or collaborations;
- developments or disputes concerning patent applications, issued patents or other intellectual property or proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to our development efforts with respect to our product candidates and any future product candidates we may develop;
- the results of our efforts to discover, develop, acquire or in-license products, product candidates, technologies or data referencing rights, and the costs of commercializing any products we are able to successfully develop;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- announcements or expectations of additional financing efforts;
- variations in our financial results or the financial results of companies that are perceived to be similar to us;
- sales of common stock by us, our executive officers, directors or principal stockholders, or others;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions; and
- the other factors described in this “Risk Factors” section.

In the past, following periods of volatility in the market price of a company’s securities, securities class-action litigation has often been instituted against that company. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms. Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our offerings or business practices. Such litigation may also cause us to incur other substantial costs to defend such claims and divert management’s attention and resources.

Our executive officers, directors and principal stockholders, if they choose to act together, have the ability to significantly influence all matters submitted to stockholders for approval.

Our executive officers, directors and our stockholders who beneficially owned more than 5% of our outstanding common stock as of May 8, 2026, in the aggregate, beneficially owned shares representing approximately 49% of our capital stock. As a result, if these stockholders were to choose to act together, they would be able to significantly influence all matters submitted to our stockholders for approval, as well as our management and affairs. For example, these persons, if they choose to act together, would significantly influence the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets.

This concentration of ownership control may:

- delay, defer or prevent a change in control;
- entrench our management and board of directors; or
- delay or prevent a merger, consolidation, takeover or other business combination involving us that other stockholders may desire.

We have broad discretion in the use of our cash, cash equivalents and marketable securities and may not use them effectively.

Our management has broad discretion in the application of our cash, cash equivalents and marketable securities and could use such funds in ways that do not improve our results of operations or enhance the value of our common stock or in ways that our stockholders may not agree with. The failure by our management to apply these funds effectively could result in financial losses that could cause the price of our common stock to decline and delay the development of our product candidates and any other product candidates we may develop.

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

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for our stockholders for the foreseeable future. There is no guarantee that our common stock will appreciate or even maintain the price at which our stockholders purchase it.

A significant portion of our total outstanding shares are eligible to be sold into the market in the near future, which could cause the market price of our common stock to drop significantly, even if our business is doing well.

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. As of May 8, 2026, we had 46,705,410 shares of common stock outstanding, which includes the 19,262,500 shares that we sold in our IPO, which may be resold in the public market immediately without restriction, unless purchased by our affiliates. The remaining shares are currently restricted as a result of securities laws or lock-up agreements but will become eligible to be sold at various times after the expiration of the applicable lock-up period. The representatives of the underwriters may release some or all of the shares of common stock subject to lock-up agreements at any time and without notice, which would allow for earlier sales of shares in the public market.

In addition, certain of our executive officers, directors and stockholders affiliated with our directors may enter into Rule 10b5-1 plans providing for sales of shares of our common stock from time to time. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the executive officer, director or affiliated stockholder when entering into the plan, without further direction from the executive officer, director or affiliated stockholder. A Rule 10b5-1 plan may be amended or terminated in some circumstances. Our executive officers, directors and stockholders affiliated with our directors also may buy or sell shares outside of a Rule 10b5-1 plan when they are not in possession of material, nonpublic information.

Moreover, beginning 180 days after the completion of the IPO, holders of an aggregate of 27,442,910 shares of our common stock will have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We have also filed a registration statement on Form S-8 to register shares of common stock that we may issue under our equity compensation plans. Shares registered under this registration statement on Form S-8 can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates, vesting arrangements, exercise of options and warrants, and the lock-up agreements entered into in connection with the IPO.

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

We are an "emerging growth company," or EGC, as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We may remain an EGC until December 31, 2031, although if the market value of our common stock that is held by non-affiliates exceeds $700.0 million as of any June 30 before that time or if we have annual gross revenues of $1.235 billion or more in any fiscal year, we would cease to be an EGC as of December 31 of the applicable year. We also would cease to be an EGC if we issue more than $1.0 billion of non-convertible debt over a three-year period. For so long as we remain an EGC, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not EGCs. These exemptions include:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict whether investors will find our common stock less attractive if we 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.

In addition, the JOBS Act permits an EGC to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected not to opt out of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (1) irrevocably elect to "opt out" of such extended transition period or (2) no longer qualify as an EGC.

We are also a "smaller reporting company" as defined in the Securities Exchange Act of 1934, or the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

We have incurred and will continue to incur increased costs as a result of operating as a public company, and our management has devoted and will continue to be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an EGC or smaller reporting company, we will incur significant legal, accounting and other expenses that we did not previously incur as a private company. The Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Select Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory "say on pay" voting requirements that will apply to us when we cease to be an emerging growth company. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Our management and other personnel devote and will need to continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs, particularly as we hire additional financial and accounting employees to meet public company internal control and financial reporting requirements, and will make some activities more time-consuming and costly compared to when we were a private company.

We are evaluating these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, we will be required to furnish a report by our management on our internal control over financial reporting beginning with our filing of an Annual Report on Form 10-K with the SEC for the fiscal year ending December 31, 2027. However, while we remain an EGC, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, including through hiring additional financial and accounting personnel, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we are unable to conclude that our internal control over financial reporting is effective, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements. Moreover, any material weakness or other deficiencies in our internal control over financial reporting may impede our ability to file timely and accurate reports with the SEC.

We have identified material weaknesses in our internal control over financial reporting. If we are unable to remedy our material weaknesses, or if we fail to establish and maintain an effective system of internal control over financial reporting, we may be unable to produce timely and accurate financial statements or prevent fraud, which could adversely impact our business and our stock price.

In connection with the audit of our consolidated financial statements for the years ended December 31, 2024 and 2025, we identified material weaknesses in our internal control over financial reporting. As defined in the standards of the Public Company Accounting Oversight Board (United States), a material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

The material weaknesses were (1) controls around the financial statement close process were not designed or operating effectively, including as a result of an inappropriate segregation of conflicting duties and insufficient evidence of performance and review of controls, and (2) information system controls around user access, segregation of conflicting duties and change management were not designed or operating effectively.

To remediate these material weaknesses, we have made and plan to continue to make improvements to the design and operating effectiveness of our internal controls over financial reporting, including the monitoring, oversight and evaluation of our internal controls. We also plan to allocate more internal resources to our internal controls, including by hiring additional staff, and intend to engage external advisors to provide training and to reassess and redesign processes and develop new controls as appropriate, including information technology controls covering access and change management as well as cyber risks, and assisting with the evaluation and documentation of the risk assessment, design and operating effectiveness of our internal controls over financial reporting.

We cannot assure our stockholders that the measures we have taken to date, and actions we plan to take in the future, will be sufficient to remediate the control deficiencies that led to the material weaknesses in our internal control over financial reporting or that they will prevent or avoid potential future material weaknesses. In addition, neither our management nor an independent registered public accounting firm has performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act because no such evaluation has been required. Had we or our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional material weaknesses may have been identified. If we are unable to successfully remediate our existing or any future material weaknesses in our internal control over financial reporting, or identify any additional material weaknesses in the future, or otherwise fail to maintain an effective system of internal controls, the accuracy and timing of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting, and the market price of our common stock may decline as a result.

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

We are subject to certain reporting requirements of the Exchange Act. Our disclosure controls and procedures are designed to reasonably assure that information required to be disclosed by us in reports we file or submit under the Exchange Act is accumulated and communicated to management, recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements or insufficient disclosures due to error or fraud may occur and not be detected.

Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current directors and members of management.

Provisions in our certificate of incorporation and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions:

- establish a classified board of directors such that only one of three classes of directors is elected each year;

- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least 75% of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our certificate of incorporation or bylaws.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, or the DGCL, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner.

Our certificate of incorporation designates the Court of Chancery of the State of Delaware and the federal district courts of the United States of America 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 and employees.

Our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for any action asserting an internal corporate claim as defined in Section 115 of the DGCL.

These choice of forum provisions will not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any claims arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

These exclusive forum provisions may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders 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. If a court were to find either exclusive forum provision contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving such action in other jurisdictions, all of which could materially adversely affect our business, financial condition and results of operations.

If securities analysts do not publish or cease publishing research or reports or publish misleading, inaccurate or unfavorable research about our business or if they publish negative evaluations of our stock, the price and trading volume of our stock could decline.

The trading market for our common stock relies, in part, on the research and reports that industry or financial analysts publish about us or our business. We do not currently have, and may never obtain, research coverage by industry or financial analysts. If no, or few, analysts commence coverage of us, the trading price of our stock would likely decrease. Even if we do obtain if one or more of the analysts covering our business

downgrade their evaluations of our stock or publish inaccurate or unfavorable research about our business, or provides more favorable relative recommendations about our competitors, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price and trading volume to decline.

General Risk Factors

Unfavorable global economic conditions could adversely affect our business, financial condition, stock price, and results of operations.

The global credit and financial markets have in recent years experienced volatility and disruptions (including as a result of actual or perceived changes in interest rates, inflation and macroeconomic uncertainties), which has included severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, high inflation, uncertainty about economic stability, global supply chain disruptions, and increases in unemployment rates. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, terrorism, or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts may also continue to adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. A severe or prolonged economic downturn could result in a variety of risks to our business, including a decrease in the demand for our product candidates and in our ability to raise additional capital when needed on acceptable terms, if at all.

Furthermore, any disruptions to our supply chain as a result of unfavorable global economic conditions, including due to geopolitical conflicts or public health crises, could negatively impact the timely execution of our ongoing and future clinical trials. In addition, current inflationary trends in the global economy may impact salaries and wages, costs of goods and transportation expenses, among other things, and recent and potential future disruptions in access to bank deposits or lending commitments due to bank failures may create market and economic instability. We cannot anticipate all of the ways in which the foregoing, and the current economic climate and financial market conditions generally, could adversely impact our business.

Changes in tax laws or in their interpretation could adversely affect our business and financial condition.

Income, sales, use or other tax laws, statutes, rules or regulations could be enacted or amended at any time, which could affect our business or financial condition, including causing potentially adverse impacts to our effective tax rate, tax liabilities and cash tax obligations. For example, the IRA was signed into law in August 2022, and the OBBBA was signed into law in July 2025. The IRA introduced new tax provisions, including a one percent excise tax imposed on certain stock repurchases by publicly traded companies. The one percent excise tax generally applies to any acquisition of stock by the publicly traded company (or certain of its affiliates) from a stockholder of the company in exchange for money or other property (other than stock of the company itself), subject to a de minimis exception. Thus, the excise tax could apply to certain transactions that are not traditional stock repurchases. The OBBBA contains numerous tax provisions that we are currently in the process of evaluating, and which may significantly affect our business or financial condition. The recent changes under the OBBBA include tax rate extensions and changes to the business interest deduction limitation, the expensing of domestic research and development expenditures (in contrast to the continued capitalization and amortization of foreign research and development expenditures), the bonus depreciation deduction rules and the international tax framework.

Regulatory guidance under the IRA, the OBBBA and additional legislation is and continues to be forthcoming, and such guidance could ultimately increase or lessen the impact of these laws on our business and financial condition. Congress may enact additional legislation, some of which could have an impact on our company. In addition, it is uncertain if and to what extent various states will conform to such legislation.

We may become involved in litigation that could divert management's attention and harm our business, and insurance coverage may not be sufficient to cover all costs and damages.

From time to time, we may be subject to litigation claims through the ordinary course of our business operations regarding, but not limited to, securities litigation, employment matters, security of patient and employee personal data, contractual relations with collaborators and licensors and intellectual property rights. In the past, securities class action litigation has often followed certain significant business transactions, such as the sale of a company or announcement of any other strategic transaction, the announcement of negative events, such as negative results from clinical trials, or periods of volatility in the market price of a company's securities. These events may also result in or be concurrent with investigations by the SEC. We may be exposed to such litigation or investigation even if no wrongdoing occurred. Litigation and investigations are usually expensive and divert management's attention and resources, which could adversely affect our business and cash resources and our ability to consummate a potential strategic transaction or the ultimate value our stockholders receive in any such transaction.

Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities.

While we maintain commercial insurance at a level we believe is appropriate against certain risks commonly insured in the industry in which we operate, there is no guarantee that our insurer will cover costs or that we will be able to obtain the desired level of coverage on acceptable terms in the future. Some of the policies we currently maintain include property, general liability, crime insurance, workers' compensation, and directors' and officers', employment practices and fiduciary liability insurance, clinical trial insurance, transportation insurance and umbrella insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Changes in the market conditions and our business operations may necessitate the addition of new insurance policies or change of our existing insurance policies. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

Operating as a U.S. public company makes it more difficult and more expensive for us to obtain director and officer liability insurance, and in the future we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult for us to attract and retain qualified people to serve on our board of directors, on our board committees or as executive officers. We do not know, however, if we will be able to maintain existing insurance with adequate levels of coverage.

Any significant uninsured liability may require us to pay substantial amounts, which would negatively affect our business, financial condition and results of operations.

Our operations are vulnerable to interruption by disasters, terrorist activity, pandemics and other events beyond our control, which could harm our business.

Our main facilities are located in Cambridge, Massachusetts and Copenhagen, Denmark. We have not undertaken a systematic analysis of the potential consequences to our business and financial results from a major flood, power loss, terrorist activity, pandemics or other regional or global disasters and generally do not have a recovery plan for such events. In addition, we do not carry sufficient insurance to compensate us for actual losses from interruption of our business that may occur, and any losses or damages incurred by us could harm our business. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Item 2. Unregistered Sales of Equity Securities.

(a) Recent Sales of Unregistered Equity Securities

Issuances of Share Capital

On March 30, 2026, in connection with the corporate reorganization, we issued 23,343 shares of Series Seed Preferred Stock, 225,866 shares of Series A Preferred Stock, 442,205 shares of Series B Preferred Stock, 512,991 shares of Series C Preferred Stock and 946,000 shares of common stock, to the then-existing shareholders of Hemab ApS in exchange for the same number and class of shares of Hemab ApS. No cash consideration was paid in connection with the corporate reorganization.

No underwriters were involved in the foregoing issuances of securities. The securities described above were issued to investors in reliance upon the exemption from the registration requirements of the Securities Act, as set forth in Section 4(a)(2) under the Securities Act and, in certain cases, Regulation D thereunder relative to transactions by an issuer not involving any public offering, or pursuant to Regulation S thereunder in that offers, sales and issuances were not made to persons in the United States and no directed selling efforts were made in the United States, to the extent an exemption from such registration was required. All purchasers received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration statement or an available exemption from such registration.

Equity Grants

From January 4, 2026 to February 16, 2026, Hemab ApS granted to certain of its employees, directors, advisors and consultants warrants to subscribe for an aggregate of 2,294,798 ordinary shares at an exercise price of $6.00.

On March 30, 2026, in connection with the corporate reorganization, each outstanding warrant to subscribe for the purchase of ordinary shares of Hemab ApS was assumed by Hemab Therapeutics Holdings, Inc. and converted into a warrant to purchase the same number of shares of common stock of Hemab Therapeutics Holdings, Inc. As a result, following the corporate reorganization, warrants for the subscription of an aggregate of 4,372,742 shares of our common stock were outstanding. Any warrant exercise price that had been denominated in DKK prior to the corporate reorganization was converted into an exercise price in U.S. dollars at the exchange rate as in effect at the close of business on the business day prior to the corporate reorganization. These warrants become exercisable upon the schedule specified in the applicable warrant agreement.

On April 23, 2026, we granted stock options to purchase an aggregate of 306,900 shares of common stock, at an exercise price per share equal to the initial public offering price, effective upon the pricing of the IPO. These stock options become exercisable upon the schedule specified in the applicable option agreement.

The securities described above were issued pursuant to written compensatory plans or arrangements with our employees, directors, advisors, and consultants, in reliance on the exemption provided by Rule 701 promulgated under the Securities Act, or pursuant to Section 4(a)(2) under the Securities Act, relative to transactions by an issuer not involving any public offering, or pursuant to Regulation S thereunder in that offers, sales and issuances were not made to persons in the United States and no directed selling efforts were made in the United States, relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. All recipients either received adequate information about our company or had access, through employment or other relationships, to such information.

On May 1, 2026, we filed a registration statement on Form S-8 under the Securities Act to register all of the shares of our common stock subject to outstanding options and warrants and all shares of our common stock otherwise issuable pursuant to our equity compensation plans.

Issuances of Common Stock upon Conversion of Preferred Stock

On May 4, 2026, in connection with the closing of our IPO, all of our outstanding shares of preferred stock were converted into an aggregate of 26,496,910 shares of common stock. The conversion of preferred stock into common stock occurred in accordance with the terms of our certificate of incorporation and did not constitute a sale for purposes of the Securities Act.

(b) Use of Proceeds from IPO

On May 4, 2026, we closed our IPO, pursuant to which we issued and sold 19,262,500 shares of our common stock, including 2,512,500 shares sold by us pursuant to the full exercise of the underwriters' option to purchase additional shares, at a public offering price of $18.00 per share for aggregate gross proceeds of approximately $346.7 million.

All of the shares of common stock issued and sold in the IPO were registered under the Securities Act pursuant to a Registration Statement on Form S-1 (File No. 333-294989), which was declared effective by the SEC on April 30, 2026. Goldman Sachs & Co. LLC, Jefferies LLC, and Evercore Group L.L.C. acted as joint book-running managers for the IPO, and Wedbush Securities Inc. acted as lead manager for the IPO. The offering commenced on April 30, 2026 and did not terminate until the sale of all of the shares offered.

We received aggregate net proceeds from the IPO of approximately $317.2 million, after deducting underwriting discounts and commissions and other offering expenses payable by us. None of the underwriting discounts and commissions or offering expenses were paid directly or indirectly to any of our directors or officers or their associates or to persons owning ten percent or more of any class of our equity securities or to any of our affiliates.

As of March 31, 2026, we had not used any of the net proceeds from the IPO because the IPO closed on May 4, 2026. There has been no material change in our planned use of proceeds from the IPO as described in the final prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on May 1, 2026.

Item 3. Defaults Upon Senior Securities.

Not Applicable.

Item 4. Mine Safety Disclosures.

Not Applicable.

Item 5. Other Information.

Director and Officer Trading Arrangements

None of our directors or officers (as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, as amended) adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement (as defined in Item 408(c) of Regulation S-K) during the quarterly period covered by this report.

Item 6. Exhibits.

Exhibit Number	Description
2.1	Share Contribution and Exchange Agreement, dated March 30, 2026, by and between the registrant and the parties thereto (incorporated by reference to Exhibit 2.1 to the registrant's Registration Statement on Form S-1 (File No. 333-294989) filed with the Securities and Exchange Commission on April 10, 2026)
3.1	Restated Certificate of Incorporation of Hemab Therapeutics Holdings, Inc. (incorporated by reference to Exhibit 3.1 to the registrant's Current Report on Form 8-K (File No. 001-43250) filed with the Securities and Exchange Commission on May 4, 2026)
3.2	Amended and Restated Bylaws of Hemab Therapeutics Holdings, Inc. (incorporated by reference to Exhibit 3.2 to the registrant's Current Report on Form 8-K (File No. 001-43250) filed with the Securities and Exchange Commission on May 4, 2026)
4.1	Investors' Rights Agreement, dated March 30, 2026, by and between the registrant and the parties thereto (incorporated by reference to Exhibit 4.3 to the registrant's Registration Statement on Form S-1 (File No. 333-294989) filed with the Securities and Exchange Commission on April 10, 2026)
4.2	Specimen Stock Certificate evidencing the shares of common stock (incorporated by reference to Exhibit 4.1 to Amendment No. 1 to the registrant's Registration Statement on Form S-1 (File No. 333-294989) filed with the Securities and Exchange Commission on April 27, 2026)
4.3	Form of Warrant Agreement (incorporated by reference to Exhibit 4.2 to the registrant's Registration Statement on Form S-1 (File No. 333-294989) filed with the Securities and Exchange Commission on April 10, 2026)
10.1	2026 Equity Incentive Plan (incorporated by reference to Exhibit 10.1 to Amendment No. 1 to the registrant's Registration Statement on Form S-1 (File No. 333-294989) filed with the Securities and Exchange Commission on April 27, 2026)
10.2	Form of Agreements under 2026 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to Amendment No. 1 to the registrant's Registration Statement on Form S-1 (File No. 333-294989) filed with the Securities and Exchange Commission on April 27, 2026)
10.3	2026 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.3 to Amendment No. 1 to the registrant's Registration Statement on Form S-1 (File No. 333-294989) filed with the Securities and Exchange Commission on April 27, 2026)
10.4	Executive Employment Agreement by and between Hemab Therapeutics Inc. and Benny Sørensen, as amended (incorporated by reference to Exhibit 10.6 to Amendment No. 1 to the registrant's Registration Statement on Form S-1 (File No. 333-294989) filed with the Securities and Exchange Commission on April 27, 2026)
10.5	Service Agreement by and between Hemab ApS and Mads Behrndt, as amended (incorporated by reference to Exhibit 10.7 to Amendment No. 1 to the registrant's Registration Statement on Form S-1 (File No. 333-294989) filed with the Securities and Exchange Commission on April 27, 2026)
10.6	Employment Offer Letter by and between Hemab Therapeutics Inc. and Catherine Madigan, as amended (incorporated by reference to Exhibit 10.8 to Amendment No. 1 to the registrant's Registration Statement on Form S-1 (File No. 333-294989) filed with the Securities and Exchange Commission on April 27, 2026)
10.7	Form of Indemnification Agreement between the Registrant and each of its Executive Officers and Directors (incorporated by reference to Exhibit 10.9 to Amendment No. 1 to the registrant's Registration Statement on Form S-1 (File No. 333-294989) filed with the Securities and Exchange Commission on April 27, 2026)

10.8	Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.10 to Amendment No. 1 to the registrant's Registration Statement on Form S-1 (File No. 333-294989) filed with the Securities and Exchange Commission on April 27, 2026)
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1†	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2†	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	The cover page from the Company's Quarterly Report on Form 10-Q for the three months ended March 31, 2026, has been formatted in Inline XBRL.

* Filed herewith.

† The certifications attached as Exhibits 32.1 and 32.2 that accompany this Quarterly Report, are deemed furnished and not filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of Hemab Therapeutics Holdings, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Quarterly Report, irrespective of any general incorporation language contained in 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.

HEMAB THERAPEUTICS HOLDINGS, INC.

Date: May 21, 2026

By: /s/ Benny Sørensen, M.D., Ph.D.
Benny Sørensen, M.D., Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: May 21, 2026

By: /s/ Mads Behrndt, M.Sc.
Mads Behrndt, M.Sc.
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

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, Benny Sørensen, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Hemab Therapeutics Holdings, Inc.;

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) 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

(c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 21, 2026

By: /s/ Benny Sørensen

Benny Sørensen
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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, Mads Behrndt, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Hemab Therapeutics Holdings, Inc.;

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

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

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

(b) 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

(c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

(a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

(b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 21, 2026

By: /s/ Mads Behrndt

Mads Behrndt
Chief Financial Officer and General Manager
(Principal Financial Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of Hemab Therapeutics Holdings, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2026, 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; 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 21, 2026

By: /s/ Benny Sørensen

Benny Sørensen
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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 Hemab Therapeutics Holdings, Inc. (the "Company") on Form 10-Q for the period ending March 31, 2026, 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; 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 21, 2026

By: /s/ Mads Behrndt

Mads Behrndt
Chief Financial Officer and General Manager
(Principal Financial Officer)