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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2023

OR

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

For the transition period from to

Commission File Number: 001-37467

Astria Therapeutics, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware (State or Other Jurisdiction of Incorporation or Organization)	**26-3687168** (IRS Employer Identification No.)
75 State Street **Suite 1400** **Boston, Massachusetts** (Address of Principal Executive Offices)	**02109** (Zip Code)

(617) 349-1971
(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, $0.001 par value per share	**ATXS**	**The Nasdaq Stock Market LLC**

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, a 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 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 October 31, 2023, there were 36,296,191 shares of the registrant's common stock, par value $0.001 per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This Quarterly Report on Form 10-Q contains forward-looking statements, which reflect our current views with respect to, among other things, our operations and financial performance, strategy, future financial condition and clinical and preclinical development programs. Such forward-looking statements are subject to various risks and uncertainties. Accordingly, there are or will be important factors that could cause actual outcomes or results to differ materially from those indicated in these statements. All statements, other than statements of historical facts, contained in this Quarterly Report on Form 10-Q, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, clinical and preclinical development programs, regulatory filings and expected market growth are forward-looking statements. The words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “would” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

These forward-looking statements include, among other things, statements about:

- our expectations regarding the timing of availability of final results from our Phase 1a clinical trial of STAR-0215;
- our expectations regarding the potential significance of the preliminary results from the Phase 1a STAR-0215 clinical trial and the anticipated nature and timing of receipt of additional data from such trial;
- our expectations regarding the timing, nature, goals and results of our Phase 1b/2 clinical trial of STAR-0215 and that favorable results from such trial could allow us to move directly into a Phase 3 pivotal trial of STAR-0215 as a potential treatment for hereditary angioedema, or HAE;
- our expectations about the design and anticipated timing of a Phase 3 pivotal clinical trial for STAR-0215 as a potential treatment for HAE, assuming positive data from the Phase 1b/2 trial;
- our expectations about the unmet medical need for HAE, the potential differentiating attributes of STAR-0215 as a potential treatment for HAE, along with the potential market impact of such differentiation, the potential of STAR-0215 to be a best-in-class monoclonal antibody inhibitor of plasma kallikrein able to provide long-acting, effective attack prevention for HAE, and our vision for STAR-0215 to become the first-choice preventative treatment for HAE with administration every three or six months with the goal of normalizing the lives of people living with HAE;
- the nature and anticipated growth of the global HAE market and HAE therapies;
- our plans to optimize the formulation of STAR-0215 and corresponding work to develop a drug-device combination for STAR-0215 for potential use in late-stage clinical trials and commercially, if approved;
- our expectations that we have scaled the manufacturing process for STAR-0215 in a manner to generate sufficient material for our planned STAR-0215 nonclinical and clinical studies;
- the potential therapeutic benefits and potential attributes of STAR-0310, a preclinical stage product candidate which we recently in-licensed, and our plans to develop STAR-0310 as a treatment for atopic dermatitis, or AD;
- our expectations regarding the timing of regulatory submissions for STAR-0310;
- our expectations about the design and anticipated timing of planned clinical trials of STAR-0310;
- our expectations regarding the timing and nature of anticipated data for planned clinical trials of STAR-0310;
- the potential commercial opportunity for STAR-0310 in AD and the likelihood that it can effectively compete in AD, assuming it is approved;
- the estimated size and anticipated growth of the AD market and the need for treatments for AD;

- the potential to pursue the development of STAR-0310 in additional indications;
- our goals and visions for the STAR-0310 program;
- our expectations regarding our ability to expand our pipeline;
- the potential benefits of any future acquisition, in-license, collaboration or preclinical development activities;
- our manufacturing plans, capabilities and strategy;
- our intellectual property position and strategy;
- our estimates regarding our cash runway, expenses, future revenue, capital requirements and needs for additional financing, including additional financing to fund our long-term operations;
- developments relating to our competitors and our industry; and
- the impact of government laws and regulations.

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 the cautionary statements included in this Quarterly Report on Form 10-Q, particularly in the sections entitled “Summary of the Material Risks Associated with Our Business” and “Risk Factors”, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or enter into.

Summary of the Material Risks Associated with Our Business

Investing in our common stock involves a high degree of risk because our business is subject to numerous risks and uncertainties. The principal factors and uncertainties that make investing in our common stock risky include, among others:

- We are entirely dependent on the success of our product candidates, STAR-0215 for the treatment of hereditary angioedema, or HAE, and STAR-0310 for the treatment of atopic dermatitis, or AD. We cannot give any assurance that we will generate preclinical, clinical or other data for STAR-0215 or STAR-0310 sufficiently supportive to receive regulatory approval, which will be required before either can be commercialized.

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

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

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

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

- We have never obtained marketing approval for a product candidate, and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any future product candidate we may seek to develop.

- Clinical trials are costly, time consuming, difficult to enroll and inherently risky, and we may fail to demonstrate safety and efficacy on the timelines that we expect or to the satisfaction of applicable regulatory authorities. We also expect that any later stage clinical trials we conduct for STAR-0310 will be larger and more expensive when compared to those we are conducting for STAR-0215 because AD, the indication for which we are developing STAR-0310, is not a rare disease.

- STAR-0215, STAR-0310 or any future product candidates may cause adverse events or undesirable side effects or have other unexpected properties that could delay or halt clinical trials, delay or prevent their regulatory approval, limit the commercial viability of an approved label, or result in significant negative consequences following marketing approval, if any.

- We face substantial competition from other pharmaceutical and biotechnology companies, and our operating results may suffer if we fail to compete effectively.

- Product development involves a lengthy and expensive process with an uncertain outcome, and results of earlier preclinical studies and clinical trials may not be predictive of future clinical trial results.

- We rely on in-licensed patent and other intellectual property rights for our STAR-0310 program and we may need to obtain licenses from third parties to other intellectual property rights for the development and commercialization of our STAR-0310 and STAR-0215 programs; if we fail to comply with our existing or future obligations under these licenses, or if these licenses are terminated, we could lose license rights that are important to our business.

- We rely on third parties to conduct our preclinical studies and clinical trials. If they do not perform satisfactorily, our business could be significantly harmed.

- We will need to maintain a cell line for STAR-0215, a master cell bank for STAR-0310 and cell lines or banks for any other future biologic candidate that generates sufficient material for preclinical, nonclinical and clinical studies, and also build and maintain sufficient preclinical, clinical and commercial manufacturing drug substance and drug product capacity, in each case, through third party manufacturers, for STAR-0215, STAR-0310 and any other future product candidate that advances into such stages, on the timetables and in a manner that, in each case, are consistent with our expected

development timetables and financial projections, the failure of which could materially harm our business and operating results and require us to raise capital sooner than we expect.

- Our forecasts of cash usage and how long we expect our existing cash, cash equivalents and short-term investments to fund operating expenses and capital expenditure requirements may not be accurate and we may therefore use our cash and cash equivalents more rapidly than we expect, which could force us to delay, reduce or eliminate our product development programs or commercialization efforts, if any, and therefore materially harm our operating results, and we could be required to raise capital sooner than we expect.

- We have incurred significant losses since inception, have a limited operating history on which to assess our business, and anticipate that we will continue to incur significant losses for the foreseeable future.

- If we are unable to obtain and maintain sufficient patent and/or regulatory protection for product candidates, or if the scope of the patent and/or regulatory protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to commercialize such product candidates successfully may be adversely affected.

- The price of our common stock has been and is likely to continue to be highly volatile, which could result in substantial losses for our stockholders.

The summary risk factors described above should be read together with the text of the full risk factors below, in the section entitled "*Risk Factors*" in Part II, Item 1A of this Quarterly Report on Form 10-Q and the other information set forth in this Quarterly Report on Form 10-Q, including under the heading "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" and our unaudited condensed consolidated financial statements and the related notes and other financial information, as well as in other documents that we file with the Securities and Exchange Commission. The risks summarized above or described in full below are not the only risks that we face. Additional risks and uncertainties not precisely known to us, or that we currently deem to be immaterial may also materially adversely affect our business, financial condition, results of operations and future growth prospects.

PART I- FINANCIAL INFORMATION

Item 1. Financial Statements

Astria Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share data)

(Unaudited)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 119,806	$ 20,525
Short-term investments	69,000	205,912
Prepaid expenses and other current assets	2,660	1,253
Total current assets	191,466	227,690
Right-of-use asset	514	948
Other assets	1,881	1,995
Total assets	$ 193,861	$ 230,633
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 1,138	$ 788
Accrued expenses	7,756	7,690
Current portion of operating lease liabilities	488	582
Total current liabilities	9,382	9,060
Long term portion of operating lease liabilities	—	357
Total liabilities	9,382	9,417
Commitments (Note 6)		
Stockholders' equity:		
Preferred stock, $0.001 par value per share, 4,908,620 shares authorized and no shares issued and outstanding	—	—
Series X redeemable convertible preferred stock, $0.001 par value per share, 91,380 shares authorized; 31,107 and 31,455 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	95,324	96,398
Common stock, $0.001 par value per share, 150,000,000 shares authorized; 28,042,296 and 27,501,340 shares issued and outstanding at September 30, 2023 and December 31, 2022, respectively	28	28
Additional paid-in capital	638,251	632,512
Accumulated other comprehensive loss	—	(79)
Accumulated deficit	(549,124)	(507,643)
Total stockholders' equity	184,479	221,216
Total liabilities and stockholders' equity	$ 193,861	$ 230,633

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

Astria Therapeutics, Inc.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share data)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 13,338	$ 7,698	$ 30,460	$ 24,673
General and administrative	6,898	4,688	18,371	14,540
Total operating expenses	20,236	12,386	48,831	39,213
Loss from operations	(20,236)	(12,386)	(48,831)	(39,213)
Other income (expense):				
Interest and investment income	2,527	437	7,404	706
Other expense, net	(18)	(48)	(54)	(64)
Total other income, net	2,509	389	7,350	642
Net loss	(17,727)	(11,997)	(41,481)	(38,571)
Net loss per share attributable to common shareholders - basic and diluted	$ (0.63)	$ (0.87)	$ (1.48)	$ (2.91)
Weighted-average common shares outstanding used in net loss per share - basic and diluted	28,040,173	13,742,385	28,002,663	13,261,422

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

Astria Therapeutics, Inc.
Condensed Consolidated Statements of Comprehensive Loss
(In thousands)

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net loss	$ (17,727)	$ (11,997)	$ (41,481)	$ (38,571)
Other comprehensive gain (loss):				
Unrealized gain (loss) on short-term investments, net of tax of $0	—	(29)	79	(215)
Total other comprehensive gain (loss):	—	(29)	79	(215)
Comprehensive loss	$ (17,727)	$ (12,026)	$ (41,402)	$ (38,786)

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

Astria Therapeutics, Inc.
Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity
(In thousands, except shares)

(Unaudited)

	Series X redeemable convertible preferred stock, shares	Series X redeemable convertible preferred stock, value	Common stock, shares	Common stock, par value	Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total stockholders equity
Balance at December 31, 2022	31,455	$ 96,398	27,501,340	$ 28	$632,512	$(507,643)	$ (79)	$ 221,216
Issuance of common stock upon the conversion of preferred stock	(348)	(1,074)	57,910	—	1,074	—	—	—
Issuance of common stock upon exercise of options and warrants	—	—	427,468	—	37	—	—	37
Stock-based compensation expense	—	—	—	—	1,220	—	—	1,220
Unrealized gain on short-term investments	—	—	—	—	—	—	75	75
Net loss	—	—	—	—	—	(11,188)	—	(11,188)
Balance at March 31, 2023	31,107	95,324	27,986,718	28	634,843	(518,831)	(4)	211,360
Issuance of common stock upon exercise of options	—	—	39,126	—	273	—	—	273
Stock-based compensation expense	—	—	—	—	1,331	—	—	1,331
Unrealized gain on short-term investments	—	—	—	—	—	—	4	4
Net loss	—	—	—	—	—	(12,566)	—	(12,566)
Balance at June 30, 2023	31,107	95,324	28,025,844	28	636,447	(531,397)	—	200,402
Issuance of common stock upon exericse of options	—	—	16,452	—	110	—	—	110
Stock-based compensation expense	—	—	—	—	1,694	—	—	1,694
Unealized gain on short-term investments	—	—	—	—	—	—	—	—
Net loss	—	—	—	—	—	(17,727)	—	(17,727)
Balance September 30, 2023	31,107	95,324	28,042,296	28	638,251	(549,124)	—	184,479

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

Astria Therapeutics, Inc.
Condensed Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Equity
(In thousands, except shares)

(Unaudited)

	Series X redeemable convertible preferred stock, shares	Series X redeemable convertible preferred stock, value	Common stock, shares	Common stock, par value	Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total stockholders' equity
Balance at December 31, 2021	31,455	$ 96,398	13,016,955	$ 13	$ 481,709	$ (455,809)	$ —	$ 122,311
Expense related to warrants inherited in acquisition of Quellis	—	—	—	—	1,542	—	—	1,542
Stock-based compensation expense	—	—	—	—	1,209	—	—	1,209
Unrealized loss on short-term investments	—	—	—	—	—	—	(53)	(53)
Net loss	—	—	—	—	—	(15,324)	—	(15,324)
Balance at March 31, 2022	31,455	96,398	13,016,955	13	484,460	(471,133)	(53)	109,685
Stock-based compensation expense	—	—	—	—	1,117	—	—	1,117
Unrealized loss on short-term investments	—	—	—	—	—	—	(133)	(133)
Net loss	—	—	—	—	—	(11,250)	—	(11,250)
Balance at June 30, 2022	31,455	96,398	13,016,955	13	485,577	(482,383)	(186)	99,419
Issuance of common stock for at-the-market offerings, net of issuance costs	—	—	2,715,166	3	24,287	—	—	24,290
Issuance of common stock upon exericse of options	—	—	16,202	—	34	—	—	34
Stock-based compensation expense	—	—	—	—	1,155	—	—	1,155
Unealized gain on short-term investments	—	—	—	—	—	—	(29)	(29)
Net loss	—	—	—	—	—	(11,997)	—	(11,997)
Balance September 30, 2022	31,455	96,398	15,748,323	16	511,053	(494,380)	(215)	112,872

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

Astria Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows
(In thousands)

(Unaudited)

	Nine Months Ended September 30,	
	2023	2022
Operating activities		
Net loss	$ (41,481)	$ (38,571)
Reconciliation of net loss to net cash used in operating activities:		
Stock-based compensation expense	4,245	3,481
Net gain on warrants inherited in acquisition of Quellis	—	1,542
Right-of-use asset - operating lease	434	—
Other non-cash items	(52)	127
Changes in assets and liabilities:		
Prepaid expenses and other assets	(1,318)	(468)
Lease liability - operating lease	(451)	24
Accounts payable	350	(766)
Accrued expenses	66	1,762
Net cash used in operating activities	(38,207)	(32,869)
Investing activities		
Purchases of short-term investments	(1,216,423)	(217,564)
Sales and maturities of short-term investments	1,353,500	185,675
Purchases of property and equipment	(9)	(60)
Net cash provided by (used in) investing activities	137,068	(31,949)
Financing activities		
Proceeds from at-the-market offering, net of issuance costs	—	24,290
Proceeds from exercise of stock options	420	34
Net cash provided by financing activities	420	24,324
Net increase (decrease) in cash, cash equivalents and restricted cash	99,281	(40,494)
Cash, cash equivalents and restricted cash, beginning of period	20,688	86,629
Cash, cash equivalents and restricted cash, end of period	$ 119,969	$ 46,135
Supplemental disclosure of non-cash transactions:		
Conversion of Series X Preferred Stock into common stock	$ 1,074	$ —
Purchases of property and equipment in accounts payable and accrued liabilities	$ —	$ 31

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

Astria Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Organization and Operations

The Company

Astria Therapeutics, Inc. (the "Company"), is a biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics for allergic and immunological diseases. The Company's lead product candidate is STAR-0215, a potential best-in-class monoclonal antibody inhibitor of plasma kallikrein in clinical development for the treatment of hereditary angioedema ("HAE"), a rare, debilitating and potentially life-threatening disease. The Company's second product candidate is STAR-0310, a monoclonal antibody OX40 antagonist that is in preclinical development for the treatment of atopic dermatitis ("AD"), an immune disorder associated with loss of skin barrier function and itching. The Company was incorporated in the State of Delaware on June 26, 2008.

Liquidity

On June 30, 2021, the Company entered into an Open Market Sale Agreement℠ with Jefferies LLC ("Jefferies"), pursuant to which the Company can issue and sell shares of common stock of up to $25.0 million under an at-the-market offering program (the "Jefferies ATM Program"). The Company pays Jefferies sales agent commissions of 3% of the gross proceeds from any common stock sold through the Jefferies ATM Program. In September 2022, the Jefferies ATM Program was modified to increase the amount of the Company's common stock that may be offered thereunder to an aggregate offering price of up to $50.0 million, with $30.5 million of such amount then being available for future issuance. In November 2022, the Jefferies ATM Program was once again modified to increase the amount of the Company's common stock that may be offered thereunder to an aggregate offering price of up to $88.1 million, with $50.0 million of such amount then being available for future issuance. As of September 30, 2023, $50.0 million of common stock remains available for sale under the Jefferies ATM Program. There was no activity from the Jefferies ATM Program during the three and nine months ended September 30, 2023. In the three and nine months ended September 30, 2022, the Company sold an aggregate of 2,715,166 shares of common stock under the Jefferies ATM Program for gross proceeds of $25.0 million and net proceeds of $24.3 million.

As of September 30, 2023, the Company had an accumulated deficit of $549.1 million and had available cash, cash equivalents and short-term investments of $188.8 million which the Company estimates are sufficient to sustain operations for at least twelve months from the issuance of these unaudited condensed consolidated financial statements. Subsequent to September 30, 2023, the Company closed an underwritten public offering of (i) 8,253,895 shares of the Company's common stock and accompanying common stock warrants to purchase an aggregate of 6,190,418 shares of common stock and (ii), in lieu of common stock to certain investors, pre-funded warrants to purchase up to an aggregate of 1,571,093 shares of common stock and accompanying common stock warrants to purchase up to an aggregate of 1,178,320 shares of common stock for aggregate gross proceeds of approximately $64.0 million, before deducting underwriting discounts and commissions and other offering expenses (the "October 2023 Financing"). Each pre-funded warrant has an exercise price of $0.001 per share. Each common stock warrant has an exercise price of $8.025 per share. The Company has been primarily involved with research and development activities and has incurred operating losses and negative cash flows from operations since its inception. The Company has not generated any product revenues and has financed its operations primarily through public offerings and private placements of its equity securities. There can be no assurance that the Company will be able to obtain additional debt, equity or other financing or generate product revenues or revenues from collaborative partners, on terms acceptable to the Company, on a timely basis or at all. The failure of the Company to obtain sufficient funds on acceptable terms when needed could have a material adverse effect on the Company's business, results of operations, and financial condition.

The Company is subject to a number of risks similar to other life science companies, including, but not limited to, successful discovery and development of its drug candidates, raising additional capital, development by its competitors of new technological innovations, protection of proprietary technology and regulatory approval and market acceptance of the Company's products. The Company anticipates that it will continue to incur significant operating losses for the next several years as it continues to develop its product candidates.

2. Summary of Significant Accounting Policies

Basis of Presentation and Principles of Consolidation

The accompanying financial statements and the related disclosures are unaudited and have been prepared in accordance with United States generally accepted accounting principles ("U.S. GAAP"). Additionally, certain information and footnote disclosures normally included in the Company's annual financial statements have been condensed or omitted from this report. Accordingly, these unaudited condensed consolidated financial statements should be read in conjunction with the financial statements as of and for the year ended December 31, 2022 and notes thereto included in the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2022 (the "2022 Annual Report on Form 10-K").

The unaudited condensed consolidated financial statements have been prepared on the same basis as the audited financial statements. In the opinion of the Company's management, the accompanying unaudited condensed consolidated financial statements contain all adjustments, including those adjustments that are of a normal and recurring nature, which are necessary to fairly present the Company's results for the interim periods presented. The results for the three and nine months ended September 30, 2023 are not necessarily indicative of the results for the year ending December 31, 2023 or for any future period.

The accompanying unaudited condensed consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries, Astria Securities Corporation and Quellis Biosciences, LLC, successor in interest to Quellis. All intercompany balances and transactions have been eliminated in consolidation.

Use of Estimates

The preparation of the Company's unaudited condensed consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the amounts reported in the unaudited condensed consolidated financial statements and accompanying notes. Actual results could differ from such estimates.

The Company utilizes certain estimates to record expenses relating to research and development contracts. These contract estimates, which are primarily related to the length of service of each contract and the amount of service provided as of each measurement date, are determined by the Company based on input from internal project management, as well as from the Company's service providers.

Net Loss Per Share

Basic net loss per share is calculated by dividing net loss attributable to common stockholders by the weighted average shares outstanding during the period, without consideration for common stock equivalents. Diluted net loss per share is calculated by adjusting weighted average shares outstanding for the dilutive effect of common stock equivalents outstanding for the period, determined using the treasury-stock method. For purposes of the Company's dilutive net loss per share calculation, preferred stock, stock options and warrants to purchase common stock were considered to be common stock equivalents but were excluded from the calculation of diluted net loss per share as their effect would be anti-dilutive; therefore, basic and diluted net loss per share were the same for all periods presented.

The following common stock equivalents, including Series X Preferred Stock shown as common stock equivalents, were excluded from the calculation of diluted net loss per share for the periods indicated because including them would have had an anti-dilutive effect:

	Three and Nine Months Ended September 30,	
	2023	2022
Series X Preferred Stock	5,184,591	5,242,501
Stock options	3,321,448	2,237,948
Common stock warrants	331,858	1,530,176
	8,837,897	9,010,625

Cash, Cash Equivalents and Restricted Cash

Cash equivalents are short-term, highly liquid investments that are readily convertible into cash, with original maturities of three months or less and reverse repurchase agreements with a maturity period of one business day at the time of purchase. Cash equivalents are mainly comprised of money market accounts invested in U.S. Treasury securities, corporate debt securities, commercial paper and reverse repurchase agreements with a maturity period of one business day at the time of purchase.

Restricted cash is comprised of deposits with a financial institution used to collateralize letters of credit related to the Company's lease arrangements. Restricted cash is presented as a component of prepaid expenses and other current assets at September 30, 2023 and other long-term assets at September 30, 2022.

The reconciliation of cash, cash equivalents and restricted cash reported within the applicable condensed consolidated balance sheet that sum to the total of the same such amount shown in the condensed consolidated statement of cash flows is as follows (in thousands):

	September 30,	
	2023	2022
Cash and cash equivalents	$ 119,806	$ 45,972
Restricted cash	163	163
Total	$ 119,969	$ 46,135

Preferred Stock Discount

In February 2021, the Company issued Series X Preferred Stock in a private placement transaction. It was determined that this transaction resulted in recognition of a beneficial conversion feature, which was valued based on the difference between the price of the shares of common stock on the date of commitment and the conversion price on the closing date, resulting in a total value of $19.6 million. Additionally, the Company incurred total issuance costs of $5.7 million related to the private placement. Both of these features were recorded as a discount on Series X Preferred Stock recognized at the close of the transaction. These features are analogous to preferred dividends and are recorded as a non-cash return to holders of Series X Preferred Stock through additional paid in capital. The discount related to the beneficial conversion feature was recognized through the earliest possible date of conversion, which occurred in June 2021. The issuance costs are recognized as a dividend at the time of conversion to shares of common stock. As of September 30, 2023, $24.4 million of the above amounts were accounted for as a non-cash dividend related to shares of Series X Preferred Stock, and $0.9 million remained to be recognized upon future conversion.

Recent Accounting Pronouncements - Adopted

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies and adopted by the Company as of the specified effective date.

In June 2016, the FASB issued Accounting Standards Update 2016-13, *Financial Instruments-Credit Losses* (Topic 326). This standard requires a financial asset to be presented at amortized cost basis at the net amount expected to be collected. It also requires that credit losses relating to available-for-sale debt securities should be recorded through an allowance for credit losses. In November 2019, the FASB issued an amendment making this standard effective for annual reporting periods beginning after December 15, 2022 for smaller reporting companies. Early adoption was permitted. The Company adopted this standard on January 1, 2023 with no material impact on the condensed consolidated financial statements.

Recent Accounting Pronouncements – Not Yet Adopted

In August 2020, the FASB issued Accounting Standards Update 2020-06, *Debt—Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging Contracts in Entity's Own Equity (Subtopic 815-40)* ("ASU 2020-06"), which reduces the number of accounting models for convertible debt instruments and convertible preferred stock as well as amends the derivatives scope exception for contracts in an entity's own equity. ASU 2020-06 is effective for the Company on January 1, 2024, with early adoption permitted. The Company believes that ASU 2020-06 will not have a material impact on the Company's financial position or results of operations upon adoption.

Summary of Significant Accounting Policies

The Company's significant accounting policies are described in Note 2, "*Summary of Significant Accounting Policies*" in the 2022 Annual Report on Form 10-K, and there were no significant changes to such policies in the three and nine months ended September 30, 2023 that had a material impact on the Company's results of operations or financial position.

3. Financial Instruments

The tables below present information about the Company's assets and liabilities that are measured at fair value on a recurring basis as of September 30, 2023 and December 31, 2022, and indicate the fair value hierarchy of the valuation techniques the Company utilized to determine such fair value. In general, fair values determined by Level 1 inputs utilize observable inputs such as quoted prices in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are either directly or indirectly observable, such as quoted prices, interest rates and yield curves. Fair values determined by Level 3 inputs utilize unobservable data points for which there is little or no market data, which require the Company to develop its own assumptions for the asset or liability. There were no transfers between fair value measurement levels during the three and nine months ended September 30, 2023 and 2022.

The Company's investment portfolio may include fixed income securities that do not always trade on a daily basis. As a result, the pricing services used by the Company apply other available information as applicable through processes such as benchmark yields, benchmarking of like securities, sector groupings and matrix pricing to prepare valuations. The Company validates the prices provided by its third party pricing services by obtaining market values from other pricing sources and analyzing pricing data in certain instances. The Company also invests in certain reverse repurchase agreements which are collateralized by deposits in the form of U.S. Government Securities and Obligations for an amount no less than 102% of their value. The Company does not record an asset or liability for the collateral as the Company is not permitted to sell or re-pledge the collateral. The collateral has at least the prevailing credit rating of U.S. Government Treasuries and Agencies. The Company utilized a third-party custodian to manage the exchange of funds and ensure that collateral received is maintained at 102% of the value of the reverse repurchase agreements on a daily basis.

The Company accounted for warrants to purchase its stock pursuant to Accounting Standards Codification ("ASC") Topic 470, *Debt*, and ASC Topic 480, *Distinguishing Liabilities from Equity*, and classifies warrants for common stock and preferred stock as liabilities or equity. The warrants classified as liabilities are reported at their estimated fair value and any changes in fair value are reflected in research and development expense. The warrants classified as equity are reported at their estimated fair value with no subsequent remeasurement.

Below is a summary of assets and liabilities measured at fair value on a recurring basis (in thousands):

	As of September 30, 2023			
	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Cash and cash equivalents:				
Money market funds	$ 3,876	$ —	$ —	$ 3,876
Short-term investments:				
Reverse repurchase agreements	—	69,000	—	69,000
Total	$ 3,876	$ 69,000	$ —	$ 72,876

	As of December 31, 2022			
	Quoted Prices in Active Markets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Total
Assets:				
Cash and cash equivalents:				
Money market funds	$ 1,944	$ —	$ —	$ 1,944
Short-term investments:				
Corporate debt securities	—	16,445	—	16,445
Yankee securities	—	1,999	—	1,999
Bonds	—	2,988	—	2,988
Treasury bills	5,980	—	—	5,980
Reverse repurchase agreements	—	178,500	—	178,500
Total	$ 7,924	$ 199,932	$ —	$ 207,856

The carrying amounts reflected in the unaudited condensed consolidated balance sheets for cash, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values due to the short-term nature of these assets and liabilities. Items measured at fair value on a recurring basis include cash equivalents and short-term investments as of September 30, 2023 and December 31, 2022.

4. Short-Term Investments

The following table summarizes the short-term investments held at September 30, 2023 and December 31, 2022 (in thousands):

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
September 30, 2023				
Reverse repurchase agreements	$ 69,000	$ —	$ —	$ 69,000
Total	$ 69,000	$ —	$ —	$ 69,000

	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
December 31, 2022				
Corporate debt securities	$ 16,508	$ —	$ (63)	$ 16,445
Treasury bills	5,983	—	(3)	5,980
Yankee securities	2,000	—	(1)	1,999
U.S. agency bonds	3,000	—	(12)	2,988
Reverse repurchase agreements	178,500	—	—	178,500
Total	$ 205,991	$ —	$ (79)	$ 205,912

The contractual maturities of all short-term investments held at September 30, 2023 and December 31, 2022 were one year or less. There were no short-term investments in an unrealized loss position as of September 30, 2023. There were 16 short-term investments in an unrealized loss position with an aggregate value of $25.6 million as of December 31, 2022. These investments were in a loss position for less than 12 months and the Company considered the loss to be temporary in nature. The Company considered the decline in market value for these securities to be primarily attributable to economic and market conditions.

Gross realized gains and losses on the sales of short-term investments are included in other income, net. Unrealized holding gains or losses for the period that have been included in accumulated other comprehensive income, as well as gains and losses reclassified out of accumulated other comprehensive income into other income, net, were not material to the Company's condensed consolidated statements of operations. The cost of investments sold or the amount reclassified out of the accumulated other comprehensive income into other income, net is based on the specific identification method for purposes of recording realized gains and losses. All proceeds in the three and nine month periods ended September 30, 2023 and 2022 related to maturities of underlying investments. The gains on proceeds from maturities of short-term investments were not material to the Company's condensed consolidated statements of operations for the three and nine months ended September 30, 2023 and 2022.

5. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	September 30, 2023	December 31, 2022
Accrued contracted costs	$ 2,863	$ 2,822
Accrued compensation	2,671	3,373
Accrued professional fees	1,891	588
Accrued other	331	407
Accrued milestones	—	500
Total	$ 7,756	$ 7,690

6. Commitments

On January 28, 2022, the Company entered into a sublease agreement (the "Sublease") with Grant Thornton LLP for new office space to replace its existing office space. The Sublease commenced on May 1, 2022 and will end on July 31, 2024 (or on such earlier date as the term may cease or expire as set forth in the Sublease).

Future minimum payments required under the Company's Sublease as of September 30, 2023 are summarized as follows (in thousands):

Period Ending December 31,	Amount
2023	$ 112
2024	395
Total lease payments	$ 507
Less: imputed interest	$ (19)
Total operating lease liabilities	$ 488

Rent expense was $0.2 million and $0.2 million for the three months ended September 30, 2023 and 2022, respectively. Rent expense was $0.5 million and $0.7 million for the nine months ended September 30, 2023 and 2022, respectively. Lease payments were $0.2 million and $0.2 million for the three months ended September 30, 2023 and 2022, respectively. Lease payments were $0.5 million and $0.7 million for the nine months ended September 30, 2023 and 2022, respectively.

7. Stockholders' Equity

Preferred Stock

Under the Company's Restated Certificate of Incorporation, the Company has 5,000,000 shares of preferred stock authorized for issuance, with a $0.001 par value per share. Preferred stock may be issued from time to time in one or more series, each series to have such terms as stated or expressed in the resolutions providing for the issue of such series adopted by the Board of Directors of the Company. Preferred stock which may be redeemed, purchased or acquired by the Company may be reissued except as otherwise provided by law.

In January 2021, the Company entered into a Stock Purchase Agreement (the "Purchase Agreement") with certain institutional and accredited investors. Pursuant to the Purchase Agreement, the Company sold an aggregate of 35,573 shares of Series X Preferred Stock for gross proceeds of approximately $110.0 million, and net proceeds of $104.3 million. Each share of Series X Preferred Stock is convertible into 166.67 shares of common stock. On January 3, 2023, a holder of Series X Preferred Stock elected to convert 348 shares of Series X Preferred Stock into 57,910 shares of common stock. As of September 30, 2023, the Company had 31,107 shares of Series X Preferred Stock outstanding and the number of shares of underlying common stock issuable upon conversion of the Series X Preferred Stock was 5,184,591.

Outstanding Warrants

The following table presents information about warrants that are issued and outstanding at September 30, 2023:

Year Issued	Equity Instrument	Warrants Outstanding	Exercise Price	Date of Expiration
2019	Common Stock	331,858	$ 37.50	2/7/2024
Total		331,858		
Weighted average exercise price			$ 37.50	
Weighted average life in years				0.36

8. Reserved for Future Issuance

The Company has reserved for future issuance the following shares of common stock:

	September 30, 2023	December 31, 2022
Series X Preferred Stock	5,184,591	5,242,501
Reserve under the 2015 Amended and Restated Stock Incentive Plan and the 2022 Inducement Stock Incentive Plan	4,566,822	1,013,520
Options outstanding to purchase common stock	3,321,448	2,253,431
Warrants for the purchase of common stock	331,858	1,530,176
Shares reserved for the employee stock purchase plan	43,060	36,982
Total	13,447,779	10,076,610

9. Stock Incentive Plans

A summary of the Company's stock option activity and related information follows:

	Shares	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2022	2,253,431	$ 15.43	8.57	$ 9,733
Granted	1,657,550	$ 12.62		
Exercised	(78,050)	$ 5.37		
Cancelled or forfeited	(510,960)	$ 16.96		
Expired	(523)	$ 138.60		
Outstanding at September 30, 2023	3,321,448	$ 14.01	8.55	$ 1,436
Vested and exercisable at September 30, 2023	994,708	$ 19.38	7.63	$ 662
Vested and expected to vest at September 30, 2023	3,321,448	$ 14.01	8.55	$ 1,436

The intrinsic value of stock options exercised in the three and nine months ended September 30, 2023 was less than $0.1 million and $0.5 million, respectively. The intrinsic value of stock options exercised was $0.1 million in both the three and nine months ended September 30, 2022. The total grant date fair value of stock options vested for the three months ended September 30, 2023 and 2022 was $0.9 million and $0.9 million, respectively. The total grant date fair value of stock options vested for the nine months ended September 30, 2023 and 2022 was $3.6 million and $4.7 million, respectively. The weighted-average grant date fair value per share of

options granted to employees and non-employees for the three months ended September 30, 2023 and 2022 was $5.89 and $2.54, respectively. The weighted-average grant date fair value per share of options granted to employees and non-employees for the nine months ended September 30, 2023 and 2022 was $7.48 and $3.66, respectively.

At September 30, 2023, the total unrecognized compensation expense related to unvested stock option awards was $14.6 million. The Company expects to recognize that cost over a weighted-average period of approximately 2.8 years.

On February 1, 2023, the Company issued stock options exercisable for 855,000 shares of common stock to certain officers of the Company subject to stockholder approval of the authorization of additional shares of common stock for issuance under the Company's 2015 Amended and Restated Stock Incentive Plan on or before January 31, 2024. On June 2, 2023, the Company's stockholders approved the addition of 4,300,000 shares of common stock to the shares of common stock authorized for issuance under this plan, which satisfied the grant condition on such officer grants. As of September 30, 2023, 755,000 of these options remain outstanding.

On February 17, 2022, the Company's Board of Directors adopted the 2022 Inducement Stock Incentive Plan (the "Inducement Plan"). The Inducement Plan provides for the grant of nonstatutory stock options, stock appreciation rights, restricted stock, restricted stock units and other stock-based awards with respect to an aggregate of 300,000 shares of the Company's common stock. On January 31, 2023, the Company's Board of Directors approved an amendment to the Inducement Plan to increase the number of shares of common stock authorized for issuance thereunder from 300,000 shares of common stock to 700,000 shares of common stock. Awards under the Inducement Plan may only be granted to persons who (a) were not previously an employee or director of the Company or (b) are commencing employment with the Company following a bona fide period of non-employment, in either case as an inducement material to the individual's entering into employment with the Company and in accordance with the requirements of Nasdaq Stock Market Rule 5635(c)(4). As of September 30, 2023, options to purchase 538,100 shares of common stock have been granted under the Inducement Plan, which are included in the table above.

10. Subsequent Events

On October 4, 2023, the Company entered into a license agreement with Ichnos Sciences SA and Ichnos Sciences Inc. (collectively "Ichnos") pursuant to which Ichnos granted to the Company an exclusive (even as to Ichnos and its affiliates), worldwide, and sublicensable right and license to certain patent rights and related know-how, or collectively the Licensed Intellectual Property, to develop, manufacture, and commercialize Ichnos' proprietary OX40 portfolio. The OX40 portfolio includes Ichnos' proprietary OX40 antagonist monoclonal antibody, with the generic name telazorlimab and also referred to by Ichnos as "ISB 830" as well as Ichnos' proprietary affinity matured next generation OX40 antagonist monoclonal antibody referred to by Ichnos as "ISB 830-X8" and referred to by the Company as "STAR-0310 candidate" (collectively, the "Licensed Compounds"). The Company agreed to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize at least one product that contains or comprises a Licensed Compound (a "Licensed Product") in the United States, France, Germany, Italy, Spain, the United Kingdom and Japan.

Under the terms of the license agreement, the Company paid Ichnos a one-time upfront license fee of $15.0 million in October 2023. The Company is obligated to pay Ichnos up to $305.0 million in milestones, consisting of up to $20.0 million upon the achievement of certain development milestones, up to $70.0 million upon the achievement of certain regulatory milestones and up to $215.0 million upon achievement of certain commercial milestones, in each case in up to three indications with respect to the first applicable Licensed Product to achieve such milestone events. The Company is also obligated to pay Ichnos tiered royalties ranging from a mid-single-digit percentage to a low double-digit percentage on aggregate annual net sales of all Licensed Products. The Company is obligated to pay royalties on a Licensed Product-by-Licensed Product and country-by-country basis until the latest of: (i) the expiration of the last valid claim covering the composition of matter of such Licensed Product in such country; (ii) the expiration of the last regulatory exclusivity with respect to such Licensed Product in such country; and (iii) twelve years following the first commercial sale of such Licensed Product in such country. The royalty rate is subject to reduction on a Licensed Product-by-Licensed Product and country-by-country basis under certain circumstances.

On October 16, 2023, the Company closed the October 2023 Financing.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited condensed consolidated financial statements and the related notes and other financial information included elsewhere in this Quarterly Report on Form 10-Q and the audited consolidated financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2022, or the 2022 Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. You should review the sections entitled "Risk Factors" and "Summary of the Material Risks Associated with Our Business" in this Quarterly Report on Form 10-Q for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. This section provides additional information regarding our business, current developments, results of operations, cash flows, financial condition, contractual commitments and critical accounting policies and estimates that require significant judgement and have the most potential impact on our unaudited condensed consolidated financial statements. This discussion and analysis is intended to better allow investors to view the Company from management's perspective.

Overview

We are a biopharmaceutical company focused on the discovery, development and commercialization of novel therapeutics for allergic and immunological diseases. Our focus is to develop first-choice therapies that improve the health and outcomes of patients with allergic and immunological diseases. Our lead product candidate is STAR-0215, a potential best-in-class monoclonal antibody inhibitor of plasma kallikrein in clinical development for the treatment of hereditary angioedema, or HAE, a rare, debilitating and potentially life-threatening disease. STAR-0215 has the potential to be the most patient-friendly chronic treatment option for HAE, based on the data generated to date and the existing HAE treatment landscape. Our second product candidate is STAR-0310, a monoclonal antibody OX40 antagonist that is in preclinical development for the treatment of atopic dermatitis, or AD, an immune disorder associated with loss of skin barrier function and itching. We believe that with both of these programs, we are advancing a pipeline of products with meaningfully differentiated profiles based on validated mechanisms.

STAR-0215

The treatment options for patients with HAE have improved in recent years, however, there is remaining unmet medical need and the global market for HAE therapy is strong and growing. The goal for STAR-0215 is to develop a best-in-class monoclonal antibody inhibitor of plasma kallikrein able to provide long-acting, effective attack prevention for HAE. Our vision for STAR-0215 is to become the first-choice preventative treatment for HAE with administration every three or six months with the goal of normalizing the lives of people living with HAE. Targeted plasma kallikrein inhibition can prevent HAE attacks by suppressing the pathway that generates bradykinin and causes excessive swelling. STAR-0215 is currently in clinical development. We submitted an investigational new drug application, or IND, for STAR-0215 in June 2022 and the FDA cleared our IND for STAR-0215 in July 2022. STAR-0215 for the treatment of HAE received FDA Fast Track designation in July 2023.

We initiated a Phase 1a clinical trial of STAR-0215 in August 2022 and we announced initial results in December 2022. We presented additional preliminary results from the trial in February 2023 and further results were shared at the American College of Allergy, Asthma, and Immunology in November 2023. This Phase 1a randomized, double-blind, placebo-controlled single ascending dose clinical trial evaluated the safety, pharmacokinetics, or PK, and pharmacodynamics, or PD, of STAR-0215 at a single U.S. center. Forty-one healthy subjects received a single dose of STAR-0215 or placebo in four cohorts of 100mg, 300mg, 600mg, and 1200mg administered subcutaneously or a fifth cohort of 600mg or placebo administered intravenously. STAR-0215 was well-tolerated at all dose levels, with no serious adverse events or discontinuations due to an adverse event, and low risk of injection pain. STAR-0215 demonstrated rapid and sustained drug levels with dose-dependent PK. STAR-0215 achieved potentially therapeutic levels in less than one day after single doses greater than 100 mg and showed an estimated half-life of up to 127 days. PK modeling of potential once every three month and once every six month clinical dose regimens over one to two years indicate STAR-0215 has the potential for PK coverage that would confer HAE attack prevention. PD data showed statistically significant inhibition of plasma kallikrein for 140 to 224 days after single doses of STAR-0215 at dose levels greater than 100 mg. Treatment-emergent anti-drug antibodies, or ADAs, were observed in six subjects from completed cohorts, all occurring after day 84. Assessment of ADA impact on PK and PD is ongoing. With a favorable safety profile, long half-life and durable PD, STAR-0215 demonstrated early proof of concept in healthy subjects as a potential HAE therapy with robust efficacy and dosing every three or six months.

The initial Phase 1a results support STAR-0215's target profile as a long-acting plasma kallikrein inhibitor and the results from December 2022 and February 2023 supported advancing STAR-0215 to a Phase 1b/2 trial called ALPHA-STAR, or Astria Long-acting Prophylaxis for Hereditary Angioedema: STAR-0215, which we initiated in February 2023. This global, multi-center, open-label, single and multiple dose proof-of-concept clinical trial in people with HAE is evaluating safety, tolerability, HAE attack rate, PK, PD, and quality of life in patients three and six months after STAR-0215 administration. We are currently enrolling patients in the third and final cohort of the trial. We expect to report initial proof-of-concept data in HAE patients in the first quarter of 2024. If the results from ALPHA-STAR are positive, we expect to progress directly to a Phase 3 pivotal trial which we anticipate initiating in the first quarter of 2025.

We have initiated and are enrolling subjects in ALPHA-SOLAR, a long-term open-label trial assessing the long-term safety and efficacy of STAR-0215. We are currently administering STAR-0215 to those patients who have completed ALPHA-STAR and have enrolled in ALPHA-SOLAR. Participants will be assigned to a 300 mg or 600 mg dosing regimen and all will receive STAR-0215 every three or six months.

In May 2023, we presented new human mechanistic modeling data at the 13th C1-Inhibitor Deficiency & Angioedema Workshop. These data support the potential for STAR-0215 to be administered once every three or six months for robust suppression of HAE attacks. At the European Academy of Allergy and Clinical Immunology Annual Meeting in June 2023, we presented an overview of the design of the ALPHA-STAR clinical trial, a summary of the positive initial Phase 1a results evaluating STAR-0215 in healthy subjects and details about STAR-0215's differentiated plasma kallikrein binding mode.

STAR-0310

On October 4, 2023, we entered into a license agreement, or the License Agreement, with Ichnos Sciences SA and Ichnos Sciences Inc., or collectively Ichnos, pursuant to which Ichnos granted to us an exclusive (even as to Ichnos and its affiliates), worldwide, and sublicensable right and license to certain patent rights and related know-how, or collectively the Licensed Intellectual Property, to develop, manufacture, and commercialize Ichnos' proprietary OX40 portfolio. The OX40 portfolio includes Ichnos' proprietary OX40 antagonist monoclonal antibody, with the generic name telazorlimab and also referred to by Ichnos as "ISB 830" as well as Ichnos' proprietary affinity matured next generation OX40 antagonist monoclonal antibody referred to by Ichnos as "ISB 830-X8" and referred to by us as the "STAR-0310 candidate." We plan to develop the STAR-0310 candidate, which was engineered with YTE half-life extension technology (and will be referred to by us as STAR-0310), for AD and potentially for other allergic and immunological diseases. STAR-0310 is currently in preclinical development. Ichnos has also agreed not to develop or commercialize any product that directly modulates the OX40 receptor.

Our vision for STAR-0310, a monoclonal antibody OX40 antagonist that incorporates YTE half-life extension technology, is to develop a potential best-in-class treatment for AD. AD is an immune disorder associated with loss of skin barrier function and itching. AD is caused by diverse mechanisms, spanning the spectrum of T cell-driven pathology. Approximately 90% of patients develop the disease within the first 5 years of life. AD is estimated to affect approximately 5% of the adult population in the United States, approximately half of which cases are reported to be moderate or severe. AD is a chronic disease and current treatment options are insufficient to address the needs of many patients. Standard of care treatments include steroids and topical medications, which can treat symptoms but do not address the underlying disease. We estimate that the moderate-to-severe AD treatment market was approximately $7 billion in 2022 and that it has the potential to grow to $26 billion by 2030 likely due to an increase in drug-treatment rates, especially with availability of new therapies and growth in biologics-treated patients owing to dermatologists' increasing comfort with biologics.

Our goal for STAR-0310 is to reduce disease activity, relapse rate, and treatment burden for patients with moderate and severe AD in order to help normalize their lives. STAR-0310 was engineered with YTE half-life extension technology with the aim of less frequent dosing of every two to three months. As a potential long-acting OX40 inhibitor, STAR-0310 aims to address the need for a safe, effective, and infrequently administered AD treatment. By targeting OX40, STAR-0310 is designed to address a wide range of T cells involved in the heterogenous AD pathology, providing the potential for better efficacy and a broader addressable patient population.

STAR-0310 was developed as a next generation of telazorlimab with 99% sequence identity. As observed in preclinical studies, STAR-0310 candidate inhibited donor T-cell proliferation similarly to rocatinlimab, an afucosylated anti-OX40 antibody currently in Phase 3 clinical development by Amgen, and at least 10-fold better than telazorlimab. In preclinical studies of donor regulatory T-cells, STAR-0310 candidate was observed to have lower antibody-dependent cellular cytotoxicity, as compared to rocatinlimab, particularly sparing regulatory T cells. In clinical trials conducted by Ichnos, telazorlimab exhibited a favorable safety and tolerability profile. As an

affinity matured next generation of telazorlimab that includes YTE modification, STAR-0310 has the potential to have a favorable safety and tolerability profile.

We anticipate submitting an IND to the FDA for STAR-0310 for the treatment of AD by year-end 2024. If the IND is cleared, we anticipate initiating a Phase 1a clinical trial in healthy subjects in the first quarter of 2025. We anticipate reporting initial results from the Phase 1a clinical in the third quarter of 2025, including PK, PD, and early signals on safety and tolerability. Pending positive results from the Phase 1a clinical trial, we plan to initiate a Phase 1b clinical trial in patients with AD in the second half of 2025, and we anticipate reporting results in the second quarter of 2026. The goals of the Phase 1b trial will be to demonstrate initial efficacy in AD as well as show differentiation on safety and tolerability.

We also see an opportunity to explore the potential of STAR-0310 in additional allergic and immunological indications, such as asthma, chronic urticaria and autoimmune indications. In October 2023, Ichnos filed with the U.S. Patent and Trademark Office a provisional patent application covering STAR-0310 and its use in treating various disorders, including AD. This provisional patent application is included in the Licensed Intellectual Property.

Underwritten Offerings

On December 19, 2022, we closed an underwritten public offering of 10,445,050 shares of our common stock, including the full exercise of the underwriters' option to purchase 1,362,397 shares of our common stock, at a price of $11.01 per share, which we refer to as the December 2022 Financing. The gross proceeds of the December 2022 Financing were approximately $115.0 million, before deducting underwriting discounts and commissions and other offering expenses. On October 16, 2023, we closed an underwritten public offering of (i) 8,253,895 shares of our common stock and accompanying common stock warrants to purchase an aggregate of 6,190,418 shares of common stock and (ii), in lieu of common stock to certain investors, pre-funded warrants to purchase up to an aggregate of 1,571,093 shares of common stock and accompanying common stock warrants to purchase up to an aggregate of 1,178,320 shares of common stock, which we refer to as the October 2023 Financing. The gross proceeds of the October 2023 Financing were approximately $64.0 million, before deducting underwriting discounts and commissions and other offering expenses.

Financial Overview

Our business is almost entirely dependent on the success of STAR-0215, which is in the early clinical stages of development, and has only produced results in a Phase 1a clinical trial, preclinical and nonclinical settings, and STAR-0310, which is in the preclinical stage of development. Our net losses were $41.5 million and $38.6 million for the nine months ended September 30, 2023 and 2022, respectively. As of September 30, 2023, we had an accumulated deficit of $549.1 million. We have not generated any product revenues and have financed our operations primarily through public offerings and private placements of our equity securities and have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical development programs.

As of September 30, 2023, we had $188.8 million in cash, cash equivalents and short-term investments, which, together with the net proceeds from the October 2023 Financing, we expect will enable us to fund our operating expenses and capital expenditure requirements into 2026. Our current operating plan includes the development of STAR-0215 and STAR-0310, including (i) for STAR-0215, support for all program activities up to the initiation of the planned Phase 3 pivotal trial and (ii) for STAR-0310, the upfront payment of $15.0 million to Ichnos in connection with our recently completed in-license of STAR-0310, the anticipated submission of an IND and the initiation and completion of the planned Phase 1a clinical trial of healthy subjects (and any related anticipated milestone payments). Advancing the development of STAR-0215, STAR-0310, or any future product candidates will require a significant amount of capital. Our existing cash, cash equivalents and short-term investments, together with the net proceeds from the October 2023 Financing, will not be sufficient to enable us to fund the completion of development of any of our product candidates, including STAR-0215 and STAR-0310. We will need to obtain substantial additional funding to complete the development and commercialization of STAR-0215, STAR-0310 or any future product candidates and support our continuing operations, future clinical trials and expansion of our pipeline. Furthermore, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional financing to fund our long-term operations sooner than planned. See the section titled “Liquidity and Capital Resources” below for additional information.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our drug discovery efforts, and the development of our product candidates, which include:

- employee-related expenses including salaries, benefits and stock-based compensation expense;
- expenses incurred under agreements with third parties, including contract research organizations, or CROs, that conduct clinical trials and research and development and preclinical activities on our behalf;
- the cost of consultants;
- the cost of lab supplies and acquiring, developing and manufacturing study materials; and
- facilities and other expenses, which include direct and allocated expenses for rent and maintenance of facilities, insurance and other supplies.

Research and development costs are expensed as incurred. Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or the services are performed.

We typically use our employee, consultant and infrastructure resources across our development programs. We track outsourced development costs by product candidate or development program, but we do not allocate personnel costs, other internal costs or external consultant costs to specific product candidates or development programs. We record our research and development expenses net of any research and development tax incentives we are entitled to receive from government authorities.

The following table summarizes our research and development expenses by program (in thousands):

	Nine Months Ended September 30,	
	2023	2022
STAR-0215	$ 18,278	$ 14,594
Other programs	2,836	1,333
Costs not directly allocated to programs:		
Employee expenses including cash compensation, benefits and stock-based compensation	7,920	5,150
Consultants and professional expenses, including stock-based compensation	957	3,013
Facilities	234	399
Other	235	184
Total costs not directly allocated to programs	9,346	8,746
Total research and development expenses	$ 30,460	$ 24,673

We expect to incur significant research and development expenses in the year ending December 31, 2023, and in future periods in connection with the clinical trials and other activities related to the development of STAR-0215 and the preclinical studies, planned clinical trials and other activities related to the development of STAR-0310. Because of this, we expect that our research and development expenses over the next several quarters will be higher than the prior year periods. Development of STAR-0215, STAR-0310 and any future product candidates is highly uncertain and we cannot reasonably estimate at this time the nature, timing and costs of the efforts that would be necessary to complete the development of any such product candidates. We are also unable to predict when, if ever, material net cash inflows would commence from STAR-0215, STAR-0310 or any other future product candidates. This is due to the fact that we would need to raise substantial additional capital to fund the completion of the clinical development of any such product candidates and the numerous risks and uncertainties associated with developing and commercializing product candidates, including the uncertainties of:

- establishing an appropriate safety profile with IND-enabling toxicology studies;
- successful design of, enrollment in, and completion of clinical trials;
- feedback from the FDA and foreign regulatory authorities on preclinical studies, manufacturing capabilities and plans, and planned trial designs;
- changes in the FDA and foreign regulatory approval processes or perspectives that may delay or prevent the approval of new products;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity;
- launching commercial sales, if we are able to obtain marketing approval, whether alone or in collaboration with others, and our ability to compete successfully with other products; and
- maintaining a continued acceptable safety profile following approval.

A change in the outcome of any of these variables with respect to the development of STAR-0215, STAR-0310 or any future product candidate, would significantly change the costs and timing associated with the development of that product candidate.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in executive, finance, accounting, pre-commercial, business development, information technology, legal and human resources functions. Other significant general and administrative costs include facility costs not otherwise included in research and development expenses, legal fees relating to patent and corporate matters, and fees for accounting and consulting services.

We anticipate that our general and administrative expenses will increase from their current levels as we continue to grow our company, develop STAR-0215 and STAR-0310, and potentially expand our pipeline to include other product candidates.

Other Income, Net

Other income, net consists of interest income earned on our cash, cash equivalents and short-term investments and net amortization expense on short-term investments, and gains and losses related to foreign currency fluctuations.

Critical Accounting Estimates

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

During the nine months ended September 30, 2023, there were no material changes to our critical accounting policies as reported in our 2022 Annual Report on Form 10-K.

Results of Operations

Comparison of the Three Months Ended September 30, 2023 and 2022

The following table summarizes our results of operations for the three months ended September 30, 2023 and 2022, together with the dollar change in those items (in thousands):

	Three Months Ended September 30,		Period-to-Period Change
	2023	2022	
Operating expenses:			
Research and development	$ 13,338	$ 7,698	$ 5,640
General and administrative	6,898	4,688	2,210
Total operating expenses	20,236	12,386	7,850
Loss from operations	(20,236)	(12,386)	(7,850)
Other income, net	2,509	389	2,120
Net loss	$ (17,727)	$ (11,997)	$ (5,730)

Research and Development Expenses

Research and development expenses increased by $5.6 million to $13.3 million for the three months ended September 30, 2023 from $7.7 million for the three months ended September 30, 2022, an increase of 73%. The increase in research and development expenses was associated with our STAR-0215 program's advancement through IND-enabling activities into our clinical trials: the Phase 1a trial initiated in August 2022, the ALPHA-STAR Phase 1b/2 trial initiated in February 2023, and we incurred initial start-up costs related to ALPHA-SOLAR, the long-term open-label trial initiated in late 2023. The increase in research and development expenses was primarily attributable to a $4.5 million increase in CRO expenses to support the ALPHA-STAR and ALPHA-SOLAR clinical trials, in addition to a $0.8 million increase in employee expenses and a $0.4 million increase in other research programs. These increases were partially offset by a $0.1 million decrease in facilities and other costs. As noted above, we expect that our research and development expenses over the next several quarters will be higher than prior periods.

General and Administrative Expenses

General and administrative expenses increased by $2.2 million to $6.9 million for the three months ended September 30, 2023 from $4.7 million for the three months ended September 30, 2022, an increase of 47%. The increase was attributable to a $1.1 million increase in professional services expenses, primarily due to increased legal fees related to the in-license of STAR-0310 and investor relation expenses, in addition to a $1.1 million increase in employee-related costs to support our clinical trials and company growth.

Other Income, Net

Other income, net increased by $2.1 million to $2.5 million for the three months ended September 30, 2023 from $0.4 million for the three months ended September 30, 2022. The increase was primarily attributable to interest income due to our higher cash balance and higher investment yields in the three months ended September 30, 2023.

Comparison of the Nine Months Ended September 30, 2023 and 2022

The following table summarizes our results of operations for the nine months ended September 30, 2023 and 2022, together with the dollar change in those items (in thousands):

	Nine Months Ended September 30,		Period-to-Period Change
	2023	2022	
Operating expenses:			
Research and development	$ 30,460	$ 24,673	$ 5,787
General and administrative	18,371	14,540	3,831
Total operating expenses	48,831	39,213	9,618
Loss from operations	(48,831)	(39,213)	(9,618)
Other income, net	7,350	642	6,708
Net loss	$ (41,481)	$ (38,571)	$ (2,910)

Research and Development Expenses

Research and development expenses increased by $5.8 million to $30.5 million for the nine months ended September 30, 2023 from $24.7 million for the nine months ended September 30, 2022, an increase of 23%. The increase in research and development expenses was associated with our STAR-0215 program's advancement through IND-enabling activities into our clinical trials: the Phase 1a trial initiated in August 2022, the ALPHA-STAR Phase 1b/2 trial initiated in February 2023, and we incurred initial start-up costs related to ALPHA-SOLAR, the long-term open-label trial initiated in late 2023. The increase in research and development expenses was primarily attributable to a $3.7 million increase in CRO expenses to support the ALPHA-STAR and ALPHA-SOLAR clinical trials, a $2.8 million increase in employee expenses and a $1.6 million increase in other research programs. These increases were partially offset by a $2.1 million decrease in professional services expenses primarily due to expense recognized in 2022 from a one-time gain on vested warrants inherited in our acquisition of Quellis and a $0.2 million decrease in facilities costs.

General and Administrative Expenses

General and administrative expenses increased by $3.8 million to $18.4 million for the nine months ended September 30, 2023 from $14.6 million for the nine months ended September 30, 2022, an increase of 26%. The increase was attributable to a $2.1 million increase in professional services expenses, primarily due to increased legal fees, recruiting costs, and consulting expenses, and a $2.1 million increase in employee related costs, partially offset by a $0.2 million decrease in insurance expense and a $0.2 million decrease in other costs, including facilities and general office expenses.

Other Income, Net

Other income, net increased by $6.7 million to $7.3 million for the nine months ended September 30, 2023 from $0.6 million for the nine months ended September 30, 2022. The increase was primarily attributable to interest income due to our higher cash balance and higher investment yields in the nine months ended September 30, 2023.

Liquidity and Capital Resources

From our inception through September 30, 2023, we raised an aggregate of $579.3 million through equity financings including private placements of preferred stock before we became a public company, our private placement of preferred stock in February 2021 and registered offerings of our common stock, including our at-the-market offering programs. Subsequent to September 30, 2023, we raised an additional $64.0 million in gross proceeds in the October 2023 Financing before deducting underwriting discounts and commissions and other offering expenses.

As of September 30, 2023, we had $188.8 million in cash, cash equivalents and short-term investments, which, together with the net proceeds from the October 2023 Financing, we expect will enable us to fund our operating expenses and capital expenditure requirements into 2026. Our current operating plan includes the development of STAR-0215 and STAR-0310, including (i) for STAR-0215, support for all program activities up to the initiation of the planned Phase 3 pivotal trial and (ii) for STAR-0310, the upfront payment of $15.0 million to Ichnos in connection with our recently completed in-license of STAR-0310, the anticipated submission of an IND and the initiation and completion of the planned Phase 1a clinical trial of healthy subjects (and any related anticipated milestone payments). Advancing the development of STAR-0215, STAR-0310 or any future product candidates will require a significant amount of capital. Our existing cash, cash equivalents, and short-term investments, together with the net proceeds from the October 2023 Financing, will not be sufficient to enable us to fund the completion of development of any of our product candidates, including STAR-0215 and STAR-0310. Furthermore, our operating plan may change as a result of many factors currently unknown to us, and we may need to seek additional financing to fund our long-term operations sooner than planned.

We will need to obtain substantial additional funding to complete the development and commercialization of STAR-0215, STAR-0310 or any future product candidates, support our continuing operations, future clinical trials and the expansion of our pipeline. In addition, STAR-0215, STAR-0310, or any future product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of product candidates that we do not expect to be commercially available for years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all. The terms of any financing may adversely affect the holdings or the rights of our stockholders. General economic conditions, both inside and outside the United States, including heightened inflation, capital market instability and volatility, interest rate and currency rate fluctuations and economic slowdown or recession as well as the COVID-19 pandemic and geopolitical events, including civil or political unrest (such as the Ukraine-Russian war and the conflict in the Middle East), may have a significant impact on the availability of funding sources and the terms on which any funding may be available. In addition, market instability and volatility, high levels of inflation and interest rate fluctuations may increase our cost of financing or restrict our access to potential sources of future liquidity. If we fail to raise capital as, and when, needed, we may be unable to continue our operations at planned levels and be forced to modify our business strategies and reduce or terminate our operations. Although we will continue to pursue these plans, there is no assurance that we will be successful in obtaining sufficient funding on terms acceptable to us to fund continuing operations when needed or at all.

December 2022 Financing

On December 19, 2022, we closed an underwritten public offering of 10,445,050 shares of our common stock for gross proceeds of approximately $115 million, and net proceeds of $107.6 million.

October 2023 Financing

On October 16, 2023, we closed an underwritten public offering of (i) 8,253,895 shares of our common stock and accompanying common stock warrants to purchase an aggregate of 6,190,418 shares of common stock and (ii), in lieu of common stock to certain investors, pre-funded warrants to purchase up to an aggregate of 1,571,093 shares of common stock and accompanying common stock warrants to purchase up to an aggregate of 1,178,320 shares of common stock for aggregate gross proceeds of approximately $64.0 million before deducting underwriting discounts and commissions and other offering expenses.

At-the-Market Offerings

On June 30, 2021, we entered into an Open Market Sale Agreement℠ with Jefferies LLC, or Jefferies, pursuant to which we can issue and sell shares of common stock of up to $25.0 million under an at-the-market offering program, or the Jefferies ATM Program. We pay Jefferies sales agent commissions of 3% of the gross proceeds from any common stock sold through the Jefferies ATM Program. In September 2022, the Jefferies ATM Program was modified to increase the amount of our common stock that may be offered thereunder to an aggregate offering price of up to $50.0 million, with $30.5 million of such amount then being available for future issuance. In November 2022, the Jefferies ATM Program was once again modified to increase the amount of our common stock that may be offered thereunder to an aggregate offering price of up to $88.1 million, with $50.0 million of such amount then being available for future issuance. As of September 30, 2023, $50.0 million of common stock remains available for sale under the Jefferies ATM Program. There was no activity from the Jefferies ATM Program during the three and nine months ended September 30, 2023. In the three and nine months ended September 30, 2022, we sold an aggregate of 2,715,166 shares of common stock under the Jefferies ATM Program for gross proceeds of $25.0 million and net proceeds of $24.3 million.

Cash Flows

Comparison of the Nine Months Ended September 30, 2023 and 2022

The following table provides information regarding our cash flows for the nine months ended September 30, 2023 and 2022 (in thousands):

	Nine Months Ended September 30,	
	2023	2022
Net cash used in operating activities	$ (38,207)	$ (32,869)
Net cash provided by (used in) by investing activities	137,068	(31,949)
Net cash provided by financing activities	420	24,324
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 99,281	$ (40,494)

Net Cash Used in Operating Activities

Net cash used in operating activities was $38.2 million for the nine months ended September 30, 2023 and consisted primarily of a net loss of $41.5 million adjusted for stock-based compensation expense of $4.2 million, an decrease to our right of use asset of $0.4 million, and offset by a net decrease in net assets of $1.3 million, which resulted primarily from an increase in prepaid expenses of $1.3 million.

Net cash used in operating activities was $32.9 million for the nine months ended September 30, 2022 and consisted primarily of a net loss of $38.6 million adjusted for stock-based compensation expense of $3.5 million, expense recognized for warrants of $1.5 million, other non-cash items of $0.1 million, and a net decrease in net assets of $0.6 million, which resulted primarily from an increase in accrued expenses of $1.8 million, partially offset by a decrease in accounts payable of $0.8 million, and an increase in prepaid expenses of $0.4 million.

Net Cash Provided by (Used in) Investing Activities

Net cash provided by investing activities was $137.1 million for the nine months ended September 30, 2023 and consisted primarily of maturities of short-term investments of $1.4 billion, partially offset by purchases of short-term investments of $1.2 billion. Net cash used in investing activities was $31.9 million for the nine months ended September 30, 2022 and consisted primarily of purchases of short-term investments of $217.6 million offset by maturities of short-term investments of $185.7 million.

Net Cash Provided by Financing Activities

Net cash provided by financing activities was $0.4 million for the nine months ended September 30, 2023, which was attributable to proceeds from exercises of stock options of $0.4 million. Net cash provided by financing activities was $24.3 million for the nine months ended September 30, 2022, which was attributable to net proceeds under the Jefferies ATM Program.

Funding Requirements

Our primary uses of capital are for compensation and related expenses, manufacturing costs for preclinical and clinical materials, third party preclinical and clinical research and development services, clinical costs, legal and other regulatory expenses, and general overhead.

As of September 30, 2023, we had an accumulated deficit of $549.1 million. We have been primarily involved with research and development activities and have incurred operating losses and negative cash flows from operations since our inception.

As of September 30, 2023, we had $188.8 million in cash, cash equivalents and short-term investments, which, together with the net proceeds from the October 2023 Financing, we expect will enable us to fund our operating expenses and capital expenditure requirements into 2026. Our current operating plan includes the development of STAR-0215 and STAR-0310, including (i) for STAR-0215, support for all program activities up to the initiation of the planned Phase 3 pivotal trial and (ii) for STAR-0310, the upfront payment of $15.0 million to Ichnos in connection with our recently completed in-license of STAR-0310, the anticipated submission of

an IND and the initiation and completion of the planned Phase 1a clinical trial of healthy subjects (and any related anticipated milestone payments).

Our estimate as to how long we expect our cash, cash equivalents and short-term investments, together with the net proceeds from the October 2023 Financing, to be able to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of biotechnology products, we are unable to estimate the exact amount of our operating capital requirements. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. Our future funding requirements will depend on many factors, including:

- the progress, timing, costs and results of clinical trials of, and research and preclinical development efforts for STAR-0215, STAR-0310 and any future product candidates, including potential future clinical trials;
- our ability to enter into and the terms and timing of any collaborations, licensing or other arrangements that we may establish;
- the number and characteristics of future product candidates that we pursue and their development requirements;
- the outcome, timing and costs of seeking regulatory approvals;
- the costs of commercialization activities for any of our product candidates that receive marketing approval to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, market access, distribution, supply chain and manufacturing capabilities, and scaling up the manufacturing of drug substance and drug product to clinical and commercial scale and developing a drug device combination, if applicable, securing all raw materials necessary to conduct such scale-up and successfully completing all other activities related thereto;
- if we obtain marketing approval of any of our product candidates, revenue, if any, received from commercial sales of our product candidates;
- if we obtain marketing approval of any of our product candidates, our ability to successfully compete against other approved products that are approved or used as treatments for the indications for which our products are approved, including with respect to STAR-0215 in HAE and STAR-0310 in AD;
- our headcount growth and associated costs;
- the amount and timing of future milestone and royalty payments potentially payable to Ichnos pursuant to the License Agreement;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims; and
- the costs of operating as a public company.

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, STAR-0215, STAR-0310 or any future product candidates, if approved, may not achieve commercial success. Our commercial revenues, if any, will be derived from sales of medicines that we do not expect to be commercially available for years, if at all. Accordingly, we will need to continue to rely on additional financing to achieve our business objectives. Adequate additional financing may not be available to us on acceptable terms, or at all.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. We do not have any committed external source of 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 our stockholders' rights. Debt financing, if available, would result in periodic payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business.

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

Material Cash Requirements from Known Contractual Obligations

Our material cash requirements from known contractual and other obligations as of September 30, 2023 primarily related to our sublease agreement for office space. For information related to our future commitments relating to our sublease agreement, see Note 6, “Commitments”, of our condensed consolidated financial statements. On October 4, 2023, we entered into the License Agreement with Ichnos for Licensed Intellectual Property, pursuant to which we may be obligated to pay to Ichnos up to $305.0 million in development, regulatory and sales milestone payments in addition to up to low double-digit royalties. For information related to such potential payments under the License Agreement, see Note 10, “Subsequent Events”, of our condensed consolidated financial statements.

We enter into agreements in the normal course of business with CROs for clinical trials and clinical supply manufacturing and with vendors for preclinical research studies and other services and products for operating purposes. The contracts are cancelable at any time by us, generally upon 60 days' prior written notice to the CRO, and therefore we believe that our non-cancelable obligations under these agreements are not material.

Item 4. Controls and Procedures

Management’s Evaluation of our Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or the Exchange Act) that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is (1) recorded, processed, summarized, and reported within the time periods specified in the U.S. Securities and Exchange Commission’s rules and forms and (2) accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate, to allow timely decisions regarding required disclosure.

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of the end of the period covered by this Quarterly Report on Form 10-Q. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Our principal executive officer and principal financial officer have concluded based upon the evaluation described above that, as of September 30, 2023, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

During the nine months ended September 30, 2023, there were no changes in our internal control over financial reporting, as such term is defined in Rules 13a-15(f) and 15(d)-15(f) promulgated under the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II – OTHER INFORMATION

Item 1A. Risk Factors

We operate in a dynamic and rapidly changing business environment that involves risks and substantial uncertainty. The following discussion addresses risks and uncertainties that could cause, or contribute to causing, actual results to differ from expectations in material ways. In evaluating our business, investors should pay particular attention to the risks and uncertainties described below, some of which have manifested and any of which may occur in the future, and in other sections of this Quarterly Report on Form 10-Q and in our subsequent filings with the U.S. Securities and Exchange Commission, or SEC. These risks and uncertainties, or other events that we do not currently anticipate or that we currently deem immaterial also may affect our results of operations, cash flows and financial condition. The trading price of our common stock could also decline due to any of these risks, and you could lose all or part of your investment.

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

Our business is entirely dependent on the success of STAR-0215 as a potential treatment for HAE and STAR-0310 as a potential treatment for AD.

Our business is entirely dependent on the success of STAR-0215, a potential best-in-class monoclonal antibody inhibitor of plasma kallikrein in clinical development for the potential treatment of hereditary angioedema, or HAE, and STAR-0310, a potential best-in-class monoclonal antibody OX40 antagonist that incorporates YTE half-life extension technology in preclinical development for the potential treatment of atopic dermatitis, or AD. We initiated a Phase 1a clinical trial of STAR-0215 in healthy subjects in August 2022 and announced the preliminary results from this trial in December 2022 and additional initial results were presented in February 2023. We initiated the Phase 1b/2 ALPHA-STAR trial of STAR-0215 in patients with HAE in February 2023 and we are currently enrolling patients in the third and final cohort of the trial. We also expect to submit an Investigational New Drug application, or IND, for STAR-0310 by year-end 2024 and, if the IND is cleared by the FDA, we plan to initiate a Phase 1a clinical trial in healthy subjects in the first quarter of 2025. We cannot give any assurance that we will generate preclinical, clinical or other data for STAR-0215 or STAR-0310 sufficiently supportive to receive regulatory approval, which will be required before either can be commercialized. We may, among other things, experience difficulties with patient recruitment, enrollment and retention, quality and provision of materials and supplies necessary to manufacture sufficient quantities of drug product to meet our preclinical study and clinical trial needs on a timely basis, or safety signals or pharmacodynamic, pharmacokinetic or efficacy data that does not align with our target profile for STAR-0215 or STAR-0310. STAR-0215 and STAR-0310 will require significant preclinical, clinical and nonclinical development, regulatory review and approval, substantial investment, access to sufficient commercial manufacturing capacity for our product candidates, and significant marketing efforts before we can generate any revenue from product sales.

We also plan to begin development of a drug device combination for STAR-0215. There is no assurance that we will be successful in developing a drug device combination on a timely basis or at all, which could impede our development and commercialization strategy for STAR-0215. The FDA or other comparable foreign regulatory authorities could require nonclinical studies or clinical trials to support introduction of a drug device combination, which could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase our clinical trial costs, delay approval of STAR-0215 and jeopardize our ability to commence product sales and generate revenue from STAR-0215, if approved.

The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of STAR-0215 and STAR-0310, which may never occur. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize STAR-0215 or STAR-0310, we may not be able to generate sufficient revenue to continue our business and our business would be materially harmed.

Interim topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more study participant data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publish interim topline or preliminary data from our clinical trials. Interim data 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 data become available. Preliminary or topline results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data

should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our reputation and business prospects.

Results of preclinical studies and early clinical trials may not be predictive of results of future clinical trials, and results of later stage clinical trials may not enable marketing approval.

The outcome of preclinical studies and early clinical trials, along with interim results from clinical trials, may not be predictive of the success of later clinical trials and may not be supportive of moving into later clinical trials. Many companies in the pharmaceutical and biotechnology industries have suffered significant clinical and regulatory delays or setbacks in late-stage clinical trials after achieving positive interim or final results in preclinical studies or early development, and we cannot be certain that we will not face similar setbacks. The design of a clinical trial can determine whether its results will support advancing into later clinical trials or approval of a product and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We have limited experience in designing clinical trials and may be unable to design and execute a clinical trial or trials to support marketing approval. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their product candidates. Even if we, or any future collaborators, believe that the results of clinical trials for our product candidates warrant marketing approval, as the case may be, the FDA or comparable foreign regulatory authorities may disagree and not grant marketing approval of our product candidates.

In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, differences in study design, changes in and adherence to the dosing regimen and other clinical trial protocols, and the rate of dropout among clinical trial participants. If we fail to receive positive results in preclinical studies or clinical trials of STAR-0215, STAR-0310 or any other future product candidate, the development timeline and regulatory approval and commercialization prospects for such product candidate, and, correspondingly, our business and financial prospects would be negatively impacted.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome. If clinical trials of a product candidate fail to satisfactorily demonstrate safety and efficacy to the FDA and other comparable foreign regulators, we, or any future collaborators, may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of such product candidates.

We, and any future collaborators, are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining approval from the FDA of a biologics licensing application, or BLA, which would be required for approval of STAR-0215 and STAR-0310, or a new drug application, or NDA. Comparable foreign regulatory authorities, such as the European Medicines Agency, or EMA, require similar approvals. We, and any future collaborators, may never receive such approvals. We, and any future collaborators, must complete extensive preclinical development and clinical trials to demonstrate the safety and efficacy in humans of any product candidate that we may choose to develop before we, or they, will be able to obtain these approvals.

Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome. We cannot guarantee that any clinical trials we initiate will be conducted as planned or completed on schedule, or at all. In addition, in the case of STAR-0215, for which we have designed our clinical trials, and plan to design future trials, with the goal of demonstrating that it can be dosed in HAE patients every three months or potentially less frequently, clinical trials will necessarily be longer given the length of time between doses in the trials. We also expect that later stage clinical trials we conduct for STAR-0310 will be larger and more expensive when compared to those we are conducting for STAR-0215 because AD, the indication for which we are developing STAR-0310, is not a rare disease. Further, the clinical development of product candidates is susceptible to the risk of failure or significant delays at any stage of drug development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, failure to utilize clinically appropriate efficacy or safety targets or measurements in a clinical trial for the disease or patient population being studied, the occurrence of adverse events that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements, failure to enroll a sufficient number of patients on a timely basis or at all, failure to retain a sufficient number of patients to complete any of our trials, determination by the FDA or any comparable foreign regulatory authority that a product candidate may not continue development or is not approvable, or the need to conduct additional studies or add cohorts to a trial before advancing into the next stage of development. Certain of these risks are heightened in the context of drug development for treatments for rare diseases, in which non-traditional study designs, and often smaller trials are utilized, to demonstrate efficacy and safety, including open-label studies, single arm studies, non-inferiority studies, studies utilizing active

comparators or studies utilizing natural history data, biomarkers or other forms of surrogate endpoints, may be utilized due to the challenges inherent in designing and conducting clinical trials for severe diseases with small patient populations. In addition, we may amend the clinical trial protocol to address any issues that we observe as a trial is progressing, including in response to factors impacting safety and the data collected or to adapt the study design to include more clinically appropriate safety or efficacy targets or measurements, or we may be required to make certain changes to clinical trial protocols in response to issues raised by the FDA, the institutional review board, or IRB, other regulatory authorities, investigators or clinical sites. Protocol amendments are subject to IRB and regulatory approval before we implement material changes, can result in additional costs, require additional data or participants, and could delay, interrupt, or limit the conduct of the clinical trial. If we terminate or experience delays in the completion of any clinical trials, the commercial prospects for our product candidates may be harmed, and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval.

It is possible that even if a product candidate that we choose to develop has a beneficial effect, that effect will not be detected during clinical evaluation as a result of one or more of a variety of factors, including the size, duration, design, measurements, conduct or analysis of our clinical trials. Conversely, as a result of the same factors, our clinical trials may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any. Similarly, in any clinical trials we conduct, we may fail to detect toxicity of or intolerability caused by a product candidate, or mistakenly believe that a product candidate is toxic or not well tolerated when that is not in fact the case. We have not previously submitted an NDA or BLA to the FDA or similar drug approval filings to comparable foreign regulatory authorities for any of our product candidates. Moreover, developing biologics is highly complex and any delay or problems in such development, including with third party contract manufacturers that we use to make and develop the drug substance and drug substance for our product candidates, may impede our ability to successfully complete clinical development of STAR-0215, and successfully initiate and complete clinical development of STAR-0310 or any future biologic product candidates we pursue and obtain FDA approval in a timely manner, if at all. Any inability to complete clinical development successfully could result in additional costs to us, or any future collaborators, and impair our ability to generate revenues from product sales, regulatory and commercialization milestones and royalties. Moreover, if (1) we, or any future collaborators, are required to modify our trial designs, such as required modifications with respect to patient populations, endpoints, comparators or trial duration, (2) we, or any future collaborators, are required to conduct additional clinical trials or other testing of a product candidate beyond the trials and testing that we, or they contemplate, (3) we, or any future collaborators, are unable to successfully commence on a timely basis or complete clinical trials of a product candidate or other testing, (4) the results of these trials or tests are unfavorable, uncertain or are only modestly favorable, or (5) there are unacceptable safety concerns associated with a product candidate, we, or any future collaborators, may:

- be delayed in obtaining marketing approval for such product candidate;
- not obtain marketing approval at all;
- obtain marketing approval for indications or patient populations that are not as broad as intended or desired;
- obtain marketing approval with labeling that includes significant use or distribution restrictions or significant safety warnings, including boxed warnings;
- be subject to additional post-marketing testing or other requirements, such as a REMS program; or
- be required to remove the product from the market after obtaining marketing approval.

Given our early stage of development, it will be years before we are able to demonstrate the safety and efficacy of a treatment sufficient to warrant approval for commercialization, and we may never be able to do so. Our failure to successfully complete clinical trials of a product candidate and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market any product candidate would significantly harm our business.

Adverse events or undesirable side effects caused by, or other unexpected properties of, a product candidate may be identified during development that could delay or prevent their marketing approval or limit their use.

Adverse events or undesirable side effects caused by, or other unexpected properties of, a product candidate could cause us, any future collaborators, an IRB or regulatory authorities to interrupt, delay or halt clinical trials of one or more of such product candidates and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or comparable foreign regulatory

authorities. If any such product candidate is associated with adverse events or undesirable side effects or has properties that are unexpected, we, or any future collaborators, may need to abandon development or limit development of that product candidate to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many compounds that initially showed promise in clinical or earlier stage testing have later been found to cause adverse events or undesirable or unexpected side effects that prevented further development of the compound.

If we, or any future collaborators, experience any of a number of possible unforeseen events in connection with clinical trials of a product candidate, potential marketing approval or commercialization of such product candidate could be delayed or prevented.

We, or any future collaborators, may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent marketing approval or commercialization of a product candidate, including:

- clinical trials may produce unfavorable or inconclusive results;
- we, or any future collaborators, may decide, or regulators may require us or them, to conduct additional clinical trials or abandon product development programs;
- the number of patients required for clinical trials may be larger than we, or any future collaborators, anticipate, particularly with respect to STAR-0310, which is being developed as a potential treatment for AD which, unlike HAE, is not a rare disease;
- patient enrollment in these clinical trials may be slower than we, or any future collaborators, anticipate, particularly with respect to STAR-0215, which is being developed as a potential treatment for HAE, which has a significant number of approved products and products in clinical development, or participants may drop out of these clinical trials at a higher rate than we, or any future collaborators, anticipate or the duration of these clinical trials may be longer than we anticipate;
- the cost of planned clinical trials may be greater than we anticipate;
- our third-party contractors or those of any future collaborators, including those manufacturing such product candidate or components or ingredients thereof, including a suitable presentation of a product candidate, such as a pre-filled syringe, or any drug device combination for a product candidate, or conducting clinical trials on our behalf or on behalf of any future collaborators, may fail to comply with regulatory requirements, program timelines or meet their contractual obligations to us or any future collaborators in a timely manner or at all;
- regulators or IRBs may not authorize us, any future collaborators or our or their investigators to commence, conduct or continue a clinical trial at a prospective trial site or may not approve a protocol amendment to an ongoing clinical trial;
- we, or any future collaborators, may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites;
- patients that enroll in a clinical trial may misrepresent their eligibility to do so or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the patients from the clinical trial, increase the needed enrollment size for the clinical trial or extend the clinical trial’s duration;
- we, or any future collaborators, may have to delay, suspend or terminate clinical trials for various reasons, including a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the product candidate, or restrictions imposed by applicable governmental authorities due to epidemics or public health outbreaks;
- regulators or IRBs may require that we, or any future collaborators, or our or their investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or their standards of conduct, a finding that the participants are being exposed to unacceptable health risks, undesirable side effects or other unexpected characteristics of the product candidate or findings of undesirable effects caused by a chemically or mechanistically similar drug or drug candidate;

- the FDA or comparable foreign regulatory authorities may disagree or subsequently find fault with our, or any future collaborators', clinical trial designs, including the size of the trials or inclusion or exclusion criteria, or our or their interpretation of data from preclinical studies and clinical trials or may require us to conduct a comparator trial in lieu of a placebo-controlled trial;

- the FDA or comparable foreign regulatory authorities may fail to approve or subsequently find fault with the manufacturing processes or facilities of third-party manufacturers with which we, or any future collaborators, enter into agreements for clinical, commercial supplies or drug device combinations for our product candidates;

- we are unable to develop or obtain a supplier for a suitable drug device combination for our product candidates that meets the requirements of the FDA or comparable foreign regulatory authorities;

- adequacy of or changes in our manufacturing process or the product formulation or method of delivery;

- the supply or quality of drug product or drug substance, raw materials or other materials necessary to conduct clinical trials may be insufficient, inadequate or not available at an acceptable cost, or we may experience interruptions in supply;

- changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; and

- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient to obtain marketing approval.

In addition, we may amend clinical trial protocols to address any issues that we observe as a trial is progressing, including in response to factors impacting safety and the data collected or to adapt the study design to include more clinically appropriate safety or efficacy targets or measurements, or we may be required to make certain changes in response to issues raised by the FDA, IRB, other regulatory authorities, investigators or clinical sites. Protocol amendments are subject to IRB and regulatory approval before we implement material changes, can result in additional costs, require additional data or participants, and could delay, interrupt, or limit the conduct of the clinical trial. If we terminate or experience delays in the completion of any clinical trials, the commercial prospects for our product candidates may be harmed, and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval.

We are planning to conduct clinical trials outside of the United States, which are subject to the risks set forth above, and certain additional risks, such as unforeseen global instability, including political instability or geopolitical events, including civil or political unrest (such as the war between Russia and Ukraine and the conflict in the Middle East), terrorist activity, unstable governments and legal systems, natural disasters or instability from an outbreak of pandemic or contagious disease, in or around any countries in which we conduct clinical trials. Such additional risks could affect our ability to enroll patients in clinical trials in these countries, prevent patients already enrolled from completing such clinical trials, and/or cause other trial delays or otherwise adversely impact such clinical trials.

Product development costs for us, or any future collaborators, will increase if we, or they, experience delays in testing or pursuing marketing approvals and we, or they, may be required to obtain additional funds to complete clinical trials and prepare for possible commercialization of any future product candidate. We do not know whether any preclinical tests or clinical trials will begin as planned, will need to be restructured, or will be completed on schedule or at all. Significant preclinical development or clinical trial delays also could shorten any periods during which we, or any future collaborators, may have the exclusive right to commercialize product candidates or allow our competitors, or the competitors of any future collaborators, to bring products to market before we, or any future collaborators, do or closer in proximity to the launches of our products or those of our collaborators, and impair our ability, or the ability of any future collaborators, to successfully commercialize product candidates and may harm our business and results of operations. In addition, many of the factors that lead to clinical trial delays may ultimately lead to the denial of marketing approval of any future product candidates.

If we, or any future collaborators, experience delays or difficulties in the enrollment of patients in clinical trials, our or their receipt of necessary regulatory approvals could be delayed or prevented.

We, or any future collaborators, may not be able to initiate or continue clinical trials for STAR-0215, STAR-0310 or any other future product candidate if we, or they, are unable to locate and enroll, and maintain the enrollment of, a sufficient number of eligible patients to participate in clinical trials as required by the FDA or comparable foreign regulatory authorities, such as the EMA. Patient enrollment is a significant factor in the timing of clinical trials, and is affected by many factors, including:

- the size and nature of the patient population;
- the severity of the disease under investigation;
- the proximity of patients to clinical sites;
- the eligibility criteria for the trial;
- the design of the clinical trial;
- efforts to facilitate timely enrollment;
- competing clinical trials; and
- clinicians' and patients' perceptions as to the potential advantages and risks of the drug being studied in relation to other available therapies, including any existing or newly approved drugs that may be approved for the indications we are investigating.

Our ability to successfully initiate and complete any clinical trial for STAR-0215 as a potential treatment for HAE, including our recently initiated Phase 1b/2 ALPHA-STAR trial, for STAR-0310 as a potential treatment for AD, including the Phase 1a clinical trial we plan to begin in 2025 (assuming we successfully and timely submit an IND by the end of 2024), or for any other future product candidate for the potential treatment of any rare disease or any other indication will be dependent upon our ability to enroll, and maintain the enrollment of, a sufficient number of patients with such disease, which will be subject to a number of risks and uncertainties. For example, rare diseases, including HAE, have small patient populations and often have only a limited number of specialist physicians that regularly treat such patients. Further, these specialized sites typically treat a range of diseases and, at any point in time, may have constrained resources and capacity to handle clinical trials. In addition, in the case of HAE, approved products are available for the rare disease, and additional products may become commercially available during the clinical development of STAR-0215, and therefore patients and their healthcare providers may feel satisfied with their treatments. As a result, patients may not feel the need to participate in a clinical trial for another product candidate for the same disease or the criteria for the trial may not allow patients on such other therapies to enroll in the trial. Additionally, in the case of HAE, diagnosis is often delayed from onset of symptoms and patients that might be eligible for enrollment in our trials may not have been diagnosed and therefore are unaware of such eligibility. Finally, other companies are and will be conducting clinical trials in HAE or may have announced plans for future clinical trials for HAE that are seeking, or are likely to seek, to enroll patients with the disease and patients are generally only able to enroll in a single trial at a time. The small population of patients, competition for these patients and the limited trial sites and their constrained resources may make it difficult for us to enroll enough patients in our clinical trials in HAE, and to maintain the enrollment of enough patients, to complete such clinical trials.

The clinical trials that we may conduct may also have inclusion and exclusion criteria that further limit the population of patients that we are able to enroll. In the case of HAE trials, the inclusion criteria may require that participants have had a certain number of attacks that occur within a defined period of time prior to being able to participate in the trial, which may impact or slow enrollment in the trial. For example, in the case of our Phase 1b/2 ALPHA-STAR trial, the inclusion criteria require that participants have had a certain number of attacks that occur within a defined period of time prior to being able to participate in the trial, which may impact or slow enrollment in the trial. These inclusion or exclusion criteria could limit the available patient pool and present challenges to clinical trial enrollment.

Our inability, or the inability of any future collaborators, to enroll a sufficient number of patients for any clinical trials, including clinical trials for STAR-0215 as a potential treatment for HAE and clinical trials for STAR-0310 as a potential treatment for AD, that we or they may determine to pursue could result in significant delays or may require us or them to abandon one or more clinical trials altogether. Enrollment delays in any such clinical trials may result in increased development costs for the applicable product candidates, delay or halt the development of and approval processes for any future product candidates and jeopardize our, or any future collaborators', ability to commence sales of and generate revenues from any product candidates, which could cause the value of our company to decline.

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

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

We face substantial competition from other pharmaceutical and biotechnology companies, and our operating results may suffer if we fail to compete effectively.

The development and commercialization of new drug products is highly competitive. We expect that we, and any future collaborators, will face significant competition from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide with respect to any product candidates that we, or they, may seek to develop or commercialize in the future.

We are developing STAR-0215 for the potential treatment of HAE. The key competitive factors affecting the success of STAR-0215, if approved, are likely to be its efficacy, safety, dosing frequency, method of administration, convenience, price and the availability of coverage and reimbursement from government and other third-party payors. In the United States, the FDA has approved four therapies for on-demand treatment of HAE: BERINERT, FIRAZYR, KALBITOR and RUCONEST. For long-term preventative treatment of HAE, the FDA has also approved four therapies: CINRYZE, HAEGARDA, TAKHZYRO and ORLADEYO. There are four main manufacturers of therapies for HAE: CSL Behring (BERINERT and HAEGARDA), Takeda (FIRAZYR, KALBITOR, CINRYZE and TAKHZYRO), Pharming (RUCONEST) and BioCryst (ORLADEYO). With the exception of KALBITOR, these therapies are also approved and commercially available outside of the United States (HAEGARDA is marketed as BERINERT SC outside of the United States). Historically, androgens and antifibrinolytic treatments have also been used as preventative treatment for HAE, however their use is declining with the availability of more-tolerable, HAE-specific therapies.

On-demand and preventative HAE therapies target one of three primary mechanisms. BERINERT and HAEGARDA, RUCONEST and CINRYZE are C1-INH replacement therapies. FIRAZYR is a Bradykinin 2 receptor, or B2R, antagonist, and KALBITOR, TAKHZYRO and ORLADEYO target plasma kallikrein. TAKHZYRO is a monoclonal antibody and KALBITOR and ORLADEYO are small molecule inhibitors.

On-demand therapies are taken as needed; BERINERT and RUCONEST are IV infusions approved for adult and pediatric patients, FIRAZYR is a SC injection, approved for adults 18 and older, and KALBITOR is a series of 3 SC injections, approved for patients 12 years and older. KALBITOR must be administered by a healthcare professional to monitor for the risk of anaphylactic reactions.

Preventative therapies are taken chronically. CINRYZE is an IV infusion and HAEGARDA is an SC injection; both are administered twice a week and are approved for adult and pediatric patients 6 years and older. TAKHZYRO is an SC injection generally administered every two weeks; however, dosing every four weeks may be considered in some patients. TAKHZYRO is approved for patients 2 years and older. ORLADEYO is an oral capsule taken once daily with food for patients 12 years and older. Given that TAKHZYRO is an approved monoclonal antibody inhibitor of plasma kallikrein, if STAR-0215 is approved, we expect that it will compete most directly with TAKHZYRO.

We are aware of additional programs in development for HAE, which are focused largely on preventative approaches. For example, CSL Behring's garadacimab (CSL312), a factor XIIa-inhibitory monoclonal antibody, or FXIIa mAb, has completed Phase 3 development for preventative treatment. Ionis Pharmaceuticals, Inc.'s donidalorsen (IONIS-PKK-LRx), an antisense inhibitor of prekallikrein synthesis is currently in Phase 3 development for preventative treatment. Pharvaris is developing two oral treatments, PHVS416, in Phase 2 for on-demand treatment, and PHVS719, in Phase 1 for preventative treatment, that are small molecule inhibitors of B2R. KalVista Pharmaceuticals, Inc. has an oral small molecule plasma kallikrein inhibitor sebetralstat (KVD900) for on-demand treatment of HAE in Phase 2 development (the Phase 2 trial for KVD824 for preventative treatment was terminated). Intellia Therapeutics has begun Phase 1/2 trials for NTLA-2002, a CRISPR knockout of the prekallikrein gene *KLKB1*. BioMarin Pharmaceutical Inc. has begun Phase 1/2 trials for BMN 331, a C1-INH gene therapy. ADARx Pharmaceuticals, Inc. has begun a Phase 1 clinical trial for ADX-324, a prekallikrein siRNA inhibitor. Preclinical development programs for preventative treatment include KalVista's oral FXIIa inhibitor and Orchard Therapeutics plc and Pharming's *ex vivo* hematopoietic stem cell gene therapy (OTL-105).

We are developing STAR-0310 for the treatment of AD. The key competitive factors affecting the success of STAR-0310, if approved, are likely to be its safety and tolerability, efficacy, frequency of dosing, method of administration, convenience, price, and the availability of coverage and reimbursement from government and other third-party payors. In the United States, the FDA has approved two oral Janus kinase, or JAK, inhibitors for the treatment of AD: RINVOQ and CIBINQO. Additionally, the FDA has approved two biologics for the treatment of AD: DUPIXENT and ADBRY. Standard of care also includes systemic steroids and topical medications which can treat symptoms but do not address underlying disease. Moderate-to-severe patients who do not respond to topical prescription therapies typically turn to biologics as their next option, and, subsequently, to JAK inhibitors.

Both DUPIXENT and ADBRY are administered subcutaneously every two weeks, and work by targeting the Th2 inflammatory pathway (IL-4/13, and IL-13, respectively). RINVOQ and CIBINQO require daily oral administration and are only available to patients who do not sufficiently respond to biologics. While they tend to have better efficacy than the two approved biologics, there are significant safety concerns (including a boxed warning) associated with JAK inhibitors.

We are aware of additional programs in development for AD, which are focused largely on biologic approaches. Galderma's nemolizumab, an IL-31 antibody, and Eli Lilly's lebrikizumab, an IL-13 antibody, are under regulatory review for approval by the FDA. Additionally, a new class of biologics is in clinical development targeting OX40, the same target as for STAR-0310. Amlitelimab (Sanofi) is an anti-OX40 ligand (OX40L) antibody that is completing a Phase 2b trial in AD. Rocatinlimab (Amgen) is an afucosylated OX40 receptor (OX40R) antibody currently in Phase 3 trials in AD.

The enrollment and retention of patients in clinical trials for STAR-0215 or STAR-0310 may be disrupted or delayed as a result of clinicians' and patients' perceptions as to the potential advantages of STAR-0215 or STAR-0310 in relation to commercially available therapies and other programs in development, including approved products as well as any other new products that may be approved in the future, for the treatment of HAE or AD.

Our competitors may succeed in developing, acquiring or licensing technologies and drug products that are more effective, have fewer or more tolerable side effects, have more convenient dosing regimens, including the potential for biannual or annual dosing regimens, or are less costly than any product candidates that we may develop, which could render any future product candidates obsolete and noncompetitive.

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, or any future collaborators, may develop. Our competitors also may obtain FDA or other marketing approval for their products before we, or any future collaborators, are able to obtain approval for ours, which could result in our competitors establishing a strong market position before we, or any future collaborators, are able to enter the market.

Our potential future competitors may 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. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies, or as a result of the development of drug products that have more convenient dosing regimens. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

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

We have limited financial and managerial resources and are focused on the preclinical and clinical development of STAR-0215 as a potential treatment for HAE, a rare disease with unmet medical need, and STAR-0310 as a potential treatment for AD. We would expect that development of any other future product candidate would also be for specific indications that we identify as most likely to succeed, in terms of both their potential for marketing approval and commercialization. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications that may prove to have greater commercial potential.

Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on STAR-0215, STAR-0310 and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to the product candidate.

Preclinical development is uncertain. Our preclinical programs may experience delays or may never advance to clinical trials and we may be unsuccessful in identifying any new product candidates.

Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support the submission of an IND in the United States, or similar applications in other jurisdictions, including clinical trial application, or CTA, submissions in the European Union, or EU. Such studies are complex and may be subject to delays or increased costs due to our dependence upon third parties to assist us with such studies and the ability to source raw materials and the appropriate animals, including non-human primates, so that we can conduct such testing. There is currently a global shortage of non-human primates available for drug development. If the shortage continues, this could increase the cost of conducting our preclinical development and could also result in delays to our development timelines. In the event that the FDA or comparable foreign regulatory authorities require us to complete additional preclinical studies or we are required to satisfy other FDA requests or other requests of comparable foreign regulatory authorities prior to commencing clinical trials, the start of our clinical trials may be delayed or take longer to complete. Even after we receive and incorporate guidance from the FDA or comparable foreign regulatory authorities, such authorities may not agree that we have satisfied their requirements to commence any clinical trial or change their position on the acceptability of our trial design or the clinical endpoints selected, which may require us to complete additional preclinical studies or clinical trials or impose stricter approval conditions than we currently expect. We cannot be certain of the timely completion or outcome of our preclinical testing and studies and cannot predict if the FDA or comparable foreign regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications, including CTA submissions in the EU, will result in the FDA or comparable foreign regulatory authorities allowing clinical trials to begin or that we can meet the requirements imposed by such authorities for beginning such trials on a timely basis or at all.

In addition, any future research programs to identify new product candidates will require substantial technical, financial and human resources, and we may be unsuccessful in our efforts to identify new product candidates. If we are unable to identify suitable additional compounds for preclinical and clinical development, our ability to develop product candidates and obtain product revenues in future periods could be compromised, which could result in significant harm to our financial position and adversely impact our stock price.

We have never obtained marketing approval for a product candidate and we may be unable to obtain, or may be delayed in obtaining, marketing approval for any future product candidate we may seek to develop.

We have never obtained marketing approval for a product candidate. We have not yet succeeded and may never succeed in demonstrating efficacy and safety for any of our product candidates in a Phase 3 clinical trial or in obtaining marketing approval thereafter.

If we are able to advance STAR-0215, STAR-0310 or any other future product candidate into late-stage development, it is possible that the FDA, EMA or other applicable foreign regulatory authority may refuse to accept for substantive review any applications that we submit for marketing approval of such product candidates or may conclude after review of our data that our applications are insufficient to obtain marketing approval of such product candidate. If the FDA, EMA or other applicable foreign regulatory authority

does not accept or approve any applications that we submit for marketing approval, they may require that we conduct additional clinical or nonclinical studies, or conduct manufacturing validation studies, and submit that data before they will reconsider our applications. Depending on the extent of these or any other required studies, approval of any application that we submit may be delayed by several years or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be considered sufficient by the FDA, EMA or other applicable foreign regulatory authority.

Any delay in obtaining, or an inability to obtain, marketing approvals would prevent us from commercializing STAR-0215, STAR-0310 or any future product candidate, generating revenues and achieving and sustaining profitability. If any of these outcomes occur, we may be forced to abandon our development efforts for STAR-0215, STAR-0310 or any future product candidates, which could significantly harm our business.

If STAR-0215, STAR-0310 or any other future 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, or that of any future collaborators, to market the drug could be compromised.

Clinical trials of product candidates are conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that clinical trials for STAR-0215, STAR-0310 and any other future product candidate, or those of any future collaborator, may indicate an apparent positive effect of such product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If, following approval of a product candidate, we, or others, discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, any of the following adverse events could occur:

- regulatory authorities may withdraw their approval of the drug or seize the drug;
- we, or any future collaborators, may be required to recall the drug, change the way the drug is administered or conduct additional clinical trials;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular drug;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we, or any future collaborators, may be required to create a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients;
- we, or any future collaborators, could be sued and held liable for harm caused to patients;
- we may become the subject of government investigations, which would be expensive to manage and potentially result in the imposition of fines, injunctions or the imposition of civil or criminal penalties;
- the drug may become less competitive; and
- our reputation may suffer.

Any of these events could have a material and adverse effect on our operations and business and could adversely impact our stock price.

Even if STAR-0215, STAR-0310 or any other future 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 and the market opportunity for the product candidate may be smaller than we estimate.

Even if STAR-0215, STAR-0310 or any other future product candidate is approved by the appropriate regulatory authorities for marketing and sale, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in

the medical community. For example, physicians are often reluctant to switch their patients from existing therapies even when new and potentially more effective or convenient treatments enter the market. Further, patients often acclimate to the therapy that they are currently taking and do not want to switch unless their physicians recommend switching products or they are required to switch therapies due to lack of reimbursement for existing therapies.

Efforts to educate the medical community and third-party payors on the benefits of future product candidates may require significant resources and may not be successful. If STAR-0215, STAR-0310 or any other future product candidate is approved but does not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of STAR-0215, STAR-0310 or any other future product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of the product;
- the potential advantages of the product compared to existing approved treatments or alternative treatments, including the convenience and ease of administration compared to alternative treatments;
- the prevalence and severity of any side effects;
- the clinical indications for which the product is approved;
- whether the product is designated under physician treatment guidelines as a first-line therapy or as a second- or third-line therapy and whether there is an existing standard of care;
- limitations or warnings, including distribution or use restrictions, contained in the product's approved labeling;
- our ability, or the ability of any future collaborators, to offer the product for sale at competitive prices;
- the product's convenience and ease of administration compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- the strength of sales, marketing, market access and distribution support;
- the approval of other new products for the same indications;
- changes in the standard of care for the targeted indications for the product;
- the timing of market introduction of our approved products in relation to competitive products;
- availability and amount of reimbursement from government payors, managed care plans and other third-party payors;
- adverse publicity about the product or favorable publicity about competitive products; and
- potential product liability claims.

The potential market opportunities for product candidates are difficult to estimate precisely. Any estimates we make as to the potential market opportunities for STAR-0215, STAR-0310 or any other future product candidates will be predicated on many assumptions, including industry knowledge and publications, third-party research reports and other surveys. These assumptions will involve the exercise of significant judgment on the part of our management, will be inherently uncertain and the reasonableness of these assumptions may not have been assessed by an independent source. If any such assumptions prove to be inaccurate, the actual markets for STAR-0215, STAR-0310 or any other future product candidate could be smaller than our estimates of the potential market opportunities.

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

We currently do not have a formal sales, marketing or distribution infrastructure. To achieve commercial success for any approved product, we would need to either develop a sales and marketing organization or outsource these functions to third parties. We expect to use a combination of focused in-house sales and marketing capabilities and third-party collaboration, licensing and distribution arrangements to sell any products that receive marketing approval.

We generally expect that we would seek to retain full commercialization rights for products that we can commercialize with a specialized sales force and to retain co-promotion or similar rights when feasible in indications requiring a larger commercial infrastructure. The development of sales, marketing and distribution capabilities will require substantial resources, will be time-consuming and could delay any product launch. If the commercial launch of a product for which we recruit a sales force and establish marketing and distribution capabilities is delayed or does not occur for any reason, we could have prematurely or unnecessarily incurred these commercialization costs. This may be costly, and our investment could be lost if we cannot retain or reposition our sales and marketing personnel. In addition, we may not be able to hire or retain a sales force that is sufficient in size or has adequate expertise in the medical markets that we plan to target. If we are unable to establish or retain a sales force and marketing and distribution capabilities, at such time as we need to, our operating results may be adversely affected. If a potential partner has development or commercialization expertise that we believe is particularly relevant to a product, then we may seek to collaborate with that potential partner even if we believe we could otherwise develop and commercialize the product independently.

We may collaborate with third parties for commercialization of any products that require a large sales, marketing and product distribution infrastructure. We intend to potentially commercialize product candidates through collaboration, licensing and distribution arrangements with third parties. As a result of entering into arrangements with third parties to perform sales, marketing and distribution services, our product revenues or the profitability of these product revenues may be lower, perhaps substantially lower, than if we were to directly market and sell products in those markets. Furthermore, we may be unsuccessful in entering into the necessary arrangements with third parties or may be unable to do so on terms that are favorable to us. In addition, we may have little or no 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, either on our own or in collaboration with third parties, we will not be successful in commercializing any product candidates that receive marketing approval.

STAR-0215, STAR-0310 and any other future biologic product candidates will be regulated as biological products, or biologics, and therefore they may be subject to competition from biologic products that are biosimilar to or interchangeable with an FDA-licensed reference biologic product.

The Biologics Price Competition and Innovation Act of 2009, or BPCIA, created 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 biological products that are biosimilar to or interchangeable with an FDA-licensed reference 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 approval for a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. In December 2022, Congress clarified through the Food and Drug Omnibus Reform Act of 2022, or FDORA, that the FDA may approve multiple first interchangeable biosimilar biological products so long as the products are all approved on the same first day on which such a product is approved as interchangeable with the reference product and the exclusivity period may be shared amongst multiple first interchangeable products. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty, and any new policies or processes adopted by the FDA could have a material adverse effect on the future commercial prospects for our biological products.

We believe that our current and any of our future product candidates we develop as biologic products 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 Congressional action or otherwise, or that the FDA will not consider subject product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once licensed, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear and will depend on a number of marketplace and regulatory factors that are still developing.

Nonetheless, the approval of biosimilar products referencing any of our product candidates would have a material adverse impact on our business due to increased competition and pricing pressures.

For more information on biosimilars and regulatory exclusivity for biologic drugs in the United States, please see the section of our 2022 Annual Report on Form 10-K entitled "Business—Government Regulation and Product Approval—Biosimilars and Regulatory Exclusivity."

If the FDA or comparable foreign regulatory authorities approve generic versions of any of our future products that receive marketing approval through the NDA pathway, or such authorities do not grant such future products appropriate periods of data exclusivity before approving generic versions of our products, our sales could be adversely affected.

Once an NDA is approved, the product covered thereby becomes a "reference-listed drug" in the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the Orange Book. Manufacturers may seek approval of generic versions of reference-listed drugs through submission of abbreviated new drug applications, or ANDAs, in the United States. In support of an ANDA, a generic manufacturer need not conduct clinical trials to assess safety and efficacy. Rather, the applicant generally must show that its product has the same active ingredient(s), dosage form, strength, route of administration and conditions of use or labeling as the reference-listed drug and that the generic version is bioequivalent to the reference-listed drug, meaning it is absorbed in the body at the same rate and to the same extent. Generic products may be significantly less costly to bring to market than the reference-listed drug and companies that produce generic products are generally able to offer them at lower prices. Thus, following the introduction of a generic drug, a significant percentage of the sales of any branded product or reference-listed drug is typically lost to the generic product.

The FDA may not approve an ANDA for a generic product until any applicable period of non-patent exclusivity for the reference-listed drug has expired. The Federal Food, Drug, and Cosmetic Act, or FDCA, provides a period of five years of non-patent exclusivity for a new drug containing a new chemical entity, or NCE. For the purposes of this provision, an NCE is a drug that contains an active moiety that has previously been approved by the FDA in any other NDA. This interpretation was confirmed with enactment of the Ensuring Innovation Act in April 2021. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. Specifically, in cases where such exclusivity has been granted, an ANDA may not be submitted to the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification that a patent covering the reference-listed drug is either invalid or will not be infringed by the generic product, in which case the applicant may submit its application four years following approval of the reference-listed drug.

The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical trials, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application.

Generic drug manufacturers may seek to launch generic products following the expiration of any applicable exclusivity period we obtain if our product candidates are approved, even if we still have patent protection for such product candidates. Competition that any such product candidates of ours may face from generic versions of such products could materially and adversely impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on the investments we may make in those product candidates.

Business disruptions could delay completion of clinical trials, seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations, and those of third-party research institution collaborators, contract research organizations, or CROs, contract manufacturing operations, and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics such as the COVID-19

pandemic, and other natural or man-made disasters or business interruptions, for which we may be partly uninsured, as well as impacts of geopolitical events, including civil or political unrest (such as the war between Russia and Ukraine and the conflict in the Middle East), terrorist activity and unstable governments and legal systems. In addition, we expect that we will rely on third-party research institution collaborators for conducting research and development of STAR-0215, STAR-0310 and any other future product candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could delay completion of any clinical trials for such product candidates, seriously harm our operations and financial condition and increase our costs and expenses.

We are subject to risks associated with public health crises and epidemics/pandemics.

Public health outbreaks, epidemics, pandemics of contagious or infectious diseases, such as COVID-19, may significantly disrupt our business. Such outbreaks pose the risk that we or our employees, contractors, suppliers, or other partners may be prevented from conducting business activities for an indefinite period of time due to the spread of disease, or due to shutdowns that may be requested or mandated by federal, state and local governmental authorities. Business disruptions could include disruptions or restrictions on our ability to travel, as well as temporary closures of our facilities or the facilities of our contractors, suppliers, and other partners.

The development of STAR-0215, STAR-0310 or any other future product candidates could be negatively impacted by public health crises, epidemics or pandemics for a variety of reasons, including delays of the initiation, recruitment and overall timing of clinical trials, delays at the FDA and other regulatory authorities, the disruption or delays of regulatory or manufacturing activities, including due to facility shut downs, capacity constraints at third party manufacturers and increased costs or the inability to source key raw materials, or other adverse effects that negatively impact our business or operations.

A pandemic could affect the health and availability of our workforce as well as those of the third parties we rely on. Furthermore, delays and disruptions experienced by our collaborators or other third parties due to a pandemic could adversely impact the ability of such parties to fulfill their obligations, which could affect the clinical development of our product candidates. For example, the COVID-19 pandemic adversely impacted the global supply chain, primarily through constraints on raw materials, and these constraints on raw materials also impacted companies outside of our direct industry, which resulted in a competitive supply environment causing higher costs for a period during and following the COVID-19 pandemic.

Measures taken by governments, actions taken to protect employees and the broad impact public health crises and epidemics/pandemics would have on all business activities may materially and adversely affect our business, results of operations and financial condition.

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

We face an inherent risk of product liability claims as a result of the clinical testing of product candidates despite obtaining appropriate informed consents from our clinical trial participants. We will face an even greater risk if we or any future collaborators commercially sell any product that we may or they may develop. For example, we may be sued if any product we develop allegedly causes injury or is found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of any future product candidates. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for any future 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 resulting litigation;
- substantial monetary awards to trial participants or patients;

- loss of revenue; and
- the inability to commercialize any products that we may develop.

Although we maintain general liability insurance of $5.0 million in the aggregate and clinical trial liability insurance of $10.0 million in the aggregate, this insurance may not fully cover potential liabilities that we may incur. The cost of any product liability litigation or other proceeding, even if resolved in our favor, could be substantial. We will need to increase our insurance coverage if and when we begin selling any product candidate that receives marketing approval. In addition, insurance coverage is becoming increasingly expensive. If we are unable to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims, it could prevent or inhibit the development and commercial production and sale of any future product candidates, which could adversely affect our business, financial condition, results of operations and prospects.

Risks Related to Our Financial Position and Need for Additional Capital

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

Developing biopharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. We are continuing to conduct clinical trials, preclinical and nonclinical studies, including our Phase 1b/2 ALPHA-STAR trial, which we initiated in February 2023, our ALPHA-SOLAR trial, a long-term open-label clinical trial assessing the long-term safety and efficacy of STAR-0215, and preclinical and nonclinical studies to support the submission of an IND for STAR-0310 by year-end 2024. Additionally, we are ramping up manufacturing of clinical supplies for STAR-0215 and plan to begin the development of drug device combinations for our potential Phase 3 pivotal clinical trial and commercialization of STAR-0215. We expect that our expenses will increase substantially as a result of all of these activities. We will need to raise additional capital in order to fund the planned Phase 3 clinical trial of STAR-0215. In addition, we may in the future initiate new research, preclinical and clinical development efforts, and seek marketing approval, for other product candidates, and would expect our expenses to increase in connection with each of these activities. If we obtain marketing approval for any of our product candidates, we may incur significant commercialization expenses related to product sales, marketing, manufacturing and distribution to the extent that such sales, marketing, manufacturing and distribution are not the responsibility of a future collaborator, and these activities would require substantial additional funding. In addition, while we may seek one or more collaborators for future development of our product candidates, we may not be able to enter into a collaboration for any of our product candidates on suitable terms or at all. In any event, our existing cash, cash equivalents and short-term investments will not be sufficient to fund all of the efforts that we plan to undertake or to fund the completion of development of any of our product candidates. Furthermore, we have incurred and will continue to incur significant additional costs associated with operating as a public company.

Accordingly, we will be required to obtain substantial additional funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. We do not have any committed external source of funds. Adequate additional funding may not be available to us on acceptable terms, on a timely basis or at all, impacting our ability to execute on our strategic plans. General economic conditions, both inside and outside the U.S., including heightened inflation, capital market instability and volatility, interest rate and currency rate fluctuations, and economic slowdown or recession as well as health epidemics, such as the COVID-19 pandemic, and geopolitical events, including civil or political unrest (such as the war between Ukraine and Russia and the conflict in the Middle East), have resulted in a significant disruption of global financial markets. If the disruption persists and deepens, we could experience an inability to access additional capital. In addition, market volatility, high levels of inflation and interest rate fluctuations may increase our cost of financing or restrict our access to potential sources of future liquidity. Our failure to raise capital on acceptable terms as and when needed may force us to delay, reduce or eliminate our research and development programs or any future efforts to seek approval for and commercialize products, and would have a material adverse effect on our business, results of operations, financial condition and ability to pursue our business strategy.

Based on our current operating plan, we expect that our existing cash, cash equivalents and short-term investments as of September 30, 2023, together with the net proceeds from our offering of common stock and warrants in October 2023, are sufficient to fund our operating expenses and capital expenditure requirements into 2026. Our current operating plan includes the development of STAR-0215 and STAR-0310, including (i) for STAR-0215, support for all program activities up to the initiation of a planned Phase 3 pivotal trial and (ii) for STAR-0310, the upfront payment of $15.0 million we made in October 2023 to Ichnos Sciences SA and Ichnos Sciences Inc., or collectively Ichnos, in connection with our recently completed in-license of STAR-0310, the anticipated submission of an IND and the initiation and completion of the planned Phase 1a clinical trial of healthy subjects (and any related anticipated

milestone payments). Our estimate as to how long we expect our cash, cash equivalents and short-term investments to be able to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. Our future funding requirements will depend on many factors, including:

- our ability to meet our overall timing expectations for STAR-0215 and STAR-0310;
- the progress, timing, costs and results of clinical trials of, and research, preclinical and clinical development, and manufacturing efforts for, STAR-0215, STAR-0310 and any other future product candidates, including potential future clinical trials and all activities necessary to initiate and conduct clinical trials;
- our ability to enter into and the terms and timing of any additional collaborations, licensing or other arrangements that we may establish;
- the number and characteristics of future product candidates that we pursue and their development requirements;
- the outcome, timing and costs of seeking regulatory approvals;
- the costs of the evaluation, selection, testing and scale up activities related to developing a drug device combination for our product candidates for late-stage clinical trials and commercialization to the extent such costs are not the responsibility of any future collaborators;
- the costs of commercialization activities for any of our product candidates that receive marketing approval to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, market access, distribution, supply chain and manufacturing capabilities, scaling up the manufacturing of drug substance and drug product to clinical and commercial scale, securing all raw materials necessary to conduct such scale-up and successfully completing all other activities related thereto;
- subject to receipt of marketing approval, revenue, if any, received from commercial sales of our product candidates;
- if we obtain marketing approval of any of our products, our ability to successfully compete against other approved products that are approved or used as treatments for the indications for which our products are approved, including with respect to STAR-0215 in HAE and with respect to STAR-0310 in AD;
- our headcount growth and associated costs;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against intellectual property related claims; and
- the costs of operating as a public company.

Furthermore, we hold a portion of cash and cash equivalents that we use to meet our working capital and operations expense needs in deposit accounts at one financial institution. The balance in these accounts typically exceed the Federal Deposit Insurance Corporation standard deposit insurance limit of $250,000. If a financial institution in which we hold such funds fails, we could be subject to a risk of loss of all or a portion of such uninsured funds or be subject to a delay in accessing all or a portion of such insured funds. Any such loss or lack of access to these funds could adversely impact our short-term liquidity and ability to meet our operating expense obligations.

We have incurred significant losses since inception. We expect to incur losses for at least the next several years and may never achieve or maintain profitability.

Our losses from operations were $51.8 million and $194.9 million (including $164.6 million of in-process research and development expenses) for the years ended December 31, 2022 and December 31, 2021, respectively. As of September 30, 2023, we had an accumulated deficit of $549.1 million. We have not generated any revenues from product sales, have not completed the development of

any product candidate and may never have a product candidate approved for commercialization. We have financed our operations to date primarily through private placements of preferred stock before we became a public company and our private placement of preferred stock in February 2021, which we refer to as the February 2021 Financing, registered offerings of our common stock and/or warrants, and our at-the-market programs, and have devoted substantially all of our financial resources and efforts to research and development, including preclinical studies and clinical development programs. Our net losses may fluctuate significantly from quarter to quarter and year to year. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital.

We expect to continue to incur significant expenses and operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter. Net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. We anticipate that we will continue to incur significant expenses and operating losses and we may incur increased expenses if and to the extent we:

- initiate and continue research and preclinical and clinical development efforts for STAR-0215, STAR-0310 and any other future product candidates;
- seek to identify and develop any other future product candidates;
- seek regulatory and marketing approvals for STAR-0215, STAR-0310 and any other future product candidate that successfully completes clinical trials, in the United States and other markets;
- establish sales, marketing, market access, distribution, supply chain and other commercial infrastructure in the future to commercialize products for which we may obtain marketing approval, if any;
- require the manufacture of larger quantities of STAR-0215, STAR-0310 and any other future product candidates for clinical development and potentially commercialization;
- implement changes in product candidate manufacturing or formulation;
- develop drug device combinations for our product candidates for late-stage clinical trials and commercialization;
- maintain, expand and protect our intellectual property portfolio; and
- hire and retain additional personnel or add information systems, equipment or physical infrastructure to support our operations.

To become and remain profitable, we or any potential future collaborators must develop and eventually commercialize at least one product candidate with significant market potential. This will require that we or our collaborators be successful in a range of challenging activities, including completing preclinical studies and clinical trials of one or more product candidates, obtaining marketing approval for one or more these product candidates, manufacturing, marketing and selling those products for which we or our collaborators may obtain marketing approval and satisfying any post-marketing requirements. We or our collaborators may never succeed in any or all of these activities and, even if we or our collaborators do succeed, we or our collaborators may never generate revenue that is significant or large enough to achieve profitability. 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 would decrease the value of our company and could impair our ability to raise capital, maintain our research and development efforts, expand our business or continue our operations. A decline in the value of our company also could cause investors to lose all or part of their investments in us.

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

We will need to raise additional capital to develop and commercialize STAR-0215 and STAR-0310 or to acquire, develop and commercialize any other future product candidates or to pursue other strategic options. To the extent that we raise additional capital through the sale of common stock, convertible securities or other equity securities, our existing stockholders' ownership interests may be substantially diluted, and the terms of these securities could include liquidation or other preferences and anti-dilution protections that could adversely affect your rights as a common stockholder. For example, in connection with the acquisition of Quellis Biosciences, Inc.

or Quellis in January 2021 and our February 2021 Financing, we issued an aggregate of 86,077 shares of Series X, of which 53,532 shares of Series X Preferred Stock automatically converted into 8,921,966 shares of our common stock upon the stockholder approval of the conversion of the Series X Preferred Stock into common stock in June 2021. Subsequently, an additional 1,090 shares were converted into 181,698 shares of common stock. On January 3, 2023, an additional 348 shares have subsequently converted into 57,910 shares of common stock. The remaining 31,107 shares of Series X Preferred Stock are convertible into 5,184,479 shares of common stock at the election of the holders thereof, subject to certain beneficial ownership limitations. In addition, our June 2018, February 2019 and October 2023 registered offerings of common stock and common stock warrants and our January 2020 and December 2022 registered offerings of common stock were highly dilutive to existing stockholders' ownership interests. Further, exercise of the common stock warrants sold in our June 2018, February 2019 and October 2023 offerings could result in additional dilution upon exercise.

Debt financing, if available, would result in periodic payment obligations and may involve agreements that include restrictive covenants that limit our ability to take specific actions, such as incurring additional debt, making capital expenditures, creating liens, redeeming stock or declaring dividends, that could adversely impact our ability to conduct our business. In addition, securing additional financing could require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee the development of any future product candidate.

If we raise additional funds through collaborations or marketing, distribution, licensing or royalty arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams 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, 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.

Risks Related to Our Dependence on Third Parties

We may seek to establish collaborations and, if we are not able to establish them on commercially reasonable terms, we may have to alter our development and commercialization plans.

The development and commercialization of product candidates require substantial cash to fund expenses. We may seek one or more collaborators for the development and commercialization of STAR-0215, STAR-0310 or any other future product candidates. Likely collaborators may include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies.

Collaborations are complex and time-consuming to negotiate and document. Further, there have been a significant number of business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. In addition, any collaboration agreements that we enter into in the future may contain, restrictions on our ability to enter into potential collaborations or to otherwise develop specified compounds.

We face significant competition in seeking appropriate collaborators and strategic partners. Whether we reach a definitive agreement for a collaboration or strategic partnership will depend, among other things, upon our assessment of the other party's resources and expertise, the terms and conditions of the proposed transaction and the proposed party's evaluation of a number of factors. Those factors may include the potential differentiation of ours or a partner's product candidate from competing product candidates, design or results of clinical trials, the likelihood of approval by the FDA or comparable foreign regulatory authorities and the regulatory pathway for any such approval, the potential market for the product candidate, the costs and complexities of manufacturing and delivering the product to patients and the potential of competing products. The collaborator or strategic partner may also be considering alternative transaction types and structures that may be more attractive than the one with us.

We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, 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 increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop the product candidate or bring it to market and generate product revenue.

If we enter into collaborations with third parties for the development and commercialization of a product candidate, our prospects with respect to such product candidate will depend in significant part on the success of those collaborations.

If we enter into collaborations for the development and commercialization of a product candidate, we will have limited control over the amount and timing of resources that our collaborators will dedicate to the development or commercialization of such product candidates. Our ability to generate revenues from these arrangements will depend on any future collaborators' abilities to successfully perform the functions assigned to them in these arrangements. In addition, any future collaborators may have the right to abandon research or development projects and terminate applicable agreements, including funding obligations, prior to or upon the expiration of the agreed upon terms. Collaborations involving product candidates pose a number of risks, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of a product candidate or may elect not to continue or renew development or commercialization programs, based on clinical trial results, changes in the market or competitive landscape, 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;
- a collaborator with marketing and distribution rights to one or more products may not commit sufficient resources to the marketing and distribution of such product or products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination 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 maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated and, if terminated, may result in negative publicity for our product candidate and the need for additional capital to pursue further development or commercialization of the applicable product candidates.

In addition, all of the risks related to product development, regulatory approval and commercialization described in this "Risk Factors" section would apply to the activities of our collaborators. Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If any future collaborator of ours is involved in a business combination or a sale or other transaction involving our collaboration, it or the party with which it entered into a business combination, sale or other transaction could decide to delay, diminish or terminate the development or commercialization of any product candidate licensed to it by us.

We rely on third parties to conduct our preclinical studies and clinical trials. If they do not perform satisfactorily, our business could be significantly harmed.

We rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct ongoing and planned preclinical studies and clinical trials of STAR-0215, STAR-0310 or any other future product candidates. Any of these third parties could terminate its engagement with us under certain circumstances or encounter, for example, business challenges, such as a loss of business, health epidemics, such as the COVID-19 pandemic, or the impacts of geopolitical events, including

civil or political unrest (such as the war between Russia and Ukraine and the conflict in the Middle East), or enter into transactions, such as business combinations, that temporarily or permanently impact the amount or type of resources that they are able or willing to devote to our engagement. We might not be able to enter into alternative arrangements or do so on commercially reasonable terms or on a timely basis. In addition, there is a natural transition period when a new CRO begins work. As a result, delays would likely occur, which could materially impact our ability to meet our expected preclinical and clinical development timelines and harm our business, financial condition and prospects.

Further, our reliance on these third parties for preclinical and clinical development activities limits our control over these activities, but we remain responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards. For example, notwithstanding the obligations of a CRO for a trial of a product candidate, we 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 and most other comparable regulatory authorities outside the United States require us to comply with standards, commonly referred to as current 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. The FDA and other comparable regulatory authorities outside the United States enforce these GCPs through periodic inspections of trial sponsors, principal investigators, clinical trial sites and IRBs. If we or any of 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 or other comparable regulatory authorities outside the United States may require us to perform additional clinical trials before approving a product candidate, which would delay the marketing approval process. We cannot be certain that, upon inspection, the FDA or other comparable regulatory authorities outside the United States will determine that any of our clinical trials comply with GCPs. Similar standards, known as Good Laboratory Practices, apply to preclinical studies and nonclinical trials and other studies. We are also required to register clinical trials and post the results of completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within certain timeframes. Other regions, including the EU, have similar requirements. The failure to comply with these registration and posting requirements can result in fines, adverse publicity and civil and criminal sanctions.

Furthermore, the third parties that conduct preclinical studies and clinical trials on our behalf are not our employees, and except for remedies available to us under our agreements with such contractors, we are not able to control whether or not they devote sufficient time, skill and resources to our development programs. Any such contractors may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other drug development activities, which could impede their ability to devote appropriate time to our preclinical and clinical programs. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our preclinical studies or clinical trials in accordance with regulatory requirements or our stated protocols, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for the applicable product candidates. If that occurs, we would not be able to, or may be delayed in our efforts to, successfully commercialize such product candidates. In such an event, our financial results and the commercial prospects for any product candidates that we seek to develop could be harmed, our costs could increase and our ability to generate revenues could be impaired.

We also rely on other third parties to store and distribute drug supplies for any clinical trials we pursue. Any performance failure on the part of any such distributors or impacts from geopolitical events, including civil or political unrest (such as the war between Ukraine and Russia and the conflict in the Middle East), terrorist activity and unstable governments and legal systems could delay clinical development or marketing approval of any future product candidates or commercialization of any resulting products, producing additional losses and depriving us of potential product revenue.

The manufacturing of pharmaceutical products and, in particular, biologics, is complex and we do not have our own manufacturing capabilities. We rely on third parties to produce preclinical, clinical and commercial supplies of any current and future product candidates.

We currently have no manufacturing facilities and rely on third-party contract manufacturers to manufacture all of our preclinical product candidate supplies and clinical trial product supplies and will need to rely on third-party contract manufacturers to manufacture any commercial supply or drug device combination for a product candidate. We are also using a contract manufacturer to build the master cell bank that will be necessary for the manufacture of STAR-0310, which we recently in-licensed. We do not own, nor do we plan to own, any manufacturing facilities. There can be no assurance that our preclinical, clinical and commercial development product supplies, including drug substance, drug product, planned drug device combinations, or the master cell bank for STAR-0310, that are being manufactured by third parties will not be delayed, limited or interrupted, or be of satisfactory quality or continue to be available at acceptable prices. Additionally, the process of manufacturing pharmaceutical products and, in particular, biologics is complex, highly regulated, and subject to multiple risks. Manufacturing biologics is highly susceptible to product loss due to contamination, equipment

failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics, difficulties in scaling the production process and use of excipients which may, among other things, impact shelf life and present concerns with process controls. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, other supply disruptions and higher costs. If microbial, viral or other contaminations are discovered at the facilities of our third-party contract manufacturers, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials, result in higher costs of drug product and adversely affect our business.

If the contract manufacturers we engage are unable to supply us with sufficient preclinical or clinical quality and quantities of our product candidates, drug device combinations for our product candidates, or to build the master cell bank for STAR-0310, and we are unable to timely establish an alternate supply from one or more third-party contract manufacturers, we will experience delays in our development efforts as we seek to locate and qualify new or additional manufacturers. In particular, any replacement of our third-party contract manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements or capacity could be limited at each of the qualified replacements. We obtain drug product and drug substance from single third-party contract manufacturers for STAR-0215, and plan to follow a similar model for STAR-0310, which exacerbates these and other related risks for us. Additionally, contract manufacturers may rely on single source suppliers for certain of the raw materials or drug components for our preclinical and clinical product supplies. We may be unable to obtain raw materials or drug components for an indeterminate period of time if any of third-party suppliers and manufacturers were to cease or interrupt production or otherwise fail to supply these materials or components to us for any reason, including due to regulatory requirements or actions (including recalls), adverse financial developments at or affecting the supplier or manufacturer, failure by the supplier or manufacturer to comply with current good manufacturing practices, or cGMPs, contaminations, business interruptions, or labor shortages or disputes. Suppliers may extend lead times, limit supplies or increase prices due to capacity constraints or other factors beyond our control. We cannot be sure that single source suppliers for our raw materials or drug components will remain in business or that they will not be purchased by one of our competitors or another company that is not interested in continuing to produce these raw materials or components for our intended purpose. If current or future suppliers are delayed or unable to supply sufficient raw materials or components to manufacture product for our preclinical studies and clinical trials, we may experience delays in our development efforts as materials are obtained or we locate and qualify new raw material manufacturers.

The manufacturing process for a clinical candidate is subject to FDA and foreign regulatory authority review. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with their standards, such as cGMPs. In the event that any of our manufacturers fail to comply with such requirements or to perform their obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third-party, which we may not be able to do on reasonable terms or on a timely basis, if at all. The transfer of the manufacturing of biologic products to a new contract manufacturer and any additional process development that may be necessary can be lengthy and involve significant additional costs. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer would negatively affect our ability to develop product candidates in a timely manner or within budget.

Further, our reliance on third-party manufacturers exposes us to risks beyond our control, including the:

- inability to meet our drug specifications, quality requirements or drug device combination requirements consistently;
- inability to initiate or continue preclinical studies or clinical trials of product candidates or drug device combinations under development;
- delay or inability to procure or expand sufficient manufacturing capacity;
- costs and validation of new equipment and facilities required for scale-up;
- inability of our third-party manufacturers to execute process development, manufacturing, technology transfers, manufacturing procedures and other logistical support requirements appropriately or on a timely basis;
- manufacturing and drug quality issues, including related to scale-up of manufacturing;

- failure to comply with cGMP and similar foreign standards;
- reliance on a limited number of sources, and in some cases, potentially single sources for drug components and raw materials, such that if we are unable to secure a sufficient supply of these drug components and raw materials, we will be unable to manufacture and sell our future product candidate in a timely fashion, in sufficient quantities or under acceptable terms;
- price increases or decreased availability of drug components or raw materials;
- lack of qualified backup suppliers for those components and raw materials that are purchased from a sole or single source supplier;
- inability to negotiate development and manufacturing agreements with third parties under commercially reasonable terms, if at all;
- breach, termination or nonrenewal of development and manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- disruption of operations of our third-party manufacturers or suppliers by conditions unrelated to our business or operations, including supply chain issues, capacity constraints, transportation and labor disruptions, global competition for resources, the bankruptcy of the manufacturer or supplier, a business combination or strategic transaction involving the manufacturer or supplier, the issuance of an FDA Form 483 notice or warning letter and/or general economic conditions, heightened inflation, interest rate and currency rate fluctuations, and economic slowdown or recession;
- disruptions of operations caused by geopolitical events, including civil or political unrest (such as the war between Ukraine and Russia and the conflict in the Middle East), terrorist activity, insurrection or other wars or significant conflicts, unstable governments and legal systems man-made or natural disasters or public health pandemics or epidemics, including, for example, the COVID-19 pandemic;
- carrier disruptions or increased costs that are beyond our control, including increases in material, labor or other manufacturing-related costs or higher supply chain logistics costs;
- failure to deliver our drugs under specified storage conditions and in a timely manner; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

Some of these events could be the basis for FDA action, including injunction, recall, seizure or total or partial suspension of production, any of which could result in a failure to begin our clinical trials or having to stop or delay ongoing clinical trials. In addition, our third-party manufacturers and suppliers are subject to numerous environmental, health and safety laws and regulations, including those governing the handling, use, storage, treatment and disposal of waste products, and failure to comply with such laws and regulations could result in significant costs associated with civil or criminal fines and penalties for such third parties. Based on the severity of the regulatory action, our preclinical, clinical or commercial supply of drug and packaging and other services could be interrupted or limited, which could harm our business.

In addition, our contract manufacturers are or may be engaged with other companies to supply and manufacture materials or products for such companies, which also exposes our suppliers and manufacturers to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may also affect the regulatory clearance of a contract supplier’s or manufacturer’s facility, which could impact the contract supplier’s or manufacturer’s ability to manufacture for us.

In addition, a material shortage, contamination, recall or restriction on the use of substances in the manufacture of our product candidates, or the failure of any of our key suppliers to deliver necessary components required for the manufacture of our product candidates, could adversely impact or disrupt the commercial manufacture or the production of preclinical or clinical material, which could materially and adversely affect our development timelines and our business, financial condition, results of operations, and future prospects.

Any of these events could lead to preclinical study or clinical trial delays or failure to obtain regulatory approval or impact our ability to successfully commercialize our current or any future product candidates once approved.

Risks Related to Our Intellectual Property

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

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to STAR-0215, STAR-0310 and any other future product candidates. If we do not adequately protect our intellectual property, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. See the section of our 2022 Annual Report on Form 10-K entitled "Business — Intellectual Property" for more details of our STAR-0215 patent portfolio. For STAR-0310, a preclinical program, in October 2023, Ichnos filed with the USPTO a provisional patent application covering STAR-0310 and its use in treating various disorders, including AD. This provisional patent application is included in the intellectual property exclusively licensed to us by Ichnos under the License Agreement, as defined below. The patent application and approval process is expensive and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. Failure to protect or to obtain, maintain or extend adequate patent and other intellectual property rights could materially adversely affect our ability to develop and market our products and product candidates. The enforcement, defense and maintenance of such patents and other intellectual property rights may be challenging and costly.

We cannot be certain that any patent application directed to our current or future product candidates will be issued in a form that provides us with adequate protection to prevent competitors from developing competing products. As a biopharmaceutical company, our patent position is uncertain because it involves complex legal and factual considerations. The standards applied by USPTO, and foreign patent offices in granting patents are not always applied uniformly or predictably. For example, there is no uniform worldwide policy regarding patentable subject matter or the scope of claims allowable in biopharmaceutical patents. Consequently, patents may not issue from any applications that are currently pending or that we file in the future. As such, we do not know the degree of future protection that we will have for our product candidates and their use. The scope of patent protection that the USPTO and foreign patent offices will grant with respect to our product candidates is uncertain. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. For example, it is possible that the USPTO and foreign patent offices will not allow broad antibody claims that specifically cover our STAR-0215 and STAR-0310 product candidates and antibodies closely related to them. As a result, upon receipt of FDA approval, or regulatory approval in foreign jurisdictions, competitors may be free to market antibodies almost identical to ours, including biosimilar antibodies, thereby decreasing our market share. However, a competitor cannot submit to the FDA an application for a biosimilar product based on STAR-0215, STAR-0310 or any future biologic products until four years following the date of approval of our "reference product," and the FDA may not approve such a biosimilar product until 12 years from the date on which the reference product was approved. See the section of our 2022 Annual Report on Form 10-K entitled "Business — Government Regulation and Product Approval — Biosimilars and Regulatory Exclusivity" for more details regarding biosimilar regulatory exclusivities.

Our owned and in-licensed pending patent applications and any future patent applications we file cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, patents are granted to the party who was the first to file a patent application. However, prior to March 16, 2013, in the United States, patents were granted to the party who was the first to invent the claimed subject matter. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions.

Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third party preissuance submission of prior art to the USPTO, or become involved in post-grant review procedures, oppositions, derivations, reexaminations, inter partes review or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity 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 antibodies or compounds similar or identical to our product candidates, or limit the duration of the patent protection of our product candidates. In addition, 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.

Patent applications may not result in patents being issued which protect any current and future product candidates, in whole or in part, or which effectively prevent others from commercializing competitive products. Changes in either the patent laws or interpretation. If the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, European patent law restricts the patentability of methods of treatment of the human body more than United States law does.

Even if patent applications that we file 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. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may also seek approval to market their own products similar to or otherwise competitive with any of our future products. Alternatively, our competitors may seek to market biosimilar versions of any approved products by submitting an application for a biosimilar product under the BPCIA. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

If we do not obtain protection under the Hatch-Waxman Act and similar non-United States legislation for extending the term of patents covering each of our product candidates, our business may be materially harmed.

Patents have a limited duration. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest United States non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates, their manufacture, or use are obtained, once the patent life has expired, we may be open to competition from competitive products, including 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 patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our United States patents, if issued, may be eligible for limited patent term extension under the Hatch-Waxman Act, or under similar legislation in other countries. The Hatch-Waxman Act permits a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. The patent term 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. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner than we expect. As a result, our revenue from applicable products could be reduced, possibly materially.

We rely on in-licensed patent and other intellectual property rights for our STAR-0310 program and we may need to obtain licenses from third parties to other intellectual property rights for the development and commercialization of our STAR-0310 and STAR-0215 programs; if we fail to comply with our existing or future obligations under these licenses, or if these licenses are terminated, we could lose license rights that are important to our business.

Our ability to develop and commercialize our STAR-0310 program is heavily dependent on an in-license to patent rights and other intellectual property granted to us by Ichnos. On October 4, 2023, we entered into a license agreement, or the License Agreement, with Ichnos, pursuant to which Ichnos granted us an exclusive (even as to Ichnos and its affiliates), worldwide, and sublicensable right and license to certain patent rights and related know-how to develop, manufacture, and commercialize Ichnos' proprietary OX40 portfolio. The OX40 portfolio includes Ichnos' proprietary OX40 antagonist monoclonal antibody, with the generic name telazorlimab and also

referred to by Ichnos as “ISB 830” as well as Ichnos’ proprietary affinity matured next generation OX40 antagonist monoclonal antibody referred to by Ichnos as “ISB 830-X8”. We are developing STAR-0310, which was engineered from ISB 830-X8 with YTE half-life extension technology modification, for AD and potentially for other allergic and immunological diseases. STAR-0310 is currently in preclinical development. Ichnos has also agreed not to develop or commercialize any product that directly modulates the OX40 receptor.

Under the License Agreement, we agreed to use commercially reasonable efforts to develop, obtain regulatory approval for, and commercialize at least one product that contains or comprises a licensed compound in the United States, France, Germany, Italy, Spain, the United Kingdom and Japan. The License Agreement imposes on us payment of development, regulatory and commercial milestones, as well as tiered royalties and other obligations. If we fail to comply with our obligations under the License Agreement, or we are subject to a bankruptcy, Ichnos may have the right to terminate the license, in which event we would not be able to market products covered by the License Agreement. Our business could suffer, for example, if the License Agreement terminates, if Ichnos fails to abide by the terms of the license, or if the licensed patents or other rights are found to be invalid or unenforceable.

In the future, we may need to obtain licenses to intellectual property rights necessary to develop and commercialize our product candidates, including STAR-0215 and STAR-0310, or may need to amend existing or future licenses. If we are unable to obtain or amend such licenses at a reasonable cost or on reasonable terms, we may be unable to develop or commercialize our product candidates, which could harm our business significantly.

As noted above, our License Agreement with Ichnos imposes, and we expect that future license agreements will impose, diligence obligations, milestone and royalty payments, indemnification and other obligations on us. If we fail to comply with our obligations under one or more of these licenses, our licensors, including Ichnos, may have the right to terminate the license agreement at issue. If one or more of these licenses is terminated, we may be unable to develop or commercialize our product candidates, including STAR-0215 and STAR-0310. Termination of any of our current or future license agreements or reduction or elimination of our licensed rights may require us to negotiate new or reinstated licenses with less favorable terms, even if available at all.

In addition, our license agreements are, and future license agreements are likely to be, 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 the licensed rights, or increase what we believe to be our diligence, development, regulatory, commercialization, financial or other obligations under the relevant agreement. In addition, if disputes over the license agreements or the in-licensed intellectual property prevent or impair our ability to maintain our current license agreements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidate. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

License agreements we may enter into in the future may be non-exclusive, or may not include all territories or fields of use of interest to us. Accordingly, third parties may also obtain licenses from such licensors to the same intellectual property rights they have licensed to us. Accordingly, the licenses granted to us may not provide us with exclusive rights to use such patent and other intellectual property rights in all relevant fields of use and in all territories in which we may wish to develop or commercialize our product candidates, which may permit competitors to develop and commercialize a competitive product.

Furthermore, in some cases, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we in-license from third parties. Therefore, we cannot be certain that any in-licensed patent rights will be prosecuted, maintained and enforced in a manner consistent with the best interests of our business. If our future licensors or collaboration partners fail to obtain, maintain or protect any patents or patent applications licensed to us, decide not to pursue litigation against third-party infringers, fail to prosecute infringement, or fail to defend against counterclaims of patent invalidity and unenforceability, our rights to such patents and patent applications may be reduced or eliminated and our right to develop and commercialize any of our product candidates that are the subject of such licensed rights could be adversely affected.

Disputes may arise among us and our current and future licensors regarding intellectual property subject to a licensing agreement, including:

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

- our right to sublicense patent and other rights to third parties under any collaboration relationships we might enter into in the future;
- our diligence obligations under the license agreement with respect to the use of licensed technology to develop and commercialize our product candidates, and what activities satisfy those diligence obligations;
- the ownership of inventions and know how resulting from the joint creation or use of intellectual property by our licensors and us; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed, or license in the future, prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents, trademarks, copyrights or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents are invalid or unenforceable, or both. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our patent claims do not cover the invention. An adverse outcome in a litigation or proceeding involving our patents could limit our ability to assert our patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive business position, business prospects and financial condition. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during litigation. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

An intellectual property litigation could lead to unfavorable publicity that could harm our reputation and cause the market price of our common stock to decline.

During the course of any patent litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our products, programs, or intellectual property could be diminished. In such event, the market price of our common stock may decline.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing current and future product candidates.

Our commercial success depends, in part, on our ability to develop, manufacture, and market our current as well as any future product candidates, without infringing the intellectual property and other proprietary rights of third parties. If any third-party patents or patent applications are found to cover our current or any future product candidates or their methods of use, or other aspects of our current

or future product candidates, we may not be free to manufacture or market such product candidates as planned without obtaining a license, which may not be available on commercially reasonable terms, or at all, or we may incur significant legal fees or damages.

In spite of our efforts to avoid obstacles and disruptions arising from third-party intellectual property, it is impossible to establish with certainty that our programs directed to our current and any future product candidates will be free of claims by third-party intellectual property holders. Even with modern databases and on-line search engines, literature searches are imperfect and may fail to identify relevant patents and published applications. Even when a third-party patent is identified, we may conclude upon a thorough analysis, that we do not infringe the patent or that the patent is invalid. If the third-party patent owner disagrees with our conclusion and we continue with the business activity in question, patent litigation may be initiated against us. Alternatively, we might decide to initiate litigation in an attempt to have a court declare the third-party patent invalid or non-infringed by our activity. In either scenario, patent litigation typically is costly and time-consuming, and the outcome is uncertain. The outcome of patent litigation is subject to uncertainties that cannot be quantified in advance, for example, the credibility of expert witnesses who may disagree on technical interpretation of scientific data. Ultimately, in the case of an adverse outcome in litigation, we could be prevented from commercializing a product or using certain aspects of our technology platform as a result of patent infringement claims asserted against us. This could have a material adverse effect on our business.

There is a substantial amount of intellectual property litigation in the biopharmaceutical industry, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our current or future product candidates, including interference proceedings before the USPTO. Third parties may assert infringement claims against us based on existing or future intellectual property rights. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The biopharmaceutical industry has produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that any current or future product candidates, products, methods, processes, modeling or similar work either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. For example, we are aware of a U.S. patent directed to an antibody that binds plasma kallikrein. In the event that the owner of this patent were to bring an infringement action against us, we may have to argue that STAR-0215, its manufacture or use does not infringe a valid claim of this patent. We cannot guarantee that a court would find in our favor on questions of infringement or validity. Furthermore, even if our arguments are successful, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product candidate or product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product candidate. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing any future product candidates or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

Our involvement in litigation, and in, e.g., any interference, derivation, reexamination, inter partes review, opposition or post-grant proceedings or other intellectual property proceedings in the United States, or other jurisdictions, may divert management time from focusing on business operations, could cause us to spend significant amounts of money and may have no guarantee of success. Any current and potential intellectual property litigation also could force us to do one or more of the following:

- stop selling, manufacturing or using our products in the United States or other jurisdictions that use the subject intellectual property;
- obtain from a third party asserting its intellectual property rights, a license to sell or use the relevant technology, which license may not be available on reasonable terms, or at all, or may be non-exclusive thereby giving our competitors access to the same technologies licensed to us;

- redesign those products or processes that use any allegedly infringing or misappropriated technology, which may result in significant cost or delay to us, or which redesign could be technically infeasible; or

- pay damages, including the possibility of treble damages in a patent case if a court finds us to have willfully infringed certain intellectual property rights.

If we are unable to protect the confidentiality of our trade secrets, the value of our technology could be materially adversely affected and our business would be harmed.

Along with patent protection, we also rely on trade secret protection for our proprietary information that is not amenable to, or that we do not consider appropriate for, patent protection, including, for example, certain aspects of our manufacturing processes. We seek to protect these trade secrets, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, consultants, independent contractors, CROs, advisors, contract manufacturers, suppliers and other third parties. We also enter into confidentiality and invention or patent assignment agreements with employees and certain consultants.

Trade secrets and confidential know-how are difficult to maintain as confidential. Although we use reasonable efforts to protect our trade secrets, any party with whom we have executed a confidentiality agreement may breach that agreement and disclose our proprietary information, including our trade secrets.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. Accordingly, we may not be able to obtain adequate remedies for such breaches, despite any legal action that we might take against persons making such unauthorized disclosures. In addition, courts outside the United States sometimes are less willing than United States courts to protect trade secrets.

If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such third party, or those to whom they communicate such technology or information, 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, our business and competitive position could be harmed.

Those with whom we collaborate on research and development related to current and future product candidates may have rights to publish data and other information to which we have rights. In addition, we sometimes engage individuals or entities to conduct research relevant to our business. The ability of these individuals or entities to publish or otherwise publicly disclose data and other information generated during the course of their research is subject to certain contractual limitations. These contractual provisions may be insufficient or inadequate to protect our confidential information. If we do not apply for patent protection prior to such publication, or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act, or the Leahy-Smith Act, signed into law in September 2011, could increase those uncertainties and costs. The Leahy-Smith Act included a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents, for example, via post grant review and inter partes review proceedings at the USPTO. In addition, the Leahy-Smith Act transformed the United States patent system into a “first to file” system. However, the Leahy-Smith Act and its implementation could make it more difficult to obtain patent protection for our inventions and 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 harm our business, results of operations and financial condition.

The United States Supreme Court has ruled on several patent cases, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations; including the scope of patent protection for antibodies. Additionally, there have been proposals for additional changes to the patent laws of the United States and other countries

that, if adopted, could impact our ability to enforce our proprietary technology. Depending on future actions by the Congress, the United States courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

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. The following examples are illustrative:

- others may be able to make antibodies that are the same as or similar to STAR-0215, STAR-0310 or any other future product candidates but that are not covered by the claims of patents that we own or have rights to;
- we or our licensors or any current or future strategic partners might not have been the first to conceive or reduce to practice the inventions covered by our pending patent application;
- we or our licensors or any future strategic partners might not have been the first to file patent applications covering certain of our inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent rights will not lead to issued patents, or that patents, if granted, may not provide us with any competitive advantage, or may be held invalid or unenforceable, 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 and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- third parties performing manufacturing or testing for us using our products or technologies could use the intellectual property of others without obtaining a proper license;
- we may not develop additional technologies that are patentable; and
- third parties may allege that our development and commercialization of STAR-0215, STAR-0310 or any other future products may infringe their intellectual property rights, the outcome of which may have an adverse effect on our business.

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

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. 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 noncompliance 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. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. If we fail to maintain the patents and patent applications covering any future product candidates, our competitive position would be adversely affected.

We may obtain only limited geographical protection with respect to certain patent rights, which may diminish the value of our intellectual property rights in those jurisdictions and prevent us from enforcing our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive. Accordingly, we may not file for patent protection in all national and regional jurisdictions where such protection may be available. In addition, we may decide to abandon national and regional patent applications before grant. Finally, the grant proceeding of each national/regional patent is an independent proceeding which may lead to situations in which applications might in some jurisdictions be refused by the relevant patent offices, while granted by others. It is also quite common that depending on the country, the scope of patent protection may vary for the same product candidate or technology.

The requirements for patentability may differ in certain countries, particularly in developing countries. 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 may obtain patent protection, but where patent enforcement is not as strong as that in the United States. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents or where any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing with us.

In addition, our ability to protect and enforce our intellectual property rights may be adversely affected by changes in foreign intellectual property laws. For example, the European Union opened a Unified Patent Court, or UPC, in June 2023. The UPC is a common patent court that hears patent infringement and revocation proceedings effective for member states of the European Union. This could enable third parties to seek revocation of any of our European patents, should they be granted, in a single proceeding at the UPC rather than through multiple proceedings in each of the jurisdictions in which the European patent is validated. Any such revocation and loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates. Moreover, the controlling laws and regulations of the UPC will develop over time, and may adversely affect our ability to enforce our European patents or defend their validity. We may decide to opt out our patent applications, if filed, and our European patents, if granted, from the UPC. If certain formalities and requirements are not met, however, our European patent applications, if filed, and European patents, if granted, could be challenged for non-compliance and brought under the jurisdiction of the UPC. We cannot be certain that our European patent applications or granted patents will avoid falling under the jurisdiction of the UPC, even if we decide to opt out of the UPC.

Additionally, laws of some countries outside of the United States and Europe do not afford intellectual property protection to the same extent as the laws of the United States and Europe. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, including India, China and other developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. 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 licensors is 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, results of operations and financial condition may be adversely affected. Consequently, we may not be able to prevent third parties from practicing our inventions in certain countries outside the United States and Europe. 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, if our ability to enforce our patents to stop infringing activities in those jurisdictions is inadequate. 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.

Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and resources from other aspects of our business. Furthermore, while we intend to protect our intellectual property rights in major markets for our products, we may not be able to initiate or maintain similar efforts in all jurisdictions in which we may wish to market our products. Accordingly, our efforts to protect our intellectual property rights in such countries may be inadequate.

We may be subject to claims by third parties asserting that our employees or we have misappropriated their intellectual property or claiming ownership of what we regard as our own intellectual property.

Many of our employees, including our senior management, were previously employed at other biopharmaceutical companies, including our competitors or potential competitors. Some of these employees, including members of our senior management, executed proprietary rights, non-disclosure and non-competition agreements, or similar agreements, in connection with such previous employment. Although we try to ensure that our employees do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such third party. Litigation may be necessary to defend against such claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel or sustain damages. 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. Such a license may not be available on commercially reasonable terms or at all. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, while we typically require 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, which may result in claims by or against us related to the ownership of such intellectual property. If we fail in prosecuting or defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to our senior management and scientific personnel.

Risks Related to Regulatory Approval and Other Legal Compliance Matters

Even if we complete the necessary preclinical studies and clinical trials, the regulatory approval process is expensive, time consuming and uncertain and may prevent us or any future collaborators from obtaining approvals for the commercialization of STAR-0215, STAR-0310 or any other future product candidates. As a result, we cannot predict when or if, and in which territories, we, or any future collaborators, will obtain marketing approval to commercialize a product candidate.

The research, testing, manufacturing, labeling, approval, selling, marketing, promotion and distribution of biopharmaceutical products are subject to extensive regulation by the FDA and comparable foreign regulatory authorities, which regulations differ from country to country. We, and any future collaborators, are not permitted to market our product candidates in the United States or in other countries until we, or they, receive approval of a BLA from the FDA, which would be required for approval of STAR-0215 and STAR-0310, or NDA or marketing approval from applicable regulatory authorities outside the United States. Product candidates in the development phase are subject to the risks of failure inherent in drug development. We have not submitted an application for or received marketing approval for any of our product candidates in the United States or in any other jurisdiction. We have no experience as a company in filing and supporting the applications necessary to gain marketing approvals and expect to rely on third parties, including third-party clinical research organizations, to assist us in this process.

The process of obtaining marketing approvals, both in the United States and abroad, 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 and efficacy. The FDA or other regulatory authorities may determine that our product candidates are not safe and effective, 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.

In addition, changes in or the enactment or promulgation of additional statutes, regulations or guidance during preclinical or clinical development, or comparable changes in the regulatory review process 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 FDORA, Congress required sponsors to develop and submit a diversity action plan for each Phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products.

Further, on January 31, 2022, the new Clinical Trials Regulation (EU) No 536/2014 became effective in the European Union and replaced the prior Clinical Trials Directive 2001/20/EC. The new regulation aims at simplifying and streamlining the authorization, conduct and transparency of clinical trials in the European Union. Under the new coordinated procedure for the approval of clinical trials, the sponsor of a clinical trial to be conducted in more than one EU Member State will only be required to submit a single application for approval. The submission will be made through the Clinical Trials Information System, a new clinical trials portal overseen by the EMA and available to clinical trial sponsors, competent authorities of the EU Member States and the public. We have not previously secured authorization to conduct clinical studies in the EU pursuant to this new regulation and have encountered certain delays as a result of the implementation of the new regulation as we have sought to expand our Phase 1b/2 clinical trial of STAR-0215 in the EU. We have encountered similar delays in the United Kingdom.

Further, regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other studies. In addition, varying interpretations of the data obtained from preclinical and clinical testing could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we, or any future collaborators, ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Finally, our ability to develop and market new drug products may be threatened by ongoing litigation challenging the FDA's approval of mifepristone. Specifically, on April 7, 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. In reaching that decision, the district court made a number of findings that numerous representatives of the pharmaceutical and biotechnology industry believe will chill the development, approval and distribution of new drug products in the United States. Among other determinations, the district court substituted its scientific judgement for that of the FDA and it held that FDA must provide a special justification for any differences between an approved drug's labeling and the conditions that existed in the drug's clinical trials. Further, the district court read the jurisdictional requirements governing litigation in federal court so as to potentially allow virtually any party to bring a lawsuit against the FDA in connection with its decision to approve an NDA or establish requirements under a REMS.

On April 13, 2023, the district court decision was stayed, in part, by the U.S. Court of Appeals for the Fifth Circuit. Thereafter, on April 21, 2023, the U.S. Supreme Court entered a stay pending disposition of the appeal of the district court decision in the Court of Appeals for the Fifth Circuit or the Supreme Court. The Court of Appeals for the Fifth Circuit held oral arguments in the case on May 17, 2023 and, on August 16, 2023, issued its decision. The court declined to order the removal of mifepristone from the market, finding that a challenge to the FDA's initial approval in 2000 is barred by the statute of limitations. But the Appeals Court did hold that changes allowing for expanded access of mifepristone that FDA authorized in 2016 and 2021 were arbitrary and capricious in violation of federal law. On September 8, 2023, the Justice Department and a manufacturer of mifepristone asked the U.S. Supreme Court to review the Appeals Court decision. Depending on the outcome of this litigation and the regulatory uncertainty it has engendered, our ability to develop new drug product candidates and to maintain approval of existing drug products and measures adopted under a REMS is at risk and could be delayed, undermined or subject to protracted litigation.

Any delay in obtaining or failure to obtain required approvals could negatively affect our ability or that of any future collaborators to generate revenue from the particular product candidate, which likely would result in significant harm to our financial position and adversely impact our stock price.

Failure to obtain marketing approval in foreign jurisdictions would prevent our product candidates from being marketed abroad. Any approval we may be granted for our product candidates in the United States would not assure approval of our product candidates in foreign jurisdictions and any of our product candidates that may be approved for marketing in a foreign jurisdiction will be subject to risks associated with foreign operations.

In order to market and sell our products in the European Union and other foreign 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, and any future collaborators, may not obtain approvals from 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 products 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-United States regulatory approvals and compliance with non-United States 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-United States approvals required to market our product candidates outside the United States or if we fail to comply with applicable non-United States 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 prospects may be adversely affected.

Additionally, we could face heightened risks with respect to seeking marketing approval in the United Kingdom as a result of the 2020 withdrawal of the United Kingdom from the European Union, commonly referred to as Brexit. The United Kingdom and European Union entered into a Trade and Cooperation Agreement in connection with Brexit that sets out certain procedures for approval and recognition of medical products in each jurisdiction. Since the regulatory framework for pharmaceutical products in the United Kingdom covering the quality, safety, and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales, and distribution of pharmaceutical products is derived from European Union directives and regulations, the consequences of Brexit the impact the future regulatory regime that applies to products and the approval of product candidates in the United Kingdom remains unclear.

As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or the MHRA, became responsible for supervising medicines and medical devices in Great Britain, comprising England, Scotland and Wales under domestic law, whereas Northern Ireland will continue to be subject to European Union rules under the Northern Ireland Protocol. The MHRA will rely on the Human Medicines Regulations 2012 (SI 2012/1916) (as amended), or the HMR, as the basis for regulating medicines. The HMR has incorporated into the domestic law the body of European Union law instruments governing medicinal products that pre-existed prior to the United Kingdom's withdrawal from the European Union. Since a significant proportion of the regulatory framework for pharmaceutical products in the United Kingdom covering the quality, safety, and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales, and distribution of pharmaceutical products is derived from European Union directives and regulations, Brexit may have a material impact upon the regulatory regime with respect to the development, manufacture, importation, approval, and commercialization of product candidates in the United Kingdom. For example, the United Kingdom is no longer covered by the centralized procedures for obtaining European Union-wide marketing authorization from the EMA, and a separate marketing authorization will be required to market product candidates in the United Kingdom. Until December 31, 2023, it is possible for the MHRA to rely on a decision taken by the European Commission on the approval of a new marketing authorization via the centralized procedure.

Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom for any product candidates, which could significantly and materially harm our business, or prevent us from commercializing any product candidate in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability.

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 (such as the war between Ukraine and Russia and the conflict in the Middle East); 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.

We, or any future collaborators, may not be able to obtain orphan drug designation or orphan drug exclusivity for any future product candidates.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. 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, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States. We, or any future collaborators, may seek orphan drug designations and may be unable to obtain such designations.

Even if we, or any future collaborators, obtain orphan drug designation for a product candidate, we, or they, may not be able to obtain orphan drug exclusivity for that product candidate. Generally, a product with orphan drug designation only becomes entitled to orphan drug exclusivity if it receives the first marketing approval for the indication for which it has such designation, in which case the

FDA or the EMA will be precluded from approving another marketing application for the same drug for that indication for the applicable exclusivity period. The applicable exclusivity period is seven years in the United States and ten years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the drug to meet the needs of patients with the rare disease or condition.

Even if we, or any future collaborators, obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because FDA has taken the position that, under certain circumstances, another drug with the same active moiety can be approved for the same condition. Specifically, the FDA's regulations provide that it can approve another drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care.

In 2017, Congress passed the FDA Reauthorization Act of 2017, or FDARA, which among other things, codified the FDA's pre-existing regulatory interpretation to require that a drug sponsor demonstrate the clinical superiority of an orphan drug that is otherwise the same as a previously approved drug for the same rare disease in order to receive orphan drug exclusivity. Under Omnibus legislation signed by President Trump on December 27, 2020, the requirement for a product to show clinical superiority applies to drugs and biologics that received orphan drug designation before enactment of FDARA in 2017, but have not yet been approved or licensed by FDA.

The FDA and Congress may further reevaluate the Orphan Drug Act and its regulations and policies. This may be particularly true in light of a decision from the Court of Appeals for the 11th Circuit in September 2021 finding that, for the purpose of determining the scope of exclusivity, the term "same disease or condition" means the designated "rare disease or condition" and could not be interpreted by the FDA to mean the "indication or use." Thus, the court concluded, orphan drug exclusivity applies to the entire designated disease or condition rather than the "indication or use." Although there have been legislative proposals to overrule this decision, they have not been enacted into law. On January 23, 2023, the FDA announced that, in matters beyond the scope of the court's order, the FDA will continue to apply its existing regulations tying orphan-drug exclusivity to the uses or indications for which the orphan drug was approved. 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, to obtain orphan drug designation in the European Union, we would need to demonstrate 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 STAR-0215, STAR-0310 or any other product candidate. In particular, there is no assurance that STAR-0215 will be able to show, to the satisfaction of European Union regulatory authorities, that it is of significant benefit to HAE patients given the currently available commercial products for HAE in the European Union and the additional products that are ahead of STAR-0215 in clinical development for HAE.

Any product candidate for which we obtain marketing approval would remain subject to ongoing regulation and could be subject to restrictions or withdrawal from the market, and we may be subject to substantial penalties if we fail to comply with regulatory requirements, when and if any of our product candidates are approved.

Any product candidate for which we obtain marketing approval will be subject to continual 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, cGMP requirements relating to quality control and manufacturing, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. In addition, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the medicine, including the requirement to implement a REMS. Accordingly, if we receive marketing approval for one or more of our product candidates, we will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we fail to comply with these requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any products could be limited, which could adversely affect our ability to achieve or sustain profitability.

We must also comply with requirements concerning advertising and promotion for any product candidate for which we obtain marketing approval. Promotional communications with respect to prescription products are subject to a variety of legal and regulatory restrictions and must be consistent with the information in the product's approved labeling. 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 or biologic. 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.

Nonetheless, we will not be able to promote any products we develop for indications or uses for which they are not approved. The FDA and other agencies, including the Department of Justice, or the DOJ, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. Violations of the Federal Food, Drug, and Cosmetic Act and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription products may lead to investigations and enforcement actions alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

In addition, later discovery of previously unknown adverse events or other problems with our products or their manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on distribution or use of a product;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- damage to relationships with collaborators;
- unfavorable press coverage and damage to our reputation;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure;
- injunctions or the imposition of civil or criminal penalties; and
- litigation involving patients using our products.

Non-compliance with European Union requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the European Union's requirements regarding the protection of personal information can also lead to significant penalties and sanctions. Further, the marketing and promotion of authorized drugs, including industry-sponsored continuing medical education

and advertising directed toward the prescribers of drugs and/or the general public, are strictly regulated in the European Union, notably under Directive 2001/83EC, as amended, and are also subject to European Union Member State laws. Direct-to-consumer advertising of prescription medicines is prohibited across the European Union.

Accordingly, assuming we, or any future collaborators, receive marketing approval for one or more of our product candidates, we, and any future collaborators, 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, are not able to comply with post-approval regulatory requirements, our or any future collaborators' 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.

We may seek certain designations for our product candidates, including Breakthrough Therapy, RMAT Therapy, Fast Track and Priority Review designations in the United States, and the 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 may seek certain designations for one or more of our product candidates that could expedite review and approval by the FDA. A Breakthrough Therapy and Regenerative Medicine Advanced Therapy, or RMAT, 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 and RMAT 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. The FDA has granted Fast Track designation to STAR-0215 for the treatment of HAE.

We may also seek a priority review designation for one or more of our product candidates. If the FDA determines that a product candidate offers major advances in treatment or provides a treatment where no adequate therapy exists, the FDA may designate the product candidate for priority review. 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.

We may also seek accelerated approval for one or more of our product candidates. Drug or biologic products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval. Accelerated approval means that a product candidate may be approved on the basis of adequate and well controlled clinical trials establishing that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity and prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a drug or biologic product candidate receiving accelerated approval perform adequate and well controlled post-marketing clinical trials. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials. With passage of the FDORA in December 2022, Congress modified certain provisions governing accelerated approval of drug and biologic products. Specifically, the new legislation authorized the FDA to: require a sponsor to have its confirmatory clinical trial underway before accelerated approval is awarded; require a sponsor of a product granted accelerated approval to submit progress reports on its post-approval studies to the FDA every six months (until the study is completed); and use expedited procedures to withdraw accelerated approval of an NDA or BLA after the confirmatory trial fails to verify the product's clinical benefit. Further, FDORA requires the FDA to publish on its website "the rationale for why a post-approval study is not appropriate or necessary" whenever it decides not to require such a study upon granting accelerated approval.

In March 2023, the FDA issued draft guidance that outlines its current thinking 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. While this guidance is currently only in draft form and will ultimately not be legally binding even when finalized, we will need to observe the FDA's guidance closely to ensure that our products qualify for accelerated approval.

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, among other things, 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 the European Union, we may seek PRIME designation for some of 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 even if such a method exists, it may offer a major therapeutic advantage over existing treatments. PRIME is limited to medicines under development and not authorized in the European Union and 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 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 EMA's grant of a marketing authorization.

We may seek a Rare Pediatric Disease priority review vouchers, or PRV, for our current and future product candidates. A BLA or NDA for our current and future product candidates may not, however, meet the eligibility criteria for a PRV, even if the BLA or NDA is approved.

With enactment of the Food and Drug Administration Safety and Innovation Act of 2012 and subsequent legislation, Congress authorized the FDA to award PRVs to sponsors of certain rare pediatric disease product applications that meet the criteria specified in the law. This provision is designed to encourage development of new drug and biological products for prevention and treatment of certain rare pediatric diseases. Specifically, under this program, a sponsor who receives approval for a new drug or biologic for a rare pediatric disease may qualify for a PRV, which can be redeemed for priority review of a subsequent marketing application for a different product. The sponsor of a rare pediatric disease drug product that receives a PRV may transfer, including by sale, the PRV to another sponsor and that PRV may be further transferred any number of times before it is used. A PRV entitles the holder to designate a single human drug application submitted under Section 505(b)(1) of the FDCA or Section 351 of the Public Health Service Act as qualifying for a priority review. An FDA priority review may expedite the review process of a marketing application reducing the review time from ten months after formal acceptance of the file to six months after formal acceptance of the file.

In order for a sponsor to receive a PRV in connection with approval of a BLA or NDA, the investigational product must be designated by the FDA as a product for a rare pediatric disease prior to submission of the marketing application. A rare pediatric disease is a disease that is serious or life-threatening and which primarily affects individuals aged from birth to 18 years and fewer than 200,000 people in the United States. Alternatively, the disease may affect more than 200,000 people in the United States if there is no reasonable expectation that the cost of developing and making available in the United States a product for such disease or condition will be recovered from sales in the United States of such product. In addition, to qualify for a PRV, the sponsor must request the voucher and the BLA or NDA must itself be given priority review, rely on clinical data derived from studies examining a pediatric population and dosages of the product intended for that population, not seek approval for a different adult indication in the original rare pediatric disease product application and be for a product that does not include a previously approved active ingredient.

There can be no assurance that the FDA will determine that a BLA or NDA for one or more of our product candidates meets the eligibility criteria for a PRV upon approval of the marketing application. Further, under the current statutory sunset provisions for the Rare Pediatric Disease PRV Program, the FDA may only award a PRV for an approved rare pediatric disease product application if the rare pediatric disease designation was granted by September 30, 2024. Moreover, the FDA may not award any rare pediatric disease PRVs after September 30, 2026. Accordingly, if we do not receive rare pediatric disease designation and approval of a BLA or NDA by these dates, respectively, and if the Rare Pediatric Disease PRV program is not further extended by Congressional action, we may not receive a PRV. Since a PRV may be sold for substantial amounts of money, or used by us to expedite approval of another marketing application, our business may be harmed if we do not qualify for a PRV in connection with approval of an NDA or BLA.

We and our contract manufacturers are subject to significant regulation. The manufacturing facilities on which we rely may not continue to meet regulatory requirements, which could materially harm our business.

All entities involved in the preparation of product candidates, including drug substance, drug product and device combinations that may be used in combination with our product candidates, for clinical trials or commercial sale, including any contract manufacturers, are subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP. These regulations govern manufacturing processes and procedures (including record keeping) and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of adventitious agents or other contaminants or to inadvertent changes in the properties or stability of our product candidates that may not be detectable in final product testing.

We or our contract manufacturers must supply all necessary documentation in support of a BLA or NDA on a timely basis and must adhere to the FDA's current good laboratory practices and cGMP regulations enforced through its facilities inspection program. Our facilities and quality systems and the facilities and quality systems of some or all of our contract manufacturers must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of any product candidate. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of our product candidates or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities do not pass a pre-approval plant inspection, FDA approval of the products will not be granted.

The regulatory authorities also may, at any time following approval of a product for sale, audit our manufacturing facilities or those of our contract manufacturers. If any such inspection or audit identifies failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or a third party to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a facility, which may lead to temporary or permanent supply shortages. Any such remedial measures imposed upon us or third parties with whom we contract could materially harm our business.

If we of our third-party manufacturers fail to maintain regulatory compliance, the FDA can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new product, or revocation of a pre-existing approval. Any such consequence would severely harm our business, financial condition and results of operations.

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

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the FDA have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. In addition, government funding of the SEC and other government agencies, including government agencies and regulatory authorities outside the United States, 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.

Disruptions or competing priorities at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. 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, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Separately, in response to the COVID-19 pandemic in 2020 and 2021, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. Although the FDA has now resumed domestic and foreign inspections, it may not be able to continue its current pace and review timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. If a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Future shutdowns or other disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets.

The Biden Administration ended the public health emergency declarations related to COVID-19 on May 11, 2023. In connection with this determination, the FDA terminated 22 COVID-19-related policies and allowed 22 others to continue for an additional 180 days. The FDA plans to retain 24 COVID-19-related policies with appropriate changes and four whose duration is not tied to the end of the public health emergency. As a result of these and other measures, we may in the future face disruptions in our ability to prepare and submit applications to regulatory authorities for drug approvals and to build and maintain a commercial infrastructure for our product and product candidates.

If a prolonged government shutdown or other disruption occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Future shutdowns or other disruptions could also affect other government agencies such as the SEC, which may also impact our business by delaying review of our public filings, to the extent such review is necessary, and our ability to access the public markets.

Current and future legislation may increase the difficulty and cost for us to obtain reimbursement for any of our product candidates that do receive marketing approval.

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates 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 in 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.

In March 2010, President Obama signed into law the ACA. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. 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. Pursuant to subsequent legislation, these Medicare sequester reductions were suspended and reduced in 2021 and 2022 but, as of July 1, 2022, the full 2% cut has resumed. 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 product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. Indeed, under current legislation, the actual reductions in Medicare payments may vary up to 4%. The Consolidated Appropriations Act, which was signed into law by President Biden in December 2022, made several changes to sequestration of the Medicare program. Section 1001 of the Consolidated Appropriations Act delays the 4% Statutory Pay-As-You-Go Act of 2010 (PAYGO) sequester for two years, through the end of

calendar year 2024. Triggered by enactment of the American Rescue Plan Act of 2021, the 4% cut to the Medicare program would have taken effect in January 2023. The Consolidated Appropriations Act's health care offset title includes Section 4163, which extends the 2% Budget Control Act of 2011 Medicare sequester for six months into fiscal year 2032 and lowers the payment reduction percentages in fiscal years 2030 and 2031.

Since enactment of the ACA, there have been, and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act, or TCJA, 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. Further, in December 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA and therefore because the mandate was repealed as part of the TCJA, the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court heard this case and in June 2021, dismissed this action after finding that the plaintiffs do not have standing to challenge the constitutionality of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

The Trump Administration also took executive actions to delay implementation of the ACA, including directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers or manufacturers of pharmaceuticals or medical devices. On January 28, 2021, however, President Biden revoked those orders and issued a new executive order which directs federal agencies to reconsider rules and other policies that limit Americans' access to health care, and consider actions that will protect and strengthen that access. Under this order, federal agencies are directed to re-examine: policies that undermine protections for people with pre-existing conditions, including complications related to COVID-19; demonstrations and waivers under Medicaid and the ACA that may reduce coverage or undermine the programs, including work requirements; policies that undermine the Health Insurance Marketplace or other markets for health insurance; policies that make it more difficult to enroll in Medicaid and the ACA; and policies that reduce affordability of coverage or financial assistance, including for dependents.

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 been the subject of considerable discussion in the United States. There have been several recent 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. In 2020 President Trump issued several executive orders intended to lower the costs of prescription products and certain provisions in these orders have been incorporated into regulations. These regulations include an interim final rule implementing a most favored nation model for prices that would tie Medicare Part B payments for certain physician-administered pharmaceuticals to the lowest price paid in other economically advanced countries, effective January 1, 2021. That rule, however, has been subject to a nationwide preliminary injunction and, on December 29, 2021, Centers for Medicare & Medicaid Services, or CMS, issued a final rule to rescind it. With issuance of this rule, CMS stated that it will explore all options to incorporate value into payments for Medicare Part B pharmaceuticals and improve beneficiaries' access to evidence-based care.

In addition, in October 2020, the Department of Health and Human Services, or 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 ("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. As of March 2023, eight states (Colorado, Florida, Maine, New Hampshire, New Mexico, North Dakota, Vermont

and Wisconsin) have passed laws allowing for the importation of drugs from Canada. Six of those states have submitted Section 804 Importation Program proposals and are awaiting FDA approval. Further, on November 20, 2020, HHS finalized a regulation that would eliminate the current safe harbor Medicare drug rebates and create new safe harbors for beneficiary point-of-sale discounts and PBM service fees. It originally was set to go into effect on January 1, 2022, but has been delayed by Congress until January 1, 2032.

In September 2021, acting pursuant to an executive order signed by President Biden, the HHS released its plan to reduce pharmaceutical prices. The key features of that plan are to: (a) make pharmaceutical prices more affordable and equitable for all consumers and throughout the health care system by supporting pharmaceutical price negotiations with manufacturers; (b) improve and promote competition throughout the prescription pharmaceutical industry by supporting market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase transparency; and (c) foster scientific innovation to promote better healthcare and improve health by supporting public and private research and making sure that market incentives promote discovery of valuable and accessible new treatments.

More recently, on August 16, 2022, the Inflation Reduction Act of 2022, or IRA, was signed into law by President Biden. The IRA 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; imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025) that would require manufacturers to cover a portion of these costs. The IRA permits the Secretary of the HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic 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 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least 9 years and biologics that have been licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. 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 our drug products or full value of our patents protecting our products if prices are set after such products have been on the market for nine years.

Further, the IRA subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the IRA 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 IRA also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The IRA also caps Medicare out-of-pocket drug costs at an estimated $4,000 a year in 2024 and, thereafter beginning in 2025, at $2,000 a year. 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, price caps on annual out-of-pocket expenses, and the requirement that manufacturers cover a portion of these costs, each of which could have potential pricing and reporting implications.

Since mid-2023, several large pharmaceutical companies, as well as U.S. Chamber of Commerce and PhRMA, have filed lawsuits 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 Constitution. Litigation involving these and other provisions of the IRA will likely continue for some time, 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, at the federal level in the U.S., in February 2023, CMS announced a model that would allow CMS to pay less for drugs and biologics approved through FDA's accelerated approval pathway before a clinical benefit has been confirmed by the required confirmatory studies. If implemented, this would impact the price that CMS would pay for Medicare Part B drugs and biologics that fit within CMS's criteria for lower payments. Implementation of this model could result in reduced reimbursement for our products and also lead to further and more expansive pricing pressure from CMS and other U.S. payors, any of which could adversely affect our business, results of operations and financial condition.

At the state level, individual states are increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional 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, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

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 our collaborators 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 may be subject to certain healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm, fines, disgorgement, exclusion from participation in government healthcare programs, curtailment or restricting of our operations, and diminished profits and future earnings.

Healthcare providers, third-party payors and others will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our future arrangements with healthcare providers and third-party payors will expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any products for which we obtain marketing approval. Potentially applicable United States federal and state healthcare laws and regulations include the following:

Anti-Kickback Statute. The federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid.

False Claims Laws. The federal false claims laws, including the civil False Claims Act, impose criminal and civil penalties, including those from civil whistleblower or qui tam actions against individuals or entities for knowingly presenting, or causing to be presented to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government.

HIPAA. The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for executing or attempting to execute a scheme to defraud any healthcare benefit program. In addition, HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or the HITECH Act, also imposes obligations on certain types of individuals and entities, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.

False Statements Statute. The federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services.

Transparency Requirements. The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to the HHS information related to physician and healthcare provider payments and other transfers of value and physician ownership and investment interests.

Analogous State and Foreign Laws. Analogous state laws and regulations, such as state anti-kickback and false claims laws, and transparency laws, may apply to sales or marketing arrangements, and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, in addition to requiring manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures. Many state laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Foreign laws also govern the privacy and security of health information in many circumstances.

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. 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.

Efforts to ensure that our business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, corporate integrity or other similar forms of agreements or decrees, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, disgorgement, contractual damages, and reputational harm, any of which could substantially disrupt our operations. If any of the physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

We are subject to stringent privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security and changes in such laws, regulations, policies, contractual obligations and 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 and use of personally-identifying information, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information, including comprehensive regulatory systems in the United States, European Union and the 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, 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. In particular, 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 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 of state residents. 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.

On January 1, 2020, the California Consumer Privacy Act, or CCPA took effect 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 European Union's General Data Protection Regulation, or GDPR, 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 the "sales" of their personal information. The CCPA contains significant penalties for companies that violate its requirements. The California Privacy Rights Act, or CPRA, went into effect on January 1, 2023, and significantly expanded the CCPA to incorporate additional 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 a new enforcement agency – the California Privacy Protection Agency – whose sole responsibility 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, at least eleven other states have passed comprehensive privacy laws similar to the CCPA and CPRA. These laws are either in effect or will go into effect sometime before the end of 2026. Like the CCPA and CPRA, 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 strongly considering or have already passed comprehensive privacy laws during the 2023 legislative sessions that will go into effect in 2024 and beyond, including New York and New Jersey. Other states will be considering similar laws in the future, and Congress has also been debating passing a federal privacy law. There are also states that are specifically regulating health information that may affect our business. For example, Washington state 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. Connecticut and Nevada have also passed similar laws regulating consumer health data. 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.

Similar to the laws in the United States, there are significant 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 European Economic Area, or EEA, and the processing of personal data that takes place in the EEA, is regulated by the GDPR, which went into effect in May 2018 and which imposes obligations on companies that operate in our industry with respect to the processing of personal data and the cross-border transfer of such data. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and policies. If our or our partners' or service providers' privacy or data security measures fail to comply with the GDPR requirements, we may be subject to litigation, regulatory investigations, enforcement notices requiring us to change the way we use personal data and/or fines of up to 20 million Euros or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, as well as compensation claims by affected individuals, negative publicity, reputational harm and a potential loss of business and goodwill.

The GDPR places restrictions on the cross-border transfer of personal data from the European Union to countries that have not been found by the European Commission to offer adequate data protection legislation, such as the United States. There are ongoing concerns about the ability of companies to transfer personal data from the EU to other countries. In July 2020 the Court of Justice of the European Union, or the CJEU, invalidated the EU-U.S. Privacy Shield, one of the mechanisms used to legitimize the transfer of personal data from the EEA to the United States. The CJEU decision also drew into question the long-term viability of an alternative means of data

transfer, the standard contractual clauses, for transfers of personal data from the EEA to the United States. While we were not self-certified under the Privacy Shield, this CJEU decision may lead to increased scrutiny on data transfers from the EEA to the United States generally and increase our costs of compliance with data privacy legislation as well as our costs of negotiating appropriate privacy and security agreements with our vendors and business partners.

Additionally, in October 2022, President Biden signed an executive order to implement the EU-U.S. Data Privacy Framework, which serves as a replacement to the EU-U.S. Privacy Shield. The European Union initiated the process to adopt an adequacy decision for the EU-U.S. Data Privacy Framework in December 2022, and the European Commission adopted the adequacy decision in July 2023. The adequacy decision permits U.S. companies who self-certify to the EU-U.S. Data Privacy Framework to rely on it as a valid data transfer mechanism for data transfers from the European Union to the United States. However, some privacy advocacy groups have already suggested that they will be challenging the EU-U.S. Data Privacy Framework. If these challenges are successful, they may not only impact the EU-U.S. Data Privacy Framework, but also further limit the viability of the standard contractual clauses and other data transfer mechanisms. The uncertainty around this issue has the potential to impact our business.

Following the withdrawal of the UK from the European Union, the UK Data Protection Act 2018 applies to the processing of personal data that takes place in the UK and includes parallel obligations to those set forth by GDPR. In relation to data transfers, both the UK and the European Union have determined, through separate “adequacy” decisions, that data transfers between the two jurisdictions are in compliance with the UK Data Protection Act and the GDPR, respectively. The UK and the U.S. have also agreed to a U.S.-UK “Data Bridge”, which functions similarly to the EU-U.S. Data Privacy Framework and provides an additional legal mechanism for companies to transfer data from the UK to the United States. In addition to the UK, Switzerland is also in the process of approving an adequacy decision in relation to the Swiss-U.S. Data Privacy Framework (which would function similarly to the EU-U.S. Data Privacy Framework and the U.S.-UK Data Bridge in relation to data transfers from Switzerland to the United States). Any changes or updates to these developments have the potential to impact our business.

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 the evolving data protection rules may be unsuccessful. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our practices. We must devote significant resources to understanding and complying with this changing landscape. Failure to comply with laws regarding data protection would expose us to risk of enforcement actions taken by data protection authorities in the EEA and elsewhere and carries with it the potential for significant penalties if we are found to be non-compliant. Similarly, failure to comply with federal and state laws in the United States regarding privacy and security of personal information could expose us to penalties under such laws. Any such failure to comply with data protection and privacy laws could result in government-imposed fines or orders requiring that we change our practices, claims for damages or other liabilities, regulatory investigations and enforcement action, litigation and significant costs for remediation, any of which could adversely affect our business. Even if we are not determined to have violated these laws, 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.

We are subject to United States and foreign anti-corruption and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

We are subject to the Foreign Corrupt Practices Act, the United States domestic bribery statute contained in 18 U.S.C. § 201, the United States Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We may have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. In addition, we may engage third party intermediaries to promote our clinical research activities abroad and/or to obtain necessary permits, licenses, and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

Noncompliance with anti-corruption and anti-money laundering laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and/or debarment from contracting with certain persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. If any subpoenas, investigations or other enforcement actions are launched, or governmental or other sanctions are imposed, or if we do not prevail in any possible civil or criminal litigation, our business, results of operations and financial condition could be materially harmed. In addition, responding to any action will likely result in a materially significant diversion of management's attention and resources and significant defense and compliance costs and other professional fees. In certain cases, enforcement authorities may even cause us to appoint an independent compliance monitor which can result in added costs and administrative burdens.

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 and the U.K. Bribery Act 2010. Violations 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 EU Member States. These requirements are provided in the national laws, industry codes, or professional codes of conduct applicable in the EU Member States. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines, or imprisonment.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could significantly harm our business.

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

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, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts, which could adversely affect our business, financial condition, results of operations or prospects. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

Our employees, independent contractors, CROs, consultants, contract manufacturers, commercial partners, vendors and principal investigators may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements.

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, CROs, consultants, contract manufacturers, commercial partners, vendors and, if we commence clinical trials, our principal investigators. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the European Union and other jurisdictions, provide accurate information to the FDA, the European Commission and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately, or 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, misconduct, kickbacks, self-dealing and other abusive practices. These laws

and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements.

Such misconduct also could 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 cause serious harm to our reputation. Even with appropriate policies and procedures, it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent such activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

Even if we, or any future collaborators, are able to commercialize any product candidate that we, or they, develop, the product may become subject to unfavorable pricing regulations, third-party payor reimbursement practices or healthcare reform initiatives that could harm our business.

The commercial success of any product that we may develop will depend substantially, both domestically and abroad, on the extent to which the costs of such product will be paid by third-party payors, including government health administration authorities and private health coverage insurers. If coverage and reimbursement is not available, or reimbursement is available only to limited levels, we, or any future collaborators, may not be able to successfully commercialize such product. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us, or any future collaborators, to establish or maintain pricing sufficient to realize a sufficient return on our or their investments. In the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors and coverage and reimbursement for products can differ significantly from payor to payor.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved drugs. Marketing approvals, pricing and reimbursement for new drug products vary widely from country to country. Many countries outside the United States, including many countries in the European Union, 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 and can be lengthy, involve extensive negotiations and potentially result in price caps, significant discounts or other budgetary control measures, which could correspondingly impact pricing and reimbursement in other markets through so-called informal or formal reference pricing schemes. These reviews and negotiations could ultimately result in a pricing and reimbursement structure for a drug that a company deems inadequate and therefore elects not launch in such markets. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. As a result, we, or any future collaborators, might obtain marketing approval for a product in a particular country, but then be subject to price regulations that delay commercial launch of the product, possibly for lengthy time periods, which may 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 or the ability of any future collaborators to recoup our or their investment in one or more product candidates, even if any future product candidates obtain marketing approval.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Therefore, our ability, and the ability of any future collaborators, to commercialize any product will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from third-party payors. Third-party payors decide which medications they will cover and establish reimbursement levels. The healthcare industry is acutely focused on cost containment, both in the United States and elsewhere. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications, which could affect our ability or that of any future collaborators to sell any products we develop profitably. These payors may not view our products, if any, as cost-effective, and coverage and reimbursement may not be available to our customers, or those of any future collaborators, or may not be sufficient to allow our products, if any, to be marketed on a competitive basis. Cost-control initiatives could cause us, or any future collaborators, to decrease the price we, or they, might establish for products, which could result in lower than anticipated product revenues. If the prices for any future products decrease or if governmental and other third-party payors do not provide coverage or adequate reimbursement, our prospects for revenue and profitability will suffer.

There may also be delays in obtaining coverage and reimbursement for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or comparable foreign regulatory authorities. Moreover, eligibility for reimbursement does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Reimbursement rates may vary, by way of example, according to the use of the drug and the clinical

setting in which it is used. Reimbursement rates may also be based on reimbursement levels already set for lower cost drugs or may be incorporated into existing payments for other services.

In addition, increasingly, third-party payors are requiring higher levels of evidence of the benefits and clinical outcomes of new technologies and are challenging the prices charged. For example, to obtain reimbursement or pricing approval in some countries, we, or any future collaborators, may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. We cannot be sure that coverage will be available for any product candidate that we, or any future collaborator, commercialize and, if available, that the reimbursement rates will be adequate. Further, the net reimbursement for drug products may be subject to additional reductions if there are changes to laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. An inability to promptly obtain coverage and adequate payment rates from both government-funded and private payors for any product candidate for which we, or any future collaborator, obtain marketing approval could significantly harm our operating results, our ability to raise capital needed to commercialize products and our overall financial condition.

Risks Related to Taxation

Changes in tax law could adversely affect our business and financial condition.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us and our stockholders. Many such changes have been made and changes are likely to continue to occur in the future. For example, the TCJA was enacted in 2017 and significantly reformed the Internal Revenue Code of 1986, as amended, or the Code. The TCJA, among other things, contained significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, a limitation of the tax deduction for net interest expense to 30% of adjusted earnings (except for certain small businesses), a limitation of the deduction for net operating losses arising in taxable years beginning after December 31, 2017 to 80% of current year taxable income and an elimination of net operating loss carrybacks (though any net operating losses generated in taxable years beginning after December 31, 2017 may be carried forward indefinitely), and the modification or repeal of many business deductions and credits.

As part of Congress' response to the COVID-19 pandemic, economic relief legislation was enacted in 2020 and 2021 containing tax provisions. The IRA was also signed into law in August 2022. 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. In addition, certain tax laws that are specific to the biopharmaceutical industry, such as the orphan drug tax credit, which was enacted as part of the Orphan Drug Act, have been limited over time and continuing limitations or restrictions of the tax credit and changes to other tax laws applicable to our business could negatively impact our business and results of operations. Additional tax legislation may also be enacted, and regulatory guidance under the TCJA continues to be forthcoming. It cannot be predicted whether, when, in what form, or with what effective dates, new tax laws may be enacted, or regulations and rulings may be enacted, promulgated or issued under existing or new tax laws, which could result in an increase in our stockholders' tax liability or require changes in the manner in which we operate in order to minimize or mitigate any adverse effects of changes in tax law or in the interpretation thereof.

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

In general, under Sections 382 and 383 of the Code, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change net operating losses or tax credits, or NOLs or credits, to offset future taxable income or taxes. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. Under Section 382, the annual limitation is determined by first multiplying the value of the corporation's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required.

As a result of, among other transactions, the shares issued in January 2021 related to the acquisition of Quellis and the February 2021 Financing, we believe we have experienced several historical ownership changes, as defined by Section 382. As a result, our utilization of the federal and state net operating loss carryforwards or research and development tax credit carryforwards are subject to annual limitation under Sections 382 and 383. Our analysis of Section 382 indicates that a significant portion of our Federal and state net operating loss carryforwards and research and development tax credit carryforwards are limited, such that a significant portion of them are anticipated to not be available or expire before utilization.

Risks Related to Employee Matters, Managing Growth and Information Technology

Our future success depends on our ability to retain our senior management and key employees.

We are highly dependent on our executive officers and key employees. If we are unable to retain our executive officers or other key employees, replacing them may be difficult and costly, and may take an extended period of time because of the nature of our current business strategy and the limited number of individuals in our industry with the relevant breadth of skills and experience. Competition to hire from this limited pool is intense, and we may be unable to hire, train, retain or motivate replacements for our executive officers or key employees on acceptable terms given the competition among numerous pharmaceutical and biotechnology companies for similar personnel.

We rely on consultants and advisors, including financial, legal, scientific and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may be employed by other entities and may have commitments under consulting or advisory contracts with those entities that may limit their availability to us.

Security breaches and other disruptions to our information technology systems could compromise our information, disrupt our business and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we collect, process and store sensitive data, including intellectual property, as well as our proprietary business information, employee data and personally identifiable information of clinical trial participants in accordance with informed consents covering such information. We also rely to a large extent on computer and information technology systems to operate our business. Remote working arrangements could impact employees' productivity and morale, strain our technology resources and introduce operational risks. Additionally, the risk of cyber-attacks or other privacy or data security incidents may be heightened as a result of our moving increasingly towards a remote working environment, which may be less secure and more susceptible to hacking attacks. We have outsourced elements of our confidential information processing and information technology structure, and as a result, we are managing independent vendor relationships with third parties who may or could have access to our confidential information. The secure maintenance of this information is important to our operations and business strategy. Despite our security measures, our information technology infrastructure, and that of our vendors and third-party providers, may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. We, our vendors and third-party providers could be susceptible to third party attacks on our and their information security systems, which attacks are of ever-increasing levels of sophistication and are made by groups and individuals with a wide range of motives and expertise, including organized criminal groups, hacktivists, nation states and others. If a ransomware attack or other cybersecurity incident occurs, either internally or at our vendors or third-party technology service providers, we could be prevented from accessing our data or systems, which may cause interruptions or delays in our business operations, cause us to incur remediation costs, subject us to demands to pay a ransom, or damage our reputation, regardless of whether we pay the ransom amount. Additionally, the risk of cyber-attacks or other privacy or data security incidents may be heightened as a result of our moving increasingly towards a remote working environment, which may be less secure and more susceptible to hacking attacks. While we continue to build and improve our information technology security systems and infrastructure, there can be no assurance that our efforts will prevent service interruptions, breakdowns or security breaches. For example, we have detected common types of attempts to attack our information technology systems and data using means that have included phishing. Any service interruptions or security breaches of our information technology systems may substantially impair our ability to operate our business and could compromise our networks, or those of our vendors and third-party providers, and the information stored could be accessed, publicly disclosed, lost or stolen.

We may be required to expend significant resources (including financial), fundamentally change our business activities and practices, or modify our operations, including our clinical trial activities, or information technology in an effort to protect against security breaches and to detect (including performing required forensics), mitigate and remediate actual and potential vulnerabilities. Relevant laws, regulations, industry standards and contractual obligations may require us to implement specific security measures or use industry-standard or reasonable measures to protect against security breaches. The costs to us to mitigate network security problems, bugs,

viruses, worms, malicious software programs, security breaches and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, data loss or corruption, delays, cessation of service and other harm to our business and our competitive position. If the information technology systems of our third-party vendors become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring.

Any such access, disclosure, or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation, any of which could adversely affect our business. Although we maintain cyber liability insurance of $1.0 million in the aggregate it may not be sufficient in type or amount to cover us against claims related to security breaches, cyber-attacks and other related breaches.

Risks Related to Our Common Stock

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

Our holders of 5% or more of our capital stock and their respective affiliates beneficially own in excess of 20.0% of our outstanding common stock. These stockholders, acting together or on their own, may be able to impact matters requiring stockholder approval. For example, they may be able to impact elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that investors may feel are in their best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with each investor's interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

The price of our common stock has been and is likely to continue to be highly volatile, which could result in substantial losses for our stockholders.

Our stock price has been and is likely to continue to be highly volatile. For example, when we announced our acquisition of Quellis, our stock price increased by approximately 70% in one day. Between January 1, 2023 and October 31, 2023, our stock price has traded at a high of $16.28 and a low of $4.48.

The stock market in general and the market for smaller pharmaceutical and 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 investors may lose some or all of their investments. The market price for our common stock may be influenced by many factors, including:

- the timing and results of clinical trials of STAR-0215, STAR-0310 or any future product candidate;
- commencement or termination of collaborations for any development programs we may pursue;
- failure or discontinuation of any of any development programs we may pursue;
- the success of existing or new competitive products or technologies;
- results of clinical trials of product candidates of competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;

- the level of expenses related to a product candidate or clinical development program;
- the results of any additional efforts to develop additional product candidates or products;
- actual or anticipated changes in estimates as to financial results or recommendations by securities analysts that cover our stock;
- announcement or expectation of additional financing efforts;
- announcement of collaborations, licenses, acquisitions or other comparable forms of transactions;
- sales of our common stock by us, our insiders or other stockholders;
- variations in our financial results or those of companies that are perceived to be similar to us;
- changes in the structure of healthcare payment systems;
- market conditions in the pharmaceutical and biotechnology sectors;
- general economic, industry and market conditions, including political instability, war or instability from an outbreak of pandemic or contagious disease; and
- the other factors described in this "Risk Factors" section.

Additionally, securities class action litigation has often been brought against a company following a decline in the market price of its securities. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

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

As a public company we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, or SOX, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Global 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. We expect that our management and other personnel will continue to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements increase our legal and financial compliance costs and make some activities more time-consuming and costly. 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 SOX, we are required to furnish reports by our management on our internal control over financial reporting with our Annual Reports on Form 10-K with the SEC. If we cease to be a smaller reporting company with less than $100 million in annual revenue, we will also be required to include attestation reports on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with SOX Section 404 within the prescribed period, we will be 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, 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 neither we nor our independent registered public accounting firm will 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 of SOX. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

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

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares of common stock intend to sell shares, could reduce the market price of our common stock. As of October 31, 2023, we had outstanding 36,296,191 shares of common stock and 31,107 shares of Series X Preferred Stock, which are convertible into 5,184,591 shares of common stock. Pursuant to our obligations under a registration rights agreement entered into in connection with the acquisition of Quellis and the February 2021 Financing, we have registered under the Securities Act of 1933, as amended, or the Securities Act, 15,399,967 shares of our common stock issued to the former Quellis stockholders or issued or issuable upon conversion of the Series X Preferred Stock. As a result, such shares are freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any significant sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

Additionally, we have an ongoing sales agreement with Jefferies LLC, pursuant to which we could issue and sell shares of common stock under an at-the-market offering program.

The number of shares of common stock underlying our outstanding warrants is significant in relation to our currently outstanding common stock, which could have a negative effect on the market price of our common stock and make it more difficult for us to raise funds through future equity offerings. In addition, in connection with any merger, consolidation or sale of all or substantially all of our assets, holders of our outstanding warrants would be entitled to receive consideration in excess of their reported beneficial ownership of our common stock and this could adversely impact the consideration our other stockholders would receive.

As of October 31, 2023, excluding the common stock and pre-funded warrants that we issued as part of our registered offering in October 2023, as described below, we had outstanding warrants to purchase 331,858 shares of common stock at a weighted average exercise price of $37.50 per share which expire on February 7, 2024.

As part of our registered offering of common stock in October 2023, we issued common stock warrants to purchase an aggregate of 7,368,738 shares of our common stock, and pre-funded warrants to purchase up to an aggregate of 1,571,093 shares of our common stock. Each pre-funded warrant has an exercise price per share of common stock equal to $0.001 per share. Each pre-funded warrant is exercisable from the date of issuance until exercised in full solely by means of a cashless exercise. Each common stock warrant has an exercise price per share of common stock equal to $8.025. Each common stock warrant is exercisable from the date of issuance until October 16, 2028. Each common stock warrant is exercisable solely by means of a cash exercise, except that the common stock warrant is exercisable via cashless exercise if at the time of exercise, a registration statement registering the issuance of the shares of common stock underlying the common stock warrants under the Securities Act is not then effective. The common stock warrants include certain rights upon “fundamental transactions” as described in the common stock warrants, including the right of the holders thereof to receive from us or a successor entity the same type or form of consideration (and in the same proportion) that is being offered and paid to the holders of common stock in such fundamental transaction in the amount of the Black Scholes value (as described in such common stock warrants) of the unexercised portion of the applicable common stock warrants on the date of the consummation of such fundamental transaction. A holder of common stock warrants (together with its affiliates) may not exercise any portion of a common stock warrant to the extent that the holder would beneficially own more than 4.99% (or, at the election of the holder, 9.99%) of our outstanding common stock immediately after exercise.

Although these warrants issued in October 2023 are subject to beneficial ownership limitations, upon exercise in full of the warrants, the shares issuable upon exercise would represent a significant portion of our outstanding common stock. As a result, the holders of these warrants may be able to exert substantial influence over our business. The concentration of voting power resulting from the exercise of the warrants could delay, defer or prevent a change of control, entrench our management and our board of directors or delay or prevent a merger, consolidation, takeover or other business combination involving us on terms that other stockholders may desire. In addition, conflicts of interest could arise in the future between us, on the one hand, and the holders of these warrants, concerning potential competitive business activities, business opportunities, the issuance of additional securities and other matters. In addition, sales of these shares could cause the market price of our common stock to decline significantly.

We have registered the issuance of shares upon exercise of these warrants under registration statements. As a result, the shares issuable upon exercise of these warrants can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates. Sales of these shares could cause the market price of our common stock to decline significantly. Furthermore, if our stock

price rises, the holders of these warrants may be more likely to exercise their warrants and sell a large number of shares, which could negatively impact the market price of our common stock and reduce or eliminate any appreciation in our stock price that might otherwise occur.

Given the amount and terms of these warrants, we may find it more difficult to raise additional equity capital on favorable terms or at all while these warrants are outstanding.

We do not anticipate paying any cash dividends on our capital stock in the foreseeable future, accordingly, stockholders must rely on capital appreciation, if any, for any return on their investment.

We have never declared nor paid cash dividends on our capital stock. We currently plan to retain all of our future earnings, if any, to finance the operation, development and growth of our business. Any future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be investors' sole source of gain for the foreseeable future.

If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our share price and trading volume could decline.

The trading market for our common stock will likely depend, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have any control over these analysts. There can be no assurance that analysts will cover us or provide favorable coverage. If one or more analysts downgrade our stock or change their opinion of our stock, our share price would likely decline. In addition, if one or more analysts cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

Risks Relating to our Certificate of Incorporation and Bylaws

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

Provisions in our corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which our investors 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 all members of the board are not elected at one time;
- 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 the board;
- establish advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on at stockholder meetings;
- 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 a special meeting of 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 certain provisions of our charter or bylaws.

In addition, as of September 30, 2023, there are 31,107 shares of our Series X Preferred Stock outstanding that we issued in connection with the acquisition of Quellis and the February 2021 Financing. Except as otherwise required by law, the Series X Preferred Stock does not have voting rights. However, as long as any shares of Series X Preferred Stock are outstanding, we may not, without the affirmative vote of the holders of a majority of the then outstanding shares of the Series X Preferred Stock, (i) alter or change adversely the powers, preferences or rights given to the Series X Preferred Stock or alter or amend the Certificate of Designation that authorized the Series X Preferred Stock, amend or repeal any provision of, or add any provision to, our Certificate of Incorporation or bylaws, or file any articles of amendment, certificate of designations, preferences, limitations and relative rights of any series of preferred stock, if such action would adversely alter or change the preferences, rights, privileges or powers of, or restrictions provided for the benefit of the Series X Preferred Stock, (ii) issue further shares of Series X Preferred Stock or increase or decrease (other than by conversion) the number of authorized shares of Series X Preferred Stock, or (iii) enter into any agreement with respect to any of the foregoing.

Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the General Corporation Law of the State of Delaware, 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. This could discourage, delay or prevent someone from acquiring us or merging with us, whether or not it is desired by, or beneficial to, our stockholders.

Our certificate of incorporation designates the state courts in the State of Delaware or, if no state court located within the State of Delaware has jurisdiction, the federal court for the District of Delaware, as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could discourage lawsuits against the company and our directors and officers.

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 does not have jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or employees to our company or our stockholders, any action asserting a claim against us arising pursuant to any provision of the General Corporation Law of the State of Delaware or our certificate of incorporation or bylaws, or any action asserting a claim against us governed by the internal affairs doctrine. 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. Alternatively, if a court were to find the choice of forum provisions contained in our certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could materially adversely affect our business, financial condition, and operating results. This exclusive forum provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act, which provides for exclusive jurisdiction of the federal courts. It could apply, however, to a suit that falls within one or more of the categories enumerated in the exclusive forum provision and asserts claims under the Securities Act, inasmuch as Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder; provided, that with respect to claims under the Securities Act, our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder.

Item 6. Exhibits

The exhibits filed as part of this Quarterly Report on Form 10-Q are set forth on the Exhibits Index below:

Exhibit Number	Exhibit
4.1	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.1 of the registrant's Current Report on Form 8-K (File No. 001-37467) filed with the SEC on October 12, 2023)
4.2	Form of Common Stock Warrant (incorporated by reference to Exhibit 4.2 of the registrant's Current Report on Form 8-K (File No. 001-37467) filed with the SEC on October 12, 2023)
10.1	Amended and Restated 2015 Stock Incentive Plan, as amended (incorporated by reference to Exhibit 10.2 of the registrant's Quarterly Report on Form 10-Q (File No. 001-37467) filed with the SEC on August 7, 2023)
31.1*	Certification of principal executive officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of 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 Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of The Sarbanes-Oxley Act of 2002, by the Registrant's principal executive officer and principal financial officer
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Presentation Linkbase Document
104	Cover Page Data File (the cover page XBRL tags are embedded within the iXBRL document).

* Filed herewith.

** Furnished herewith.

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.

Astria Therapeutics, Inc.

Date: November 13, 2023

By: /s/ NOAH C. CLAUSER
Noah C. Clauser
Chief Financial Officer (Principal Financial Officer)

Exhibit 31.1

CERTIFICATION

I, Jill C. Milne, certify that:

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

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

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

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

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

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

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

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

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

Date: November 13, 2023

/s/ JILL C. MILNE, PH.D.
Jill C. Milne, Ph.D.
President and Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

CERTIFICATION

I, Noah C. Clauser, certify that:

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

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

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

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

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

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

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

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

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

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

Date: November 13, 2023

/s/ NOAH C. CLAUSER
Noah C. Clauser
Chief Financial Officer (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 on Form 10-Q of Astria Therapeutics, Inc. (the "Company") for the period ended September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned officers of the Company hereby certify, pursuant to 18 U.S.C. Section 1350, 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: November 13, 2023

/s/ JILL C. MILNE, PH.D.
Jill C. Milne, Ph.D.
President and Chief Executive Officer (Principal Executive Officer)

Date: November 13, 2023

/s/ NOAH C. CLAUSER
Noah C. Clauser
Chief Financial Officer (Principal Financial Officer)