UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 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, 2026

OR

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

For the transition period from _____ to _____

Commission File Number: 001-43233

Kailera Therapeutics, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**99-3088927**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
180 Third Avenue, 4th Floor Waltham, MA	**02451**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (781) 317-0290

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, par value $0.00001 per share	KLRA	Nasdaq Global Select Market

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of October 29, 2026, the registrant had 129,850,481 shares of common stock, $0.00001 par value per share, outstanding.

SPECIAL NOTE REGARDING FORWARD LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties. All statements contained in this Quarterly Report on Form 10-Q that do not relate to matters of historical fact should be considered forward-looking statements, including, but not limited to, statements regarding our future results of operations and financial position, business strategy, product candidate development, prospective products, product candidate approvals, research and development activities and costs, future revenue, timing and likelihood of success of our business plans, plans and objectives of management, future results and timing of clinical trials, treatment potential of our product candidates, and the market potential of our product candidates. In some cases, you can identify forward-looking statements by terms such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "target," "should," "will," or "would" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words.

These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects. However, there can be no assurance that management's expectations, beliefs, and projections will result or be achieved. Actual results may differ materially from these expectations due to changes in global, regional, or local economic, business, competitive, market, regulatory, and other factors, many of which are beyond our control. We believe that these factors include but are not limited to those described under "Risk Factors" and the following:

- the success, cost, timing, progress and results of nonclinical studies and clinical trials for our current and future product candidates and the reporting and interpretation of data from those studies and trials;
- our ability to develop our current product candidates and additional potential product candidates in our pipeline;
- our ability to identify and enroll a specified and sufficient number of eligible patients to participate and remain in our clinical trials;
- the timing or likelihood of regulatory filing and approvals or of alternative regulatory pathways for our product candidates and any related restrictions, limitations or warnings in the label of an approved product candidate;
- our ability to establish scaled third-party manufacturing prior to commercial launch of our product candidates;
- the likelihood of our clinical trials demonstrating safety and efficacy of our product candidates and other positive results;
- the timing of announcement of interim, topline and preliminary results from clinical trials;
- our ability to commercialize our product candidates and to establish, manage, or expand our marketing, distribution, and manufacturing capabilities;
- the scope of protection we are able to establish and maintain for intellectual property rights covering our product candidates;
- developments related to our competitors and our industry and market acceptance of our current and future product candidates;
- our ability to maintain the Hengrui License Agreement underlying our product candidates;
- our ability to identify and enter into future license agreements and collaborations and the terms of such future agreements;
- our reliance on third parties having accurately generated, collected, interpreted and reported data from certain nonclinical studies and clinical trials that were previously conducted for our product candidates;
- the pricing and cost-effectiveness of our products, if approved, in relation to alternative treatments and therapies;
- our ability to attract and retain highly qualified management, clinical and scientific personnel;
- regulatory developments in the United States and foreign countries;
- our expectations regarding the period during which we will qualify as an emerging growth company under the JOBS Act or a smaller reporting company; and
- our financial performance, cash runway, estimates of our expenses, capital requirements and needs for additional financing.

These forward-looking statements speak only as of the date of this Quarterly Report on Form 10-Q and are subject to a number of risks, uncertainties and assumptions described in the section titled “Risk Factors” and elsewhere in this Quarterly Report on Form 10-Q. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements.

In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Quarterly Report on Form 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete.

Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

SUMMARY OF RISKS ASSOCIATED WITH OUR BUSINESS

Our business is subject to numerous risks and uncertainties that you should be aware of before making an investment decision, including those described in Part II, Item 1A. "Risk Factors" in this Quarterly Report on Form 10-Q. These risks include, but are not limited to, the following:

- We are a clinical-stage biotechnology company with a limited operating history. We have incurred significant financial losses since our inception and anticipate that we will continue to incur significant financial losses for the foreseeable future.
- We have not generated any revenues to date and may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.
- We will require substantial additional capital to finance our operations, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our 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 depend heavily on the success of ribupatide injection and our other product candidates. If we are unable to successfully develop or commercialize ribupatide injection or any other product candidates, or experience significant delays in doing so, we may continue to incur significant financial losses.
- The FDA or comparable foreign regulatory authorities may disagree with our regulatory plan for our product candidates.
- Clinical and nonclinical development involves a lengthy and expensive process with an uncertain outcome, and the results of prior clinical trials and studies involving our product candidates are not necessarily predictive of our future results. Our product candidates may not show favorable results in nonclinical studies or clinical trials or receive regulatory approval on a timely basis, if at all.
- We may find it difficult to enroll patients in our clinical trials. If we encounter difficulties or delays enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- Use of any of our current or future product candidates could be associated with side effects, adverse events or other properties or safety risks, which could delay or preclude regulatory approval, cause us to suspend or discontinue clinical trials, abandon any of our current or future product candidates, limit the commercial profile of an approved label or result in other significant negative consequences that could severely harm our business, financial condition, results of operations and prospects.
- We currently, and may in the future, conduct certain of our clinical trials for our product candidates outside of the United States. However, the FDA and foreign regulatory authorities may not accept data from such trials, which could materially harm our business.
- Our business is subject to the risks associated with having a collaboration partner located in China.
- We depend on our license agreement with, and the comprehensiveness of the intellectual property licensed from, Hengrui. Termination of the Hengrui License Agreement, and issues related to intellectual property we license from Hengrui, would have a material adverse effect on our business.
- We are dependent on Hengrui having accurately generated, collected, interpreted and reported data from certain nonclinical studies and clinical trials that were previously conducted for our product candidates.
- We rely on third parties to conduct our clinical trials and nonclinical studies. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements, or meet expected deadlines, any of our current or future product candidates and our ability to seek or obtain regulatory approval for or commercialize any of our current or future product candidates may be delayed.
- We rely on the use of third parties, including Hengrui, to manufacture our product candidates, which may increase the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable time and cost, which could delay, prevent or impair our development or commercialization efforts.
- We face significant competition from entities that have made substantial investments into developing novel treatments for patients with obesity, including large pharmaceutical companies with approved therapies in our current indications, and

biopharmaceutical, specialty pharmaceutical and biotechnology companies developing novel treatments and technology platforms.

- The commercial success of any of our current or future product candidates will depend upon the degree of market acceptance of such product candidates by physicians, patients, healthcare payors and others in the medical community.
- If we or our current or future licensors are unable to obtain, maintain, defend and enforce patent or other intellectual property protection for any of our current or future product candidates or technology, or if the scope of the patent or other intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize any of our current or future product candidates may be adversely affected.
- Third-party claims of intellectual property infringement, misappropriation, or other violations against us or our collaborators could be expensive and time-consuming and may prevent or delay the development and commercialization of any of our current or future product candidates.
- The trading price of the shares of our common stock could be highly volatile, and purchasers of our common stock could incur substantial losses.

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

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

Kailera Therapeutics, Inc.
Condensed consolidated balance sheets
(amounts in thousands, except share data) (unaudited)

	September 30, 2026 (unaudited)	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 106,537	$ 160,267
Marketable securities	794,917	385,789
Prepaid expenses and other current assets	18,302	11,481
Total current assets	919,756	557,537
Property and equipment, net	1,652	1,955
Restricted cash	761	761
Long-term marketable securities	136,187	106,672
Non-current clinical deposits	14,129	12,185
Operating lease right-of-use assets	9,630	10,463
Other non-current assets	63	2,721
Total assets	$ 1,082,178	$ 692,294
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 9,434	$ 7,529
Accrued expenses and other current liabilities	31,590	37,836
Operating lease liabilities, current	1,092	1,040
Total current liabilities	42,116	46,405
Operating lease liabilities, non-current	8,879	9,713
Other non-current liabilities	67	270
Total liabilities	51,062	56,388
Commitments and contingencies (Note 12)		
Convertible preferred stock:		
Series A convertible preferred stock: $0.00001 par value; no shares authorized, issued and outstanding at September 30, 2026; 35,677,603 shares authorized, issued and outstanding at December 31, 2025	—	390,306
Series B convertible preferred stock: $0.00001 par value; no shares authorized, issued and outstanding at September 30, 2026; 43,084,539 shares authorized, issued and outstanding at December 31, 2025	—	602,058
Stockholders' equity (deficit):		
Preferred stock, $0.00001 par value; 10,000,000 shares authorized and no shares issued and outstanding at September 30, 2026; no shares authorized, issued and outstanding at December 31, 2025	—	—
Common stock, $0.00001 par value; 800,000,000 shares and 105,384,000 shares authorized at September 30, 2026 and December 31, 2025, respectively; 129,684,183 and 19,048 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	—	—
Additional paid-in capital	1,689,358	11,981
Accumulated other comprehensive (loss) income	(3,737)	229
Accumulated deficit	(654,505)	(368,668)
Total stockholders' equity (deficit)	1,031,116	(356,458)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	$ 1,082,178	$ 692,294

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

Kailera Therapeutics, Inc.
Condensed consolidated statements of operations and comprehensive loss
(amounts in thousands, except share data for all periods presented and per share data for 2026) (unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating expenses				
Research and development	$ 84,667	$ 26,994	$ 256,601	$ 56,645
General and administrative	21,669	13,115	55,768	34,572
Total operating expenses	106,336	40,109	312,369	91,217
Loss from operations	(106,336)	(40,109)	(312,369)	(91,217)
Other income				
Interest income	10,611	2,251	26,321	6,052
Other income (expense), net	60	(1,765)	211	(1,388)
Total other income	10,671	486	26,532	4,664
Net loss	$ (95,665)	$ (39,623)	$ (285,837)	$ (86,553)
Other comprehensive loss				
Unrealized (loss) gain	(1,943)	56	(3,966)	24
Comprehensive loss	(97,608)	(39,567)	(289,803)	(86,529)
Net loss per share attributable to common stockholders - basic and diluted	$ (0.74)	$ (39,623)	$ (3.68)	$ (86,553)
Weighted-average common stock outstanding - basic and diluted	129,653,008	1	77,685,234	1

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

Kailera Therapeutics, Inc.
Condensed consolidated statements of convertible preferred stock and stockholders' equity (deficit)
(amounts in thousands, except share data) (unaudited)

	Series A-1 convertible preferred stock		Series A-2 convertible preferred stock		Series A-2 (NV) convertible preferred stock		Series B convertible preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total stockholders' equity (deficit)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
December 31, 2025	30,000,000	$ 8	4,968,789	$ 01	708,814	$ 47	43,084,539	$ 58	19,048	$ —	$ 11,981	$ 229	(368,668)	$ (356,458)
Exercise of stock options	—	—	—	—	—	—	—	—	10,905	—	57	—	—	$ 57
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	3,939	—	—	$ 3,939
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	—	—	—	(761)	—	$ (761)
Net loss	—	—	—	—	—	—	—	—	—		—	—	(78,865)	$ (78,865)
March 31, 2026	30,000,000	$ 8	4,968,789	$ 01	708,814	$ 47	43,084,539	$ 58	29,953	$ —	$ 15,977	$ (532)	$ (447,533)	$ (432,088)
Conversion of convertible preferred stock to common stock	(30,000,000)	(294,358)	(4,968,789)	(84,501)	(708,814)	(11,447)	(43,084,539)	(602,058)	84,596,391	—	992,364	—	—	$ 992,364
Issuance of common stock upon completion of initial public offering, net of commissions, underwriting discounts and other offering costs	—	—	—	—	—	—	—	—	44,921,875	—	661,983	—	—	$ 661,983
Exercise of stock options	—	—	—	—	—	—	—	—	72,151	—	430	—	—	$ 430
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	8,344	—	—	$ 8,344
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	—	—	—	(1,262)	—	$ (1,262)
Net loss	—	—	—	—	—	—	—	—	—		—	—	(111,307)	$ (111,307)
June 30, 2026	—	$ —	—	$ —	—	$ —	—	$ —	129,620,370	$ —	$ 1,679,098	$ (1,794)	$ (558,840)	$ 1,118,464
Exercise of stock options	—	—	—	—	—	—	—	—	63,813	—	339	—	—	$ 339
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	9,921	—	—	$ 9,921
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	—	—	—	(1,943)	—	$ (1,943)
Net loss	—	—	—	—	—	—	—	—	—		—	—	(95,665)	$ (95,665)
September 30, 2026	—	$ —	—	$ —	—	$ —	—	$ —	129,684,183	$ —	$ 1,689,358	$ (3,737)	$ (654,505)	$ 1,031,116

	Series A-1 convertible preferred stock		Series A-2 convertible preferred stock		Series A-2 (NV) convertible preferred stock		Series B convertible preferred stock		Common stock		Additional paid-in	Accumulated other comprehensive income	Accumulated	Total stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	capital	(loss)	deficit	equity (deficit)
December 31, 2024	30,000,000	$ 8	4,968,789	$ 01	708,814	$ 47	—	$ —	1	$ —	$ 941	$ —	$ (219,713)	$ (218,772)
Exercise of stock options	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	1,523	—	—	1,523
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	—	—	—	(6)	—	(6)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(17,983)	(17,983)
March 31, 2025	30,000,000	$ 8	4,968,789	$ 01	708,814	$ 47	—	$ —	1	$ —	$ 2,464	$ (6)	$ (237,696)	$ (235,238)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	1,631	—	—	1,631
Unrealized loss on marketable securities	—	—	—	—	—	—	—	—	—	—	—	(26)	—	(26)
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(28,947)	(28,947)
June 30, 2025	30,000,000	$ 8	4,968,789	$ 01	708,814	$ 47	—	$ —	1	$ —	$ 4,095	$ (32)	$ (266,643)	$ (262,580)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	4,269	—	—	4,269
Unrealized gain on marketable securities	—	—	—	—	—	—	—	—	—	—	—	56	—	56
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	(39,623)	(39,623)
September 30, 2025	30,000,000	$ 8	4,968,789	$ 01	708,814	$ 47	—	$ —	1	$ —	$ 8,364	$ 24	$ (306,266)	$ (297,878)

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

Kailera Therapeutics, Inc.
Condensed consolidated statements of cash flows
(amounts in thousands) (unaudited)

	Nine Months Ended September 30,	
	2026	**2025**
Cash flows from operating activities:		
Net loss	$ (285,837)	$ (86,553)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization expense	303	188
Stock-based compensation expense	22,204	7,423
Change in fair value of preferred stock tranche right liability	—	(1,400)
Non-cash lease expense	833	354
Accretion of discounts on investments, net	(5,246)	(1,134)
Change in fair value of convertible promissory notes	—	2,781
Other	(13)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(7,120)	(7,715)
Non-current clinical deposits	(1,944)	—
Other non-current assets	2,343	67
Accounts payable	2,075	(38)
Accrued expenses and other current liabilities	(6,119)	12,318
Operating lease liabilities	(781)	(421)
Other non-current liabilities	(203)	—
Net cash used in operating activities	(279,505)	(74,130)
Cash flows from investing activities:		
Purchases of property and equipment	—	(443)
Purchases of marketable securities	(775,319)	(178,892)
Maturities of marketable securities	337,970	77,205
Net cash used in investing activities	(437,349)	(102,130)
Cash flows from financing activities:		
Proceeds from the exercise of stock options	826	—
Proceeds from issuance of convertible promissory notes	—	100,000
Proceeds from issuance of common stock, net of commissions and underwriting discounts	668,438	—
Payments of deferred offering costs	(6,140)	(243)
Net cash provided by financing activities	663,124	99,757
Net decrease in cash, cash equivalents and restricted cash	(53,730)	(76,503)
Cash, cash equivalents and restricted cash at beginning of period	161,028	175,178
Cash, cash equivalents and restricted cash at end of period	$ 107,298	$ 98,675
Reconciliation of cash, cash equivalents and restricted cash		
Cash and cash equivalents	$ 106,537	$ 97,914
Restricted cash	761	761
Total cash, cash equivalents and restricted cash	$ 107,298	$ 98,675
Supplemental disclosure of non-cash investing and financing activities:		
Conversion of convertible preferred stock to common stock	$ 992,364	$ —
Deferred offering costs included in accounts payable and accrued expenses	$ —	$ 733
Purchases of property and equipment included in accounts payable and accrued expenses	$ —	$ 215
Increase in right-of-use assets and operating lease liabilities from lease modifications	$ —	$ 32

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

1. Nature of the business

Kailera Therapeutics, Inc. (the "Company" or "Kailera") is an advanced clinical-stage biotechnology company focused on elevating the next era of obesity care by advancing a diversified pipeline to provide options for people living with obesity no matter where they are in their treatment journey.

Risks and Uncertainties

The Company was incorporated in May 2024 and is subject to risks and uncertainties common to early-stage companies in the biopharmaceutical industry, including but not limited to, new technological innovations, protection of proprietary technology, dependence on key personnel, compliance with government regulations, reliance on third-party organizations for the discovery, manufacturing, clinical support of its product candidates, and the need to obtain additional financing. Product candidates currently under development will require significant additional research and development efforts, including extensive nonclinical and clinical testing and regulatory approval, prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure and extensive compliance-reporting capabilities.

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

Initial Public Offering

On April 20, 2026, the Company completed its initial public offering, in which it issued and sold an aggregate of 44,921,875 shares of its common stock (inclusive of 5,859,375 shares pursuant to the full exercise of the underwriters' overallotment option) at a public offering price of $16.00 per share. The Company received aggregate net proceeds of $662.0 million after deducting commissions, underwriting discounts and other offering costs.

Liquidity and Going Concern

Through September 30, 2026, the Company has funded its operations primarily with proceeds from the sale and issuance of shares of convertible preferred stock, the issuance of convertible promissory notes, which converted into shares of convertible preferred stock and the sale and issuance of common stock as part of its initial public offering. The Company has incurred losses since its inception, including a net loss of $285.8 million for the nine months ended September 30, 2026. In addition, as of September 30, 2026, the Company had an accumulated deficit of $654.5 million. The Company expects to continue to generate operating losses for the near future. The future viability of the Company is dependent on its ability to raise additional capital to finance its operations. The Company's inability to raise capital as and when needed could have a negative impact on its financial condition and ability to pursue its business strategies, and could require it to significantly delay, scale back or discontinue the development and commercialization of one or more of its product candidates. There can be no assurance that the current operating plan will be achieved or that additional funding will be available on terms acceptable to the Company, or at all.

The Company believes the cash, cash equivalents and marketable securities on hand of $1,037.6 million as of September 30, 2026 will be sufficient to fund its operations and capital expenditure requirements for at least twelve months from the date these condensed consolidated financial statements are issued.

2. Summary of significant accounting policies

Basis of Presentation

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

Unaudited interim financial information

The condensed consolidated balance sheet as of December 31, 2025 was derived from audited financial statements but does not include all disclosures required by GAAP. The accompanying unaudited financial statements as of September 30, 2026 and for the three and nine months ended September 30, 2026 and 2025 have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission, or SEC, for interim financial statements. Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted pursuant to such rules and regulations. These financial statements should be read in conjunction with the Company's audited financial statements included in its final prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act of 1933, as amended, on April 17, 2026 (the "Prospectus"). The unaudited condensed consolidated financial statements have been prepared on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, consisting only of normal recurring adjustments necessary for a fair presentation of the Company's financial position as of September 30, 2026, and the results of operations for the three and nine months ended September 30, 2026 and 2025 and cash flows for the nine months ended September 30, 2026. The results of operations for the three and nine months ended September 30, 2026 are not necessarily indicative of the results of operations that may be expected for the year ending December 31, 2026 or any other period.

Significant Accounting Policies

As of September 30, 2026, the Company's significant accounting policies, which are described in Note 2 of the Notes to the Consolidated Financial Statements for the year ended December 31, 2025 included in the Prospectus related to the initial public offering filed with the SEC pursuant to Rule 424(b)(4) under the Securities Act of 1933, have not changed, except as noted below.

Stock-based compensation

For stock-based awards issued to employees, non-employees, and members of the Company's board of directors (the "Board") for their services on the Board, the Company measures the estimated fair value of the stock-based award on the date of grant and recognizes compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. The Company issues stock-based awards with service-based vesting conditions and records the expense for these awards using the straight-line method. The Company issues performance-based awards and records the expense for these awards over the expected vesting term and recognizes expense only if it is probable the performance-based conditions will be achieved. The Company issues stock-based awards with market-based vesting conditions and recognizes expense as the requisite service is rendered by the employee, regardless of when, if ever, the market-based vesting conditions are satisfied. The Company accounts for forfeitures as they occur.

The Company classifies stock-based compensation expense in its condensed consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's cash compensation costs are classified.

The fair value of each stock option award with either service-based vesting conditions or performance-based conditions is estimated on the date of grant using the Black-Scholes option pricing model. As there is limited trading history of its common stock, the Company determined the volatility for awards granted based on an analysis of reported data for a group of guideline companies that issued options with substantially similar terms. The expected volatility has been determined using a weighted average of the historical volatility measures of this group of guideline companies. The Company expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. The Company has not paid, and does not anticipate paying, cash dividends on its common stock; therefore, the expected dividend yield is assumed to be zero.

The fair value of each stock option award with market-based vesting conditions is estimated on the date of grant using a Monte Carlo simulation model.

Emerging growth company status and smaller reporting company status

The Company is an "emerging growth company," as defined in the Jumpstart Our Business Startups Act (the "JOBS Act"), and may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. The Company may take advantage of these exemptions until the Company is no longer an emerging growth company. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. The Company has elected to use the extended transition period for complying with new or revised accounting standards and as a result of this election, its financial statements may not be comparable to companies that comply with public company effective dates. The Company may take advantage of these

exemptions up until the last day of the fiscal year following the fifth anniversary of its initial public offering, or December 31, 2031, or such earlier time that it is no longer an emerging growth company. The Company would cease to be an emerging growth company if it has more than $1.235 billion in annual revenue, if it has more than $700.0 million in market value of our stock held by non-affiliates (and it has been a public company for at least 12 months and has filed one annual report on Form 10-K) or the Company issues more than $1.0 billion of non-convertible debt securities over a three-year period.

As of the date of the issuance of these financial statements, the Company is also a "smaller reporting company", meaning that the market value of the Company's stock held by non-affiliates is less than $700 million and its annual revenue was less than $100 million during the most recently completed fiscal year. The Company may continue to be a smaller reporting company if either (i) the market value of its stock held by non-affiliates is less than $250 million or (ii) its annual revenue is less than $100 million during the most recently completed fiscal year and the market value of its stock held by non-affiliates is less than $700 million. If the Company is a smaller reporting company at the time it ceases to be an emerging growth company, the Company may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company the Company may choose to present only the two most recent fiscal years of audited financial statements in its Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Recently issued and adopted accounting pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed below, the Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial statements and disclosures.

In November 2024, the FASB issued ASU 2024-03, *Income Statement-Reporting Comprehensive Income-Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses* ("ASU 2024-03"). The amendments in ASU 2024-03 require public entities to disclose specified information about certain costs and expenses. ASU 2024-03 is effective for fiscal years beginning after December 15, 2026, and for interim periods within those fiscal years beginning after December 15, 2027. The Company is currently evaluating the impact of this standard on its condensed consolidated financial statements.

In September 2025, the FASB issued ASU 2025-06, *Intangibles – Goodwill and Other – Internal-Use Software* ("ASU 2025-06"). The amendments change (i) the criteria regarding the timing of the capitalization of costs for internal-use software and (ii) the accounting for website development costs. The amendments are effective for annual periods beginning after December 15, 2027. The Company is currently evaluating the impact of the amendments on its condensed consolidated financial statements.

In September 2025, the FASB issued ASU 2025-07, *Derivatives Scope Refinements and Scope Clarification for Share-Based Noncash Consideration from a Customer in a Revenue Contract* ("ASU 2025-07"). The guidance refines the scope of ASC Topic 815, Derivatives and Hedging, to clarify which contracts are subject to derivative accounting. The guidance also provides clarification under ASC 606 for share-based payments from a customer in a revenue contract. The Company adopted the standard on a modified retrospective basis as of January 1, 2026. As a result of the new derivative scope exception created by the standard, certain previously identified derivatives no longer meet the criteria for derivative accounting. These derivatives did not have any fair value as of December 31, 2025, and therefore no amounts are recognized related to the adoption of the standard. The guidance of ASU 2025-07 related to share-based noncash consideration received in exchange for the transfer of goods or services to a customer did not have any impact on the Company's condensed consolidated financial statements upon adoption.

In December 2025, the FASB issued ASU 2025-12, *Codification Improvements* ("ASU 2025-12"). ASU 2025-12 addresses suggestions received from stakeholders on the ASC and to make other incremental improvements to U.S. GAAP. The update represents changes to the ASC that (1) clarify, (2) correct errors, or (3) make minor improvements. The amendments make the ASC easier to understand and apply. The guidance is effective for fiscal years beginning after December 15, 2026, including interim periods within those fiscal years. The Company is currently evaluating the impact of this standard on its condensed consolidated financial statements.

3. Marketable securities

The following table summarizes the amortized cost and estimated fair value of the Company's investments, which are considered to be available-for-sale investments, and were included in marketable securities and long-term marketable securities (in thousands):

	September 30, 2026			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable securities:				
U.S. government agency debt securities	$ 270,176	$ —	$ (760)	$ 269,416
Corporate debt securities	318,934	—	(1,428)	317,506
Commercial paper	208,332	—	(337)	207,995
	$ 797,442	$ —	$ (2,525)	$ 794,917
Long-term marketable securities:				
U.S. government agency debt securities	$ 81,133	$ —	$ (627)	80,506
Corporate debt securities	56,262	—	(581)	55,681
	$ 137,395	$ —	$ (1,208)	$ 136,187

	December 31, 2025			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Marketable securities:				
U.S. government agency debt securities	$ 169,690	$ 108	$ —	$ 169,798
Corporate debt securities	122,737	23	(47)	122,713
Commercial paper	93,241	37	—	93,278
	$ 385,668	$ 168	$ (47)	$ 385,789
Long-term marketable securities:				
U.S. government agency debt securities	$ 62,038	$ 80	$ —	$ 62,118
Corporate debt securities	44,537	18	(1)	44,554
	$ 106,575	$ 98	$ (1)	$ 106,672

Certain short-term marketable securities with original maturities of less than 90 days are included in cash and cash equivalents on the consolidated balance sheets and are not included in the tables above. As of September 30, 2026, all short-term marketable securities had contractual maturities within one year and all long-term marketable securities had contractual maturities between one to two years.

As of September 30, 2026 and December 31, 2025, the Company held 144 and 12 securities, respectively, that were in an unrealized loss position, with a total fair market value of $922.5 million and $79.0 million, respectively. As of September 30, 2026 and December 31, 2025, there were no available-for-sale securities in a continuous unrealized loss position for greater than 12 months. The Company evaluated its securities for potential impairment and considered the decline in market value to be primarily attributable to current economic and market conditions. Additionally, the Company does not intend to sell the investments in an unrealized loss position and does not expect it will be required to sell the investments before recovery of their amortized cost bases, which may be at maturity. Given the Company's intent and ability to hold such investments until recovery, and the lack of a significant change in credit risk for these investments, the Company does not consider these investments to be impaired and there were no allowances for credit losses as of September 30, 2026 and as of December 31, 2025.

4. Fair value of financial assets and liabilities

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

	Fair value measurements as of September 30, 2026			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 93,202	$ —	$ —	$ 93,202
Corporate debt securities	—	—	—	—
Commercial paper	—	9,917	—	9,917
Marketable securities:				
U.S. government agency debt securities	—	349,922	—	349,922
Corporate debt securities	—	373,187	—	373,187
Commercial paper	—	207,995	—	207,995
Total fair value of financial assets	$ 93,202	$ 941,021	$ —	$ 1,034,223

	Fair value measurements as of December 31, 2025			
	Level 1	Level 2	Level 3	Total
Cash equivalents:				
Money market funds	$ 104,212	$ —	$ —	$ 104,212
Corporate debt securities	—	27,353	—	27,353
Commercial paper	—	25,922	—	25,922
Marketable securities:				
U.S. government agency debt securities	—	231,915	—	231,915
Corporate debt securities	—	167,268	—	167,268
Commercial paper	—	93,278	—	93,278
Total fair value of financial assets	$ 104,212	$ 545,736	$ —	$ 649,948

For the nine months ended September 30, 2026, there were no transfers between Level 1, Level 2 and Level 3.

5. Prepaid expenses and other current assets

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

	September 30, 2026	December 31, 2025
Prepaid research and development	7,150	4,539
Interest receivable	6,260	2,725
Other	4,892	4,217
	$ 18,302	$ 11,481

6. Leases

In March 2025, the Company executed a new, seven-year, non-cancellable operating lease agreement for approximately 39,500 square feet of office space in Waltham, Massachusetts for its corporate headquarters. The lease commenced in October 2025, following completion of construction to prepare the premises for the Company's intended use. The lease provided for base rent of $2.2 million for the first year, which will increase by approximately 2% each year. The Company's lease payments also include real estate taxes and other operating expenses allocable to the leased premises, which exceed base year amounts. The Company has the option to extend the lease for one additional five-year term with base rent calculated on the then-market rate. In accordance with the lease agreement, the Company maintained a letter of credit of $0.8 million, which is refundable at the end of the lease term. As of September 30, 2026, the underlying cash balance collateralizing this letter of credit was classified as restricted cash (non-current) on the condensed consolidated balance sheets based on the release date of the restrictions of this cash. In connection with the new lease agreement, the Company

amended its previous lease in Waltham, Massachusetts to extend the lease term to end shortly after the lease commencement date of its new lease agreement, which occurred in the fourth quarter of 2025.

Upon commencement of the lease for its corporate headquarters, the Company recognized operating lease liabilities of $10.6 million, based on an expected contractual obligation of $15.9 million and an incremental borrowing rate of 12.0% and recognized a right-of-use asset of $10.6 million.

The following table summarizes the effect of lease costs in the Company's condensed consolidated statements of operations and comprehensive loss (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Operating lease costs	$ 568	$ 114	$ 1,765	$ 371
Variable lease costs	—	—	—	—
Total lease costs	$ 568	$ 114	$ 1,765	$ 371

For the nine months ended September 30, 2026 and 2025, the Company made cash payments for operating leases of $1.7 million and $0.4 million, respectively.

The following table summarizes the future minimum lease payments due under operating leases as of September 30, 2026 (in thousands):

	Total minimum lease payments
Year Ending December 31,	
2026	$ 549
2027	2,220
2028	2,259
2029	2,299
2030	2,338
2031 and thereafter	4,387
Total lease payments	14,052
Less: interest	(4,081)
Total lease liabilities	$ 9,971

The total lease liabilities are presented on the Company's consolidated balance sheets based on maturity dates. As of September 30, 2026, $1.1 million is classified under "operating lease liabilities, current" for the portion due within twelve months, and $8.9 million is classified under "operating lease liabilities, non-current."

As of September 30, 2026, the weighted average remaining lease term was 6.1 years and the weighted average incremental borrowing rate used to determine the operating lease liability was 12%.

7. Accrued expenses and other current liabilities

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

	September 30, 2026	December 31, 2025
Accrued research and development	$ 18,930	$ 24,000
Accrued employee compensation and benefits	11,115	9,054
Other	1,545	4,782
	$ 31,590	$ 37,836

8. Convertible preferred stock

As of September 30, 2026, the authorized capital stock of the Company included 10,000,000 shares of $0.00001 par value preferred stock, of which there were no shares issued or outstanding.

As of December 31, 2025, the preferred stock consisted of the following:

			December 31, 2025		
	Preferred shares authorized	Preferred shares issued and outstanding	Carrying value	Liquidation preference	Common stock issuable upon conversion
Series A-1 convertible preferred stock	30,000,000	30,000,000	$ 294,357,583	$ 300,000,000	30,000,000
Series A-2 voting convertible preferred stock	4,968,789	4,968,789	84,500,659	49,687,890	9,477,719
Series A-2 nonvoting convertible preferred stock	708,814	708,814	11,447,346	7,088,140	2,034,133
Total Series A-2 convertible preferred stock	5,677,603	5,677,603	95,948,005	56,776,030	11,511,852
Series B convertible preferred stock	43,084,539	43,084,539	602,057,535	603,183,546	43,084,539
Total	78,762,142	78,762,142	$ 992,363,123	$ 959,959,576	84,596,391

On April 20, 2026, the Company completed its initial public offering and all outstanding shares of convertible preferred stock were converted into 84,596,391 shares of common stock.

9. Common stock

As of September 30, 2026, the authorized capital stock of the Company included 800,000,000 shares of common stock, $0.00001 par value with 129,684,183 shares of common stock issued and outstanding. As of December 31, 2025, the authorized capital stock of the Company included 105,384,000 shares of common stock, $0.00001 par value, with 19,048 shares of common stock issued and outstanding.

On April 20, 2026, the Company completed its initial public offering in which it issued and sold an aggregate of 44,921,875 shares of its common stock (inclusive of 5,859,375 shares pursuant to the full exercise of the underwriters' overallotment option) at a public offering price of $16.00 per share. The Company received aggregate net proceeds of $662.0 million after deducting commissions, underwriting discounts and other offering costs.

As part of the initial public offering, all outstanding shares of convertible preferred stock were converted into 84,596,391 shares of common stock. The certificate of incorporation was also amended and restated which, among other things, adjusted the number of authorized shares to 800,000,000 shares and 10,000,000 shares of common stock and preferred stock, respectively.

Each share of common stock entitles the holder to one vote, together with the holders of the preferred stock. Common stockholders are entitled to receive dividends, subject to the preferential dividend rights of the preferred stock. Through September 30, 2026, no cash dividends have been declared or paid.

As of September 30, 2026 and December 31, 2025, the Company has reserved the following shares of common stock for future issuance:

	September 30, 2026	December 31, 2025
Shares reserved for conversion of Series A-1 preferred stock	—	30,000,000
Shares reserved for conversion of Series A-2 preferred stock	—	11,511,852
Shares reserved for conversion of Series B preferred stock	—	43,084,539
Shares reserved for exercise of outstanding stock options	19,150,119	13,470,409
Shares reserved for issuance under all equity compensation plans	10,451,957	2,028,232
Total shares of authorized common stock reserved for future issuance	29,602,076	100,095,032

10. Stock-based compensation

Incentive Plans

The Company's 2024 Equity Incentive Plan (the "2024 Plan") provides for the Company to sell or issue common stock or restricted stock, or to grant incentive stock options or nonqualified stock options for the purchase of common stock, to employees, directors and consultants of the Company. The 2024 Plan is administered by the Board, or its delegee.

On April 16, 2026, in connection with the Company's initial public offering, the Company adopted the 2026 Incentive Award Plan (the "2026 Plan"), which provides for the issuance of cash and equity awards. The number of shares initially available for issuance under awards granted pursuant to the 2026 Plan was 14,011,037 shares. The 2026 Plan provides that, on the first day of each calendar year beginning on and including January 1, 2027 and ending on and including January 1, 2036, the number of shares available for issuance under the 2026 Plan shall be increased by that number of shares equal to the lesser of (a) 5% of the aggregate number of shares outstanding on the final day of the immediately preceding calendar year and (b) such smaller number of shares as determined by the Board. Following the adoption of the 2026 Plan, any shares subject to an award issued under the 2024 Plan or the 2026 Plan that expires, lapses or is terminated, exchanged for or settled in cash, surrendered, repurchased, or canceled without having been fully exercised/settled, will become available for future grant under the 2026 Plan. As of September 30, 2026, 9,156,475 shares remained available for future grant under the 2026 Plan.

The exercise prices, vesting and other restrictions are determined at the discretion of the Board, or its delegee, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the common stock on the date of grant and the term of the stock option may not be greater than ten years. The Company generally grants stock-based awards with service conditions only ("service-based" awards) which generally vest over three or four years. The Company also has granted performance-based awards which vest upon the achievement of specified events and market condition awards which vest upon the satisfaction of certain market-based conditions. Stock options generally expire after ten years.

Employee Stock Purchase Plan

On April 16, 2026, in connection with the Company's initial public offering, the Company adopted the 2026 Employee Stock Purchase Plan (the "ESPP"), which provides for the issuance of up to 1,295,482 shares of common stock. The ESPP provides that, on the first day of each calendar year beginning on and including January 1, 2027 and ending on and including January 1, 2036, the number of shares available for issuance under the ESPP shall be increased by that number of shares equal to the lesser of (a) 1% of the aggregate number of shares outstanding on the final day of the immediately preceding calendar year and (b) such smaller number of shares as determined by the Board.

Stock option activity

The following table summarizes the Company's stock option activity during the nine months ended September 30, 2026:

	Number of options	Weighted-average exercise price	Weighted-average remaining contractual term (years)	Aggregate intrinsic value (in thousands)
Outstanding as of December 31, 2025	13,470,409	$ 6.20	9.17	$ 52,398
Granted	6,741,274	15.34		
Exercised	(146,869)	5.30		
Cancelled or forfeited	(914,695)	8.38		
Outstanding as of September 30, 2026	19,150,119	$ 9.32	8.83	$ 67,099
Exercisable at September 30, 2026	3,895,203	$ 5.37	7.72	$ 23,557

The aggregate intrinsic value of stock options is calculated as the amount by which the fair value of the Company's common stock exceeds the exercise prices of the underlying stock options. The intrinsic value of stock options exercised during the three and nine months ended September 30, 2026 was $0.8 million and $2.0 million, respectively. There were no stock options exercised during the three and nine months ended September 30, 2025.

The weighted-average grant-date fair value of the Company's stock options granted for the three and nine months ended September 30, 2026 was $13.52 and $10.69, respectively. The weighted-average grant-date fair value of the Company's stock options granted for the three and nine months ended September 30, 2025 was $3.85 and $3.81, respectively.

Stock option valuation

The Company uses the Black-Scholes model to value its stock option grants that vest based on the passage of time or the achievement of certain performance criteria and expenses the related compensation cost using the straight-line method over the vesting period. The assumptions that the Company used to determine the grant-date fair value of stock options granted during the three and nine months ended September 30, 2026 and 2025 were as follows, presented on a weighted-average basis:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Expected option life (years)	6.1	6.0	6.0	6.1
Risk-free interest rate	4.5%	4.0%	4.0%	4.1%
Expected volatility	80.2%	80.4%	81.1%	78.4%
Expected dividend yield	—%	—%	—%	—%

During the three and nine months ended September 30, 2026, the Company also granted stock options that vest upon the achievement of certain share price thresholds. The Company accounted for these stock options as market condition awards and used the Monte Carlo valuation model to determine the fair value of the stock options and an expense recognition period of approximately 1.3 years. As of September 30, 2026, there were a total of 1,302,000 market condition stock options outstanding.

Stock-based compensation

Stock-based compensation expense was allocated as follows (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development	$ 2,952	$ 291	$ 6,353	$ 787
General and administrative	6,969	3,978	15,851	6,636
Total stock-based compensation expense	$ 9,921	$ 4,269	$ 22,204	$ 7,423

As of September 30, 2026, total unrecognized compensation cost related to the unvested stock-based awards was $92.3 million, which is expected to be recognized over a weighted-average period of 2.7 years.

11. Net loss per share

For purposes of the diluted net loss per share calculation, stock options, unvested restricted stock and convertible preferred stock are considered to be common stock equivalents but have been excluded from the calculation of diluted net loss per share, as their effect would be anti-dilutive for the periods presented. Therefore, the weighted-average number of common shares outstanding used to calculate both basic and diluted net loss per share attributable to common stockholders is the same.

The following potentially dilutive common stock equivalents, presented based on amounts outstanding at the period end, were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods indicated because including them would have had an anti-dilutive effect:

	As of September 30,	
	2026	2025
Options to purchase common stock	19,150,119	7,557,013
Convertible preferred stock (as converted to common stock)	—	39,487,338
Total	19,150,119	47,044,351

12. Commitments and contingencies

Legal proceedings

The Company, from time to time, may be party to litigation arising in the ordinary course of business. The Company was not subject to any material legal proceedings during the nine months ended September 30, 2026 and 2025, and, to the best of its knowledge, no material legal proceedings are currently pending or threatened as of September 30, 2026.

Significant agreements

Hengrui license and collaboration agreement

In May 2024, the Company entered into a license and collaboration agreement (the "Hengrui License Agreement") with Jiangsu Hengrui Pharmaceuticals Co., Ltd. ("Hengrui"). Upon execution of the Hengrui License Agreement, the Company paid $100.0 million in cash as a non-refundable upfront payment and incurred a $10.0 million technology transfer fee, which was paid in December 2024. The Company also issued 5,677,603 shares of Series A-2 convertible preferred stock. The fair value of these shares was accounted for as additional consideration for the acquired license.

Under the terms of the Hengrui License Agreement, the Company obtained the exclusive right to develop, manufacture and commercialize specified programs worldwide, excluding China, Hong Kong, Macau, and Taiwan (the "Territory"). The Company is obligated to use commercially reasonable efforts to advance these programs. The Company may not pursue development of any competitive products, as defined in the Hengrui License Agreement, for a period of two years. The Company also has a right of first refusal on certain programs that are under development by Hengrui as well as options to license specified new form products and combination products developed by Hengrui.

Hengrui must provide certain transition and data sharing services and must also manufacture clinical materials on behalf of the Company upon request. The Company is responsible for all costs of developing and commercializing the programs in the Territory.

The Company is obligated to make clinical and regulatory milestone payments of up to an aggregate of $200.0 million. In addition, the Company is obligated to make commercial milestone payments of up to an aggregate of $5.7 billion. The Company is also obligated to make tiered royalty payments ranging from mid-single digit to low-tens based on a percentage of net sales by the Company.

If the Company elects to receive rights to the specified new form products or combination products, the Company must make option exercise payments of either a mid-seven figure amount or low-eight figure amount, which may be refundable with respect to combination products in certain circumstances.

The Company accounted for the arrangement as an asset acquisition of in-process research and development technology. No expenses were incurred or payments made, under the arrangement, during the nine months ended September 30, 2026 and 2025. All other future payments will be recognized upon achievement.

13. Related party transactions

In May 2024, the Company entered into the Hengrui License Agreement. As partial consideration for this arrangement, the Company issued shares of Series A-2 convertible preferred stock, which represented 19.9% of the outstanding capital stock of the Company at issuance, on a fully-diluted basis.

In addition, as part of the agreement with Hengrui, Hengrui has agreed to provide the Company with manufacturing services and supplies. In connection with these services, the Company recognized $0.6 million and $2.1 million in research and development expenses for the three and nine months ended September 30, 2026, respectively. The Company did not recognize material research and development expenses in connection with these services during the three months ended September 30, 2025. During the nine months ended September 30, 2025, the Company recognized $0.7 million in research and development expenses in connection with these services. Amounts due to Hengrui by the Company in connection with these services totaled $2.2 million and $0.2 million as of September 30, 2026 and December 31, 2025, respectively, which amounts were included in accrued expenses on the consolidated balance sheets.

14. Segment reporting

The Company operates and manages its business as a single operating segment for the purposes of assessing performance and making operating decisions. The Company’s current focus is on the development of a broad, advanced, and differentiated portfolio of clinical-stage injectable and oral therapies for the treatment of obesity. The Company has one reportable segment. The determination of reportable segments is based on the Chief Operating Decision Maker's ("CODM") use of financial information provided for the purpose of assessing performance and making operating decisions. The Company's CODM is its Chief Executive Officer.

The CODM assesses performance for the segment based on net loss. The measure of segment assets is reported on the balance sheet as total assets.

To date, the Company has not generated any product revenue. The Company expects to continue to incur significant expenses and operating losses for the foreseeable future as it advances product candidates through all stages of development and clinical trials and, ultimately, seeks regulatory approval. As such, the CODM uses cash forecast models in deciding how to invest into the segment. Such cash forecast models are reviewed to assess the entity-wide operating results and performance. Net loss is used to monitor budget versus actual results. Monitoring budgeted versus actual results is used in assessing performance of the segment, along with cash forecast models.

The table below summarizes the expense categories reviewed by the CODM for the three and nine months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
External research and development[1]				
Ribupatide injection	$ 53,966	$ 12,830	$ 175,106	$ 27,506
Ribupatide oral	1,582	—	3,272	—
Safiglipron	8,606	3,551	22,471	4,507
KAI-4729	850	74	1,638	412
Unallocated research and development and other[2]	4,470	2,450	12,789	5,200
General and administrative[3]	7,060	3,461	19,213	10,537
Personnel related (including stock-based compensation)[4]	29,802	17,743	77,880	43,055
Interest income	(10,611)	(2,251)	(26,321)	(6,052)
Other (income) expense, net	(60)	1,765	(211)	1,388
Net loss	$ 95,665	$ 39,623	$ 285,837	$ 86,553

1) External research and development is allocated to the Company's programs, and includes nonclinical, clinical trial, contract manufacturing, non-employee consultant and contractor, and other research and development costs.

2) Unallocated research and development includes external costs that are not program specific primarily related to consultant and contractor costs, in addition to research and development allocated rent expense and depreciation.

3) General and administrative includes external costs related to the Company's executive, finance, legal, and other administrative functions, such as professional fees for legal, patent, consulting, accounting, audit and tax services. General and administrative also includes information technology costs and general and administrative allocated rent expense and depreciation.

4) Internal costs includes salaries and related costs, including stock-based compensation, for employees.

15. Subsequent events

The Company has completed an evaluation of all subsequent events after September 30, 2026 through the issuance of the unaudited condensed consolidated financial statements, to ensure that these condensed consolidated financial statements include appropriate disclosure of events both recognized in the condensed consolidated financial statements as of September 30, 2026, and events which occurred subsequently but were not recognized in the condensed consolidated financial statements. No subsequent events have occurred that would require recognition in the unaudited condensed consolidated financial statements or disclosure in the accompanying notes.

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

The following discussion and analysis of our financial condition and results of operations should be read together with the unaudited condensed consolidated financial statements and related notes included elsewhere in this Quarterly Report on Form 10-Q, as well as our audited financial statements and notes thereto as of and for the year ended December 31, 2025 and the related Management's Discussion and Analysis of Financial Condition and Results of Operations included in our final prospectus filed with the Securities and Exchange Commission ("SEC") pursuant to Rule 424(b) under the Securities Act of 1933, as amended (the "Securities Act") on April 17, 2026 (the "Prospectus") that forms a part of our Registration Statement on Form S-1 (File No. 333-294690). This discussion and analysis contains forward-looking statements that involve risks and uncertainties. Factors that could cause or contribute to those differences include, but are not limited to, those identified below and those discussed in the section titled "Risk Factors" in Part II, Item 1A of this Quarterly Report on Form 10-Q. See also the section titled "Special Note Regarding Forward-Looking Statements." Additionally, our historical results are not necessarily indicative of the results that may be expected in any future period. Unless the context otherwise requires, all references in this section to the "Company", "Kailera", "we", "our" or "us" refers to the business of Kailera Therapeutics, Inc. and its subsidiaries.

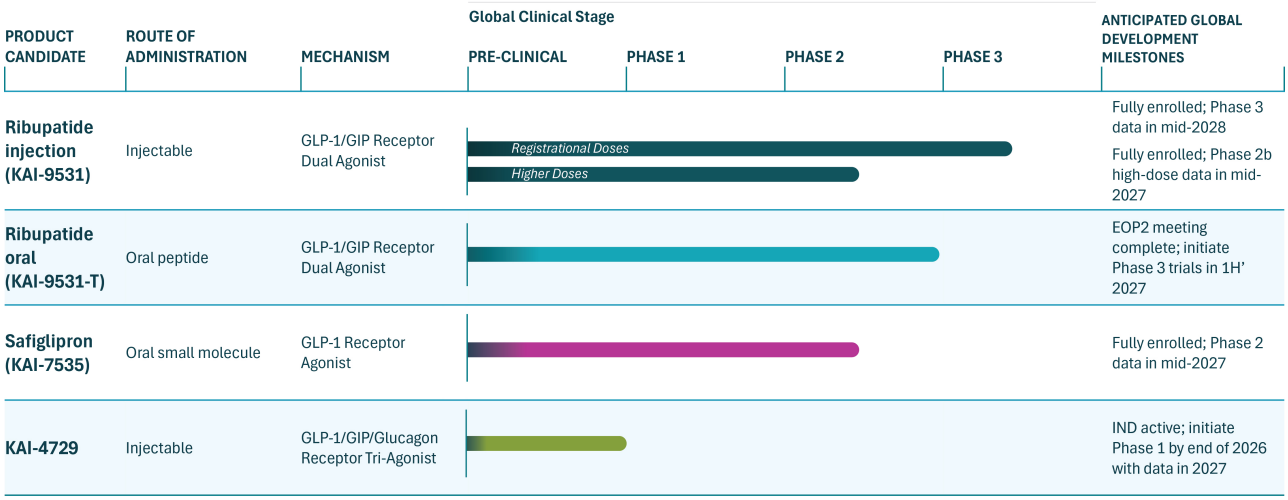
Overview

We are a clinical-stage biotechnology company focused on elevating the next era of obesity care by advancing a diversified pipeline to provide options for people living with obesity no matter where they are in their treatment journey. Obesity is a chronic, progressive and debilitating disease that impacts over 1 billion people globally and requires long-term comprehensive treatment. Since obesity is the driving factor for more than 200 comorbidities and represents a significant contributor to increased morbidity and mortality, our vision is to deliver category-leading obesity management medications that give people the power to restore their health and transform their lives. With our obesity-first focus, we have built a diversified pipeline of product candidates specifically designed to address critical needs in the current therapeutic landscape with a lead product candidate that we believe offers the potential for the greatest weight loss.

We are rapidly progressing four clinical-stage product candidates, leveraging multiple glucagon-like peptide-1, or GLP-1, based mechanisms of action and routes of administration. Our lead product candidate, ribupatide injection (also known as KAI-9531), is currently being evaluated in global Phase 3 trials as a once-weekly injectable GLP-1/glucose-dependent insulinotropic polypeptide, or GIP, receptor dual agonist peptide that we believe offers the potential for the greatest weight loss compared to all obesity management medications currently available or in development. However, we have not conducted head-to-head clinical trials of ribupatide injection or any of our other product candidates against currently approved products or those in development; all of our product candidates are still in clinical development in the United States, and it will take several years to develop and, if approved, commercialize them; and even if we are successful in obtaining regulatory approval, there can be no guarantee as to our product candidates' ability to outperform other therapies in terms of efficacy or tolerability. We are expanding our ribupatide franchise by developing a once-daily oral tablet formulation, ribupatide oral, to provide a convenient oral option with the potential for highly differentiated tolerability with compelling weight loss among oral treatments. Additionally, we are advancing a second oral product candidate, safiglipron (also known as KAI-7535), a once-daily small molecule GLP-1 receptor agonist with the potential to improve on the clinical profile of existing oral treatments. Finally, we are developing KAI-4729, a once-weekly injectable GLP-1/GIP/glucagon receptor tri-agonist that leverages an incremental mechanism to potentially deliver compelling weight loss, improved liver fat reduction and a differentiated tolerability profile.

We have in-licensed ribupatide injection and our other product candidates through a strategic collaboration with Jiangsu Hengrui Pharmaceuticals Co., Ltd., or Hengrui, a global pharmaceutical company with extensive experience in drug discovery and development. In May 2024, we entered into a license and collaboration agreement with Hengrui, or the Hengrui License Agreement, which provides us with exclusive rights to the development and commercialization of our product candidates outside of China, Hong Kong, Macau and Taiwan, or Greater China, with Hengrui responsible for development and commercialization within Greater China.

Our diversified GLP-1-based pipeline is summarized below:



Recent developments

- In September 2026, we announced that we completed enrollment in the KaiNETIC global Phase 3 program, with data anticipated in mid-2028. The program encompasses three global, double-blind, randomized, placebo-controlled Phase 3 trials enrolling approximately 5,000 participants and is evaluating once-weekly ribupatide injection doses of up to 10 mg over 76 weeks in adults living with obesity or overweight.
- In November 2026, we announced that we completed an End-of-Phase 2 meeting with the U.S. Food and Drug Administration, or FDA, and expect to initiate a global Phase 3 program of ribupatide oral in obesity in the first half of 2027. The Phase 3 program will include two trials evaluating once-daily ribupatide oral doses up to 25 mg over 60 weeks in adults living with obesity or overweight with comorbidities, with and without type 2 diabetes, or T2D.
- In November 2026, we announced that we completed enrollment in the global Phase 2 trial of safiglipron in obesity, with data anticipated in mid-2027. The double-blind, randomized, placebo-controlled Phase 2 trial enrolled approximately 300 adult participants in the U.S. and Australia with a body mass index, or BMI, of 30 or greater or a BMI of 27 or greater with at least one co-morbidity, which may include T2D. This trial is designed to further optimize safiglipron's clinical profile for the treatment of obesity by evaluating a wide range of doses over 44 weeks, with a starting dose of 15 mg, and following a gradual, stepwise titration schedule designed to improve tolerability and determine the optimal balance between weight loss and tolerability.
- In November 2026, we announced that the KAI-4729 Investigational New Drug application was active with the FDA and that we are on track to initiate a Phase 1 single-dose injection site/ethnic bridging trial by the end of 2026, with data anticipated in 2027.

Risks and uncertainties

Since our inception in May 2024, we have devoted substantially all of our resources to organizing and staffing our company, business planning, raising capital, acquiring intellectual property rights, and conducting research and development activities for our product candidates. We do not have any products approved for sale and have not generated any revenue from any sources, including product sales. Through the issuance of the condensed consolidated financial statements included elsewhere in this Quarterly Report on Form 10-Q, we have funded our operations primarily with proceeds from the sale and issuance of shares of our convertible preferred stock, the issuance of convertible promissory notes, which converted into shares of convertible preferred stock, and the sale and issuance of common stock as part of our initial public offering.

Since our inception, we have incurred significant operating losses. Our ability to generate product revenue sufficient to achieve profitability will depend heavily on the successful development and eventual commercialization of one or more of our current or future product candidates. Our net loss was $285.8 million for the nine months ended September 30, 2026. As of September 30, 2026, we had an accumulated deficit of $654.5 million. We expect to continue to incur significant expenses and recognize operating losses for at least

the next several years as we advance our product candidates through later stage clinical development and seek regulatory approval of our product candidates. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. We may also incur expenses in connection with the in-licensing or acquisition of additional product candidates.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time, if ever, that we can generate product revenue sufficient to achieve profitability, we expect to finance our operations with proceeds from outside sources, with a majority of such proceeds to be derived from sales of equity securities. As we continue to pursue our business plan, we expect to finance our operations through a combination of equity offerings, debt financings, royalty financings or other capital sources, including current or potential future collaborations, licenses, and other similar arrangements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as, and when, needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

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

As of September 30, 2026, we had cash, cash equivalents and marketable securities of $1,037.6 million. We believe that the cash, cash equivalents and marketable securities on hand as of September 30, 2026 will be sufficient to fund our operations into mid-2028. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect. See "—Liquidity and capital resources."

Components of our consolidated results of operations

Revenue

Through September 30, 2026, we have not generated revenue from any sources, including product sales, and do not expect to generate any revenue from the sale of products in the near future. If development efforts for our product candidates are successful and result in regulatory approval, we may generate revenue in the future from product sales.

Operating expenses

Research and development expenses

Research and development expenses consist primarily of costs incurred in connection with the development of our product candidates. These expenses include:

- employee-related expenses, including salaries, related benefits, and stock-based compensation expense for employees engaged in research and development;
- costs incurred related to the Hengrui License Agreement;
- expenses incurred in connection with the nonclinical and clinical development of our product candidates, including under agreements with third parties, such as consultants and contract research organizations, or CROs;
- the cost of manufacturing drug products for use in our nonclinical studies and clinical trials, including under agreements with third parties, such as consultants and contract manufacturing organizations, or CMOs;
- costs related to compliance with regulatory requirements;
- allocated facilities costs, depreciation and other expenses, which include rent and utilities; and
- other expenses incurred as a result of research and development activities.

We expense research and development costs as incurred. Non-refundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed, or when it is no longer expected that the goods will be delivered or the services rendered.

Our direct research and development expenses are tracked on a program-by-program basis for our product candidates and consist primarily of external costs, such as fees paid to consultants, contractors, CROs, and CMOs in connection with our nonclinical, clinical and manufacturing development activities. We do not allocate employee costs and costs associated with facilities, including rent and depreciation, or other indirect costs, to specific product candidates because these costs are deployed across multiple product candidates and, as such, are not separately classified. We use internal resources primarily to conduct our research and discovery activities, as well as to manage our nonclinical, clinical and manufacturing development activities. These employees work across multiple product candidates and, therefore, we do not track these costs by product candidate.

Research and development activities are central to our business model. Product candidates in later stages of clinical development, particularly in obesity, generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. As a result, we expect that our research and development expenses will increase substantially over the next several years for increased costs related to the development of our product candidates as we conduct our global Phase 3 trials for ribupatide injection, initiate our global Phase 3 trials for ribupatide oral, as well as continue to advance the development of our other product candidates. We also expect to incur additional expenses related to milestone payments payable related to the acquired intellectual property rights to these product candidates.

The successful development and commercialization of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the development of any of our product candidates or when, if ever, material net cash inflows may commence from any of our product candidates. This uncertainty is due to the numerous risks and uncertainties associated with product development and commercialization, including the uncertainty of:

- the scope, progress, outcome and costs of our research and development activities;
- successful patient enrollment in, and the initiation and completion of, clinical trials;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- development and timely delivery of drug formulations that can be used in our clinical trials and for commercial launch;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- significant and changing government regulation;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others; and
- maintaining a continued acceptable safety profile of the product candidates following approval.

A change in the outcome of any of these variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. We may elect to discontinue, delay or modify clinical trials of some product candidates or focus on others. In addition, we may never succeed in obtaining regulatory approval for any of our product candidates. Even if approved, our product candidates may not achieve commercial success.

General and administrative expenses

General and administrative expenses consist primarily of salaries, related benefits, and stock-based compensation expense for personnel in executive, finance, legal, and other administrative functions. General and administrative expenses also include professional fees for legal, patent, consulting, accounting, audit and tax services, information technology costs, and general and administrative allocated rent expense and depreciation.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued development of our product candidates. We also anticipate that we will incur increased accounting, audit, legal, regulatory, compliance, and director and officer insurance costs, as well as investor and public relations expenses associated with being a public company.

Interest income

Interest income consists of interest earned on our cash equivalents and marketable securities balances.

Other income (expense), net

Other income (expense), net, primarily consists of the change in fair value of the preferred stock tranche right liability, convertible promissory notes for which we elected the fair value measurement option, as well as miscellaneous income and expense unrelated to our core operations.

Consolidated Results of Operations

Comparison of Three Months Ended September 30, 2026 and 2025

The following table summarizes our results of operations for the three months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,		
	2026	2025	$ Change
Operating expenses:			
Research and development	$ 84,667	$ 26,994	$ 57,673
General and administrative	21,669	13,115	8,554
Total operating expenses	106,336	40,109	66,227
Loss from operations	(106,336)	(40,109)	(66,227)
Other income			
Interest income	10,611	$ 2,251	8,360
Other income (expense), net	60	$ (1,765)	1,825
Total other income	10,671	486	10,185
Net loss	$ (95,665)	$ (39,623)	$ (56,042)

Research and development expenses

The following table summarizes our research and development expenses by program for the three months ended September 30, 2026 and 2025 (in thousands):

	Three Months Ended September 30,		
	2026	2025	$ Change
Ribupatide injection	$ 53,966	$ 12,830	$ 41,136
Ribupatide oral	1,582	$ —	1,582
Safiglipron	8,606	3,551	5,055
KAI-4729	850	74	776
Personnel related (including stock-based compensation)	15,193	8,089	7,104
Unallocated research and development expenses and other	4,470	2,450	2,020
Total research and development expenses	$ 84,667	$ 26,994	$ 57,673

Research and development expenses increased by $57.7 million for the three months ended September 30, 2026, compared to the three months ended September 30, 2025. The increase was primarily driven by product candidate development and the related nonclinical, clinical, and contract manufacturing costs associated with our portfolio of injectable and oral development programs, as well as an increase in headcount, resulting in an increase in personnel-related expenses, including stock-based compensation expense, to support our ongoing research and development activities.

Personnel-related expenses primarily includes salaries, related benefits, and stock-based compensation expense for employees engaged in research and development.

Unallocated research and development expenses and other primarily includes external costs that were not program specific, primarily related to consultant and contractor costs, in addition to research and development allocated rent expense and depreciation.

General and administrative expenses

General and administrative expenses increased by $8.6 million for the three months ended September 30, 2026, compared to the three months ended September 30, 2025. The increase was primarily driven by the expansion of our operations, resulting in increases in professional service costs and personnel-related expenses, including an increase of $3.0 million in stock-based compensation expenses.

Interest income

Interest income increased by $8.4 million for the three months ended September 30, 2026, compared to the three months ended September 30, 2025. The increase was primarily driven by higher cash equivalents and marketable securities balances.

Other income (expense), net

Other income, net, increased by $1.8 million for the three months ended September 30, 2026, compared to other expense, net, during the three months ended September 30, 2025. Other income, net for the three months ended September 30, 2026 primarily consisted of miscellaneous income unrelated to our core operations. Other expense, net, for the three months ended September 30, 2025 primarily consisted of expense due to the change in fair value of our convertible promissory notes issued in May 2025.

Comparison of Nine Months Ended September 30, 2026 and 2025

The following table summarizes our results of operations for the nine months ended September 30, 2026 and 2025 (in thousands):

	Nine Months Ended September 30,		
	2026	2025	$ Change
Operating expenses:			
Research and development	$ 256,601	$ 56,645	$ 199,956
General and administrative	55,768	34,572	21,196
Total operating expenses	312,369	91,217	221,152
Loss from operations	(312,369)	(91,217)	(221,152)
Other income			
Interest income	26,321	6,052	20,269
Other income (expense), net	211	(1,388)	1,599
Total other income	26,532	4,664	21,868
Net loss	$ (285,837)	$ (86,553)	$ (199,284)

Research and development expenses

The following table summarizes our research and development expenses by program for the nine months ended September 30, 2026 and 2025 (in thousands):

	Nine Months Ended September 30,		
	2026	2025	$ Change
Ribupatide injection	$ 175,106	$ 27,506	$ 147,600
Ribupatide oral	3,272	—	3,272
Safiglipron	22,471	4,507	17,964
KAI-4729	1,638	412	1,226
Personnel related (including stock-based compensation)	41,325	19,020	22,305
Unallocated research and development expenses and other	12,789	5,200	7,589
Total research and development expenses	$ 256,601	$ 56,645	$ 199,956

Research and development expenses increased by $200.0 million for the nine months ended September 30, 2026, compared to the nine months ended September 30, 2025, primarily driven by product candidate development and the related nonclinical, clinical, and contract manufacturing costs associated with our portfolio of injectable and oral development programs, as well as an increase in headcount, resulting in an increase in personnel-related expenses, including stock-based compensation expense, to support our ongoing research and development activities.

Personnel-related expenses primarily includes salaries, related benefits, and stock-based compensation expense for employees engaged in research and development.

Unallocated research and development expenses and other primarily includes external costs that were not program specific, primarily related to consultant and contractor costs, in addition to research and development allocated rent expense and depreciation.

General and administrative expenses

General and administrative expenses increased by $21.2 million for the nine months ended September 30, 2026, compared to the nine months ended September 30, 2025. The increase was primarily driven by the expansion of our operations, resulting in increases in professional service costs and personnel-related expenses, including an increase of $9.2 million in stock-based compensation expenses.

Interest income

Interest income increased by $20.3 million for the nine months ended September 30, 2026, compared to the nine months ended September 30, 2025. The increase was primarily driven by higher cash equivalents and marketable securities balances.

Other income (expense), net

Other income, net, increased by $1.6 million for the nine months ended September 30, 2026, compared to other expense, net, during the nine months ended September 30, 2025. Other income, net for the nine months ended September 30, 2026 primarily consisted of miscellaneous income unrelated to our core operations. Other expense, net, for the nine months ended September 30, 2025 consisted primarily of expense due to the change in fair value of our convertible promissory notes issued in May 2025, partially offset by income due to the change in fair value of the preferred stock tranche right liability.

Liquidity and capital resources

Since our inception, we have not generated revenue from any sources, including from product sales, and have incurred significant operating losses and negative cash flows from our operations. As of September 30, 2026, we had cash, cash equivalents and marketable securities of $1,037.6 million and an accumulated deficit of $654.5 million. Through September 30, 2026 we have funded our operations primarily with proceeds from the sale and issuance of shares of convertible preferred stock, the issuance of convertible promissory notes, which converted into shares of convertible preferred stock, and the sale and issuance of common stock as part of our initial public offering.

Cash flows

The following table summarizes our cash flows for the nine months ended September 30, 2026 and 2025 (in thousands):

	Nine Months Ended September 30,	
	2026	2025
Net cash used in operating activities	$ (279,505)	$ (74,130)
Net cash used in investing activities	(437,349)	(102,130)
Net cash provided by financing activities	663,124	99,757
Net decrease in cash, cash equivalents and restricted cash	$ (53,730)	$ (76,503)

Operating activities

During the nine months ended September 30, 2026, operating activities used $279.5 million of cash, cash equivalents and restricted cash, primarily due to a net loss of $285.8 million and changes in operating assets and liabilities of $11.7 million, partially offset by net

non-cash expenses of $18.1 million. The changes in operating assets and liabilities primarily related to an increase in prepaid expenses and other current assets of $7.1 million, a net decrease in accrued expenses and other current liabilities of $6.1 million, an increase in non-current clinical deposits of $1.9 million, partially offset by a $2.1 million increase in accounts payable and a $2.3 million decrease in other non-current assets. Non-cash changes primarily consisted of $22.2 million in stock-based compensation expense, partially offset by $5.2 million in net accretion of discounts on our investment portfolio.

During the nine months ended September 30, 2025, operating activities used $74.1 million of cash, cash equivalents and restricted cash, primarily due to a net loss of $86.6 million, partially offset by non-cash charges of $8.2 million and changes in operating assets and liabilities of $4.2 million. Non-cash changes primarily consisted of $7.4 million in stock-based compensation expense and $2.8 million change in the fair value of the convertible promissory notes, partially offset by $1.4 million change in the fair value of the preferred stock tranche right liability and by $1.1 million in net accretion of discounts on our investment portfolio. The net change in operating assets and liabilities was primarily driven by a $12.3 million increase in accrued expenses and other current liabilities, partially offset by a $7.7 million increase in prepaid expenses and other current assets.

Investing activities

During the nine months ended September 30, 2026, investing activities used $437.3 million in cash, cash equivalents and restricted cash consisting of purchases of investments of $775.3 million, partially offset by maturities of investments of $338.0 million.

During the nine months ended September 30, 2025, investing activities used $102.1 million in cash, cash equivalents and restricted cash consisting primarily of purchases of investments of $178.9 million, partially offset by maturities of investments of $77.2 million.

Financing activities

During the nine months ended September 30, 2026, financing activities provided $663.1 million in cash, cash equivalents and restricted cash consisting of $668.4 million in net proceeds received from our initial public offering after deducting commissions and underwriting discounts and payments of deferred offering costs, and $0.8 million in proceeds from the exercise of stock options, partially offset by $6.1 million in payments of deferred offering costs related to our initial public offering.

During the nine months ended September 30, 2025, financing activities provided $99.8 million in cash, cash equivalents and restricted cash consisting of proceeds from the issuance of convertible promissory notes.

Funding requirements

We expect our expenses, excluding costs related to the acquisition of in-process intellectual property rights, to increase substantially in connection with our ongoing activities, particularly as we advance our product candidates into later stages of development. Our expenses will also increase as we:

- advance global Phase 3 clinical trials for ribupatide injection and initiate global Phase 3 clinical trials for ribupatide oral;
- continue the development of our other product candidates, including advancing an ongoing global Phase 2 clinical trial for safiglipron and initiating a Phase 1 clinical trial for KAI-4729;
- seek to in-license or acquire additional product candidates and technologies;
- seek regulatory and marketing approvals for any product candidates that successfully complete clinical trials, if any;
- hire and retain additional personnel, such as clinical, quality control, commercial and scientific personnel;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval;
- expand our infrastructure and facilities to accommodate our growing employee base;
- maintain, expand and protect our intellectual property portfolio;
- make milestone, royalty or other payments due under the Hengrui License Agreement and any future license or collaboration agreements;
- make milestone, royalty, interest or other payments due under any future financing or other arrangements with third parties; and
- add operational, legal, compliance, financial and management information systems and personnel to support our operations as a public company.

We believe that the cash, cash equivalents and marketable securities on hand as of September 30, 2026 will be sufficient to fund our operations into mid-2028. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect.

Until such time, if ever, that we can generate product revenue sufficient to achieve profitability, we expect to finance our cash needs through a combination of equity offerings, debt financings, royalty financings or other capital sources, including potential future collaborations, licenses, or other similar arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through government and other third-party funding, royalty financings, collaboration agreements, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. We do not currently have any committed external source of funds. If we are unable to raise additional funds through equity or debt financings 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 products or product candidates that we would otherwise prefer to develop and market ourselves.

Contractual obligations and commitments

The following table summarizes our contractual obligations as of September 30, 2026, and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

	Payments due by period				
	Total	Less than 1 Year	1 to 3 Years	4 to 5 Years	More than 5 Years
			(in thousands)		
Operating lease commitments	$ 14,052	$ 2,210	$ 4,538	$ 4,696	$ 2,608
Total	$ 14,052	$ 2,210	$ 4,538	$ 4,696	$ 2,608

In March 2025, we executed a new, seven-year, non-cancellable operating lease agreement for approximately 39,500 square feet of office space in Waltham, Massachusetts for our corporate headquarters. The lease commenced in October 2025 following completion of construction to prepare the premises for our intended use. The lease provides for base rent of $2.2 million for the first year, which will increase by approximately 2% each year. Our lease payments also include real estate taxes and other operating expenses allocable to the leased premises, which exceed base year amounts. Upon commencement of the lease, future minimum lease payments for the corporate headquarters were $15.9 million. We have the option to extend the lease for one additional five-year term with base rent calculated on the then-market rate. In accordance with the lease agreement, we maintained a letter of credit of $0.8 million, which is refundable at the end of the lease term. As of September 30, 2026, the underlying cash balance collateralizing this letter of credit was classified as restricted cash (non-current) on our condensed consolidated balance sheets based on the release date of the restrictions of this cash. In connection with the new lease agreement, we amended our existing lease in Waltham, Massachusetts to extend the lease term to end shortly after the lease commencement date of our new lease agreement, which occurred in the fourth quarter of 2025.

We enter into contracts in the normal course of business with CROs, CMOs and other third parties for nonclinical, clinical, manufacturing, and other development services. Payments due upon cancellation generally consist only of payments for services provided or expenses incurred, including noncancelable or committed obligations of our service providers, up to the date of cancellation. These payments are not included in the preceding table as the amount and timing of such payments are not known.

In addition, pursuant to the Hengrui License Agreement, we are required to make certain milestone, royalty and other payments, which are contingent on the achievement or non-achievement of certain specified events. These payments are not included in the preceding table as the amount and timing of such payments are not known.

Critical accounting estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenue, costs and expenses, and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions and any such difference may be material.

During the nine months ended September 30, 2026, there were no material changes to our critical accounting estimates or in the methodology used for estimates from those described in "Management's discussion and analysis of financial condition and results of operations" for the year ended December 31, 2025 included in the Prospectus, except as noted below.

Stock-based compensation

For stock-based awards issued to employees, non-employees, and members of our board of directors (the "Board") for their services on the Board, we measure the estimated fair value of the stock-based award on the date of grant and recognize compensation expense for those awards over the requisite service period, which is generally the vesting period of the respective award. We issue stock-based awards with service-based vesting conditions and record the expense for these awards using the straight-line method. We issue performance-based awards and record the expense for these awards over the expected vesting term and recognize expense only if it is probable the performance-based conditions will be achieved. We issue stock-based awards with market-based vesting conditions and recognize expense as the requisite service is rendered by the employee, regardless of when, if ever, the market-based vesting conditions are satisfied. We account for forfeitures as they occur.

We classify stock-based compensation expense in our condensed consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's cash compensation costs are classified.

The fair value of each stock option award with either service-based vesting conditions or performance-based conditions is estimated on the date of grant using the Black-Scholes option pricing model. As there is limited trading history of our common stock, we determined the volatility for awards granted based on an analysis of reported data for a group of guideline companies that issued options with substantially similar terms. The expected volatility has been determined using a weighted average of the historical volatility measures of this group of guideline companies. We expect to continue to do so until such time as we have adequate historical data regarding the volatility of our own traded stock price. The expected term of our stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. We have not paid, and do not anticipate paying, cash dividends on our common stock; therefore, the expected dividend yield is assumed to be zero.

The fair value of each stock option award with market-based vesting conditions is estimated on the date of grant using a Monte Carlo simulation model.

Emerging growth company status and smaller reporting company status

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies. We may take advantage of these exemptions until we are no longer an emerging growth company. Section 107 of the JOBS Act provides that an emerging growth company can take advantage of the extended transition period afforded by the JOBS Act for the implementation of new or revised accounting standards. We have elected to use the extended transition period for complying with new or revised accounting standards and, as a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates. We intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act of 2002. We may take advantage of these exemptions up until the last day of the fiscal year following the fifth anniversary of our initial public offering, or December 31, 2031, or such earlier time that we are no longer an emerging growth company. We would cease to be an emerging growth company if we have more than $1.235 billion in annual revenue, we have more than $700.0 million in market value of our stock held by non-affiliates (and we have been a public company for at least 12 months and have filed one annual report on Form 10-K) or we issue more than $1.0 billion of non-convertible debt securities over a three-year period.

We are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our stock held by non-affiliates is less than $250 million or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than $700 million.

If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Off-balance sheet arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Recently issued accounting pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations, and cash flows is disclosed in Note 2 to our condensed consolidated financial statements appearing elsewhere in this Quarterly Report on Form 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company, as defined by Rule 12b-2 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and in Item 10(f)(1) of Regulation S-K, and are not required to provide the information under this item.

Item 4. Controls and Procedures.

Limitations on Effectiveness of Controls and Procedures

In designing and evaluating our disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures must reflect the fact that there are resource constraints, and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Management's Evaluation of Disclosure Controls and Procedures

Our management, including our principal executive officer and principal financial officer, evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. Based on such evaluation, our principal executive officer and principal financial officer concluded that as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fiscal quarter ended September 30, 2026 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

The information required to be set forth under this Item 1 is incorporated by reference to Note 12—Commitments and Contingencies—Legal proceedings in the notes to the condensed consolidated financial statements included in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. You should carefully consider the risks and uncertainties described below and the other information in this Quarterly Report on Form 10-Q, including our financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," before making an investment in our common stock. Our business, financial condition, results of operations, or prospects could be materially and adversely affected if any of these risks occurs, and as a result, the market price of our common stock could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operation. This Quarterly Report on Form 10-Q also contains forward-looking statements that involve risks and uncertainties. See "Special note regarding forward-looking statements." Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors, including those set forth below.

Risks Related to Our Limited Operating History, Financial Position and Capital Requirements

We are a clinical-stage biotechnology company with a limited operating history. We have incurred significant financial losses since our inception and anticipate that we will continue to incur significant financial losses for the foreseeable future.

We are a clinical-stage biotechnology company with a limited operating history. We were formed in May 2024 and our operations to date have been limited to pre-commercial activities. All of our current product candidates were initially discovered and initially developed for the Chinese Market by Jiangsu Hengrui Pharmaceuticals Co., Ltd., or Hengrui, which we licensed pursuant to a license and collaboration agreement with Hengrui, or the Hengrui License Agreement, shortly after our formation. We have not yet demonstrated an ability to complete large-scale clinical trials, obtain regulatory approvals, generate revenues, manufacture any product on a commercial scale, or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization.

To date, we have focused primarily on organizing and staffing our company, business planning, establishing our intellectual property portfolio, raising capital, conducting nonclinical studies and, more recently, clinical trials, and providing general and administrative support for these operations. We have no products approved for commercial sale and have not generated any revenue from product sales to date.

Since our inception, we have not generated revenue from any sources, including from product sales, are not profitable and have incurred significant operating losses and negative cash flows from our operations. 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 losses for the foreseeable future, and we expect these losses to increase as we continue our research and development of, and seek regulatory approvals for, our product candidates.

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

- advance global Phase 3 clinical trials for ribupatide injection and initiate global Phase 3 clinical trials for ribupatide oral;
- continue the development of our other product candidates, including advancing an ongoing global Phase 2 clinical trial for safiglipron and initiating a Phase 1 trial for KAI-4729;
- advance our manufacturing strategy to support global scale and long-term continuity;
- seek to in-license or acquire additional product candidates and technologies;
- seek regulatory and marketing approvals for any product candidates that successfully complete clinical trials, if any;
- hire and retain additional personnel, such as clinical, quality control, commercial and scientific personnel;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval;

- expand our infrastructure and facilities to accommodate our growing employee base;
- maintain, expand and protect our intellectual property portfolio;
- make milestone, royalty or other payments due under the Hengrui License Agreement and any future license or collaboration agreements;
- make milestone, royalty, interest or other payments due under any future financing or other arrangements with third parties; and
- add operational, legal, compliance, financial and management information systems and personnel to support our operations as a public company.

Pharmaceutical product development entails substantial upfront capital expenditures and significant risks that any potential product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, secure market access and reimbursement and become commercially viable, and therefore any investment in us is highly speculative. Accordingly, before making an investment in us, you should consider our prospects, factoring in the costs, uncertainties, delays and difficulties frequently encountered by clinical-stage biotechnology companies such as ours. Any predictions you make about our future success or viability may not be as accurate as they would otherwise be if we had a longer operating history or a history of successfully developing and commercializing pharmaceutical products.

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

In addition, our expenses could increase beyond our expectations if we are required by the U.S. Food and Drug Administration, or FDA, or other regulatory authorities to perform clinical trials in addition to those that we currently expect, or if there are any delays in establishing appropriate manufacturing arrangements for, or in completing, our clinical trials or the development of any of our product candidates.

We have not generated any revenues to date and may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.

To generate revenue and become and remain profitable, we must succeed in developing, obtaining regulatory approvals for, and eventually commercializing products that generate significant revenue. This will require us to be successful in a range of challenging activities, including completing clinical trials and obtaining regulatory approval for one or more of our current or future product candidates, and manufacturing, marketing, and selling any products for which we may obtain regulatory approval. We are in the preliminary stages of only a few of these activities. We may never succeed in these activities and, even if we do, we may never generate revenue that is significant enough to achieve profitability. In addition, we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the pharmaceutical industry. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable may have an adverse effect on the value of our company and could impair our ability to raise capital, expand our business, maintain our research and development efforts, diversify our product candidates, achieve our strategic objectives or even continue our operations. A decline in the value of our company could also cause you to lose all or part of your investment.

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

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to continue the clinical and nonclinical development of our product candidates, particularly given the capital-intensive nature of obesity clinical trials. We will need to raise additional capital to complete our currently planned clinical trials and any future clinical trials. Other unanticipated costs may arise in the course of our development efforts. If we are able to gain marketing approval for product candidates that we develop, we will require significant additional amounts of funding in order to launch and commercialize such product candidates and will also be required to make certain milestone and royalty payments under the Hengrui License Agreement. We cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any product candidate we develop, and we may need substantial additional funding to complete the development and commercialization of our product candidates.

We could use our capital resources sooner than we currently expect, requiring us to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. Our failure to raise capital or enter into such other arrangements when needed would have a negative impact on our financial condition and could force us to delay, limit, reduce or terminate clinical trials, our research and development programs or other operations, or lead us to grant rights to third parties to develop and market product candidates that we would otherwise prefer to develop and market ourselves. In addition, we may seek additional capital opportunistically due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. Attempting to secure additional financing may divert our management from our day-to-day activities. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and capital resources."

Our future capital requirements will depend on, and could increase significantly because of many factors including:

- the scope, progress, results and costs of researching and developing our current product candidates, as well as other additional product candidates we may develop and pursue in the future;
- the timing of, and the costs involved in, obtaining marketing approvals for our product candidates and any other additional product candidates we may develop and pursue in the future;
- the number of future product candidates that we may pursue and their development requirements;
- subject to receipt of regulatory approval, the costs of commercialization activities for our product candidates, to the extent such costs are not the responsibility of any future collaborators, including the costs and timing of establishing product sales, marketing, distribution and manufacturing capabilities;
- subject to receipt of regulatory approval, revenue, if any, received from commercial sales of our product candidates or any other additional product candidates we may develop and pursue in the future;
- the achievement of milestones that trigger payments to Hengrui under the Hengrui License Agreement;
- the royalty payments due to Hengrui under the Hengrui License Agreement;
- the extent to which we license or acquire rights to other products, product candidates or technologies;
- our ability to establish collaboration arrangements for the development of our product candidates on favorable terms, if at all;
- our headcount growth and associated costs as we expand our research and development and market development and pre-commercial planning activities;
- the costs of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights, including enforcing and defending intellectual property related claims; and
- the costs of operating as a public company.

We cannot be certain that additional funding will be available on acceptable terms, or at all. For instance, our trading price and the trading prices for other biopharmaceutical companies have been highly volatile. We may face difficulties raising capital through sales of our equity or debt securities or such sales may be on unfavorable terms. Similarly, adverse market or macroeconomic conditions or market volatility resulting from global economic developments, political unrest, high inflation, rising interest rates, future public health epidemics or other factors, could materially and adversely affect our ability to consummate an equity or debt financing on favorable terms, or at all.

Furthermore, we expect to incur additional costs associated with operating as a public company. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we will be forced to delay, reduce, or eliminate programs, and may be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition, results of operations and prospects.

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

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our operations through a combination of equity offerings, debt financings, royalty financings or other capital sources, including potential future collaborations, licenses, or other similar 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, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences and anti-dilution protections that could adversely affect your rights as a stockholder. Debt financing and equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions,

such as incurring additional debt, making capital expenditures or declaring dividends, that could adversely impact our ability to conduct our business. If we raise additional funds through government and other third-party funding, royalty financings, collaboration agreements, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our future revenue streams, research programs or drug candidates, or grant licenses on terms that may not be favorable to us. We do not currently have any committed external source of funds. If we are unable to raise additional funds through equity or debt financings 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 products or product candidates that we would otherwise prefer to develop and market ourselves, obtain funds through arrangements with collaborators on terms unfavorable to us or pursue other strategies, all of which could adversely affect your holdings or you as a stockholder.

Our ability to use net operating loss carryforwards and other tax attributes may be limited in connection with our initial public offering or other ownership changes.

We have incurred substantial losses during our history, do not expect to become profitable in the near future and may never achieve profitability. Our U.S. federal net operating loss, or NOL, carryforwards and other tax attributes are subject to expiration, review and possible adjustment by the Internal Revenue Service, or IRS, and state tax authorities.

In addition, under Section 382 of the U.S. Internal Revenue Code of 1986, as amended, or the Code, our federal NOL carryforwards may be or become subject to an annual limitation in the event we have had or have in the future an "ownership change." For these purposes, an "ownership change" generally occurs if one or more stockholders or groups of stockholders who own at least 5% of a company's stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three-year period. Similar rules may apply under state tax laws. Although we believe there have been one or more ownership changes resulting from past transactions, we have not determined the amount of the cumulative change in our ownership resulting from our initial public offering or other transactions, or any resulting limitations on our ability to utilize our NOL carryforwards and other tax attributes. However, we believe that our ability to utilize our NOL carryforwards and other tax attributes to offset future taxable income or tax liabilities may be limited as a result of ownership changes, including potential changes in connection with our initial public offering. If we earn taxable income, such limitations could result in increased future income tax liability to us and our future cash flows could be adversely affected.

We have recorded a full valuation allowance related to our NOL carryforwards and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets.

Risks Related to the Development and Regulatory Approval of Our Product Candidates

We depend heavily on the success of ribupatide injection and our other product candidates. If we are unable to successfully develop or commercialize ribupatide injection or any other product candidates, or experience significant delays in doing so, we may continue to incur significant financial losses.

We have invested, and plan to continue to invest, a significant portion of our efforts and financial resources in the development of ribupatide injection, which is currently in a Phase 3 program. Our ability to generate product revenues, which may not occur for several years, if ever, will depend heavily on the successful development and commercialization of ribupatide injection and our other product candidates. The success of our product candidates depends on a number of factors, including, but not limited to, the following:

- successful patient enrollment in, and completion, of global clinical trials;
- our ability to demonstrate to the satisfaction of the FDA or any comparable foreign regulatory authority that the applicable product candidate's risk-benefit ratio for its proposed indication is acceptable;
- receipt of authorizations to conduct clinical trials and future marketing approvals from applicable regulatory authorities in all the countries where we intend to conduct clinical trials or seek marketing approval;
- our ability to meet any required post-regulatory approval commitments to applicable regulatory authorities and other post-marketing requirements;
- establishing supply chain and commercial manufacturing arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity;
- protecting our rights in our intellectual property portfolio;
- establishing sales, marketing and distribution capabilities;

- launching commercial sales of ribupatide injection and our other product candidates, if and when approved, whether alone or in collaboration with others;
- acceptance of ribupatide injection and our product candidates, if and when approved, by patients, the medical community and third-party payors;
- obtaining timely and adequate coverage and reimbursement from payors;
- ensuring no disruption in supply or lack of sufficient quantities of ribupatide injection and our other product candidates;
- effectively competing with other therapies; and
- maintaining an acceptable safety profile of ribupatide injection and our other product candidates during development and following approval.

Risks and uncertainties related to these factors could cause us to experience significant delays or an inability to successfully commercialize ribupatide injection and our other product candidates, which would materially harm our business.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

We are not permitted to commercialize, market, promote or sell any product candidate in the United States without obtaining regulatory approval from the FDA. Foreign regulatory authorities impose similar requirements. The time required to obtain approval by the FDA and comparable foreign authorities is inherently unpredictable, but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary among jurisdictions. For instance, jurisdictions outside of the United States, such as Australia, Canada, the United Kingdom, or UK, the European Union, or EU, or Japan, may have different requirements for regulatory approval, which may require us to conduct additional clinical, nonclinical or chemistry, manufacturing and control studies. To date, we have not submitted a New Drug Application, or NDA, to the FDA or similar drug approval submissions to comparable foreign regulatory authorities for any product candidate. We must complete additional nonclinical studies and clinical trials to demonstrate the safety and efficacy of our product candidates in humans before we will be able to seek or obtain approvals for our product candidates.

Our current and future product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities, such as those in Australia or Japan, may disagree as to the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from clinical trials or nonclinical studies;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of an NDA to the FDA or similar submissions to foreign regulatory authorities or to obtain regulatory approval in the United States, the EU or elsewhere;
- the FDA, European Medicines Agency, or EMA, or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; 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 for approval.

This lengthy approval process as well as the unpredictability of clinical trial results may result in our failing to obtain regulatory approval to market any product candidate we develop, which would substantially harm our business, results of operations and prospects. The FDA and other comparable foreign authorities have substantial discretion in the approval process and determining when or whether

regulatory approval will be granted for any product candidate that we develop. Even if we believe the data collected from future clinical trials of our product candidates are promising, such data may not be sufficient to support approval by the FDA or any other regulatory authority. In addition, even if we were to obtain approval, regulatory authorities may approve any of our product candidates for fewer or more limited indications than we request, may not approve the price we intend to charge for our products, may grant approval contingent on the performance of costly post-marketing clinical trials or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. For instance, the regulatory landscape related to clinical trials in the EU recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the EU Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state in which the clinical trial takes place, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application for multi-center trials. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. The CTR transition period ended on January 31, 2025, and all clinical trials (and related applications) are now fully subject to the provisions of the CTR. Compliance with the CTR requirements by us and our third-party service providers, such as contract research organizations, or CROs, may impact our development plans.

In addition, FDA and foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, the EU pharmaceutical legislation has been undergoing a complete review in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission introduced legislative proposals in April 2023 that, if adopted, will replace the current regulatory framework in the EU for all medicines (including those for rare diseases and for children). The proposed changes were since discussed and negotiated by the European Parliament and the Council of the EU as part of the EU ordinary legislative process. In April 2024, the European Parliament adopted its position on the legislative proposals and, in June 2025, the Council of the EU adopted its position. A provisional agreement on the text was reached on December 11, 2025. Following positive votes by member states and the European Parliament on the provisional agreement in March 2026, the proposed revisions (affecting the duration of regulatory data protection and market protection, including for orphan medicinal products, revising the eligibility for expedited pathways, etc.) must now be formally adopted by the Ministers of Health in the Employment, Social Policy, Health and Consumer Affairs Council, or EPSCO, and the European Parliament Plenary, currently anticipated in the second half of 2026. The proposed changes are not expected to become applicable before 2028 but may have a significant impact on the pharmaceutical industry and our business in the long term.

Furthermore, on April 28, 2025, the UK adopted an amendment to the Medicines for Human Use (Clinical Trials) Regulations 2004 intended to support a more streamlined and flexible regulation of clinical trials, removing unnecessary administrative burdens on trial sponsors, whilst protecting the interests of trial participants. It also intends to bring the UK regulatory framework for clinical trials, which is still based on the EU Clinical Trials Directive, into closer alignment with the (EU) CTR. The amendment will become applicable on April 28, 2026 following a one-year transition period. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be adversely impacted.

The FDA or comparable foreign regulatory authorities may disagree with our regulatory plan for our product candidates.

In order to obtain FDA approval of our product candidates, we must, among other things, demonstrate substantial evidence of the effectiveness of such product candidates. FDA has generally considered this demonstration to require data gathered from two or more adequate and well-controlled clinical trials of the product candidate in the relevant patient population, or in some cases, one adequate and well-controlled trial plus other confirmatory evidence. Adequate and well-controlled clinical trials typically involve a large number of patients, have significant costs and take years to complete. The FDA or other regulatory authorities may disagree with us about whether a clinical trial is adequate and well-controlled or may request that we conduct additional clinical trials prior to granting any regulatory approval. In addition, there is no assurance that the doses, endpoints and trial designs that we intend to use for our planned clinical trials, including those that we have developed based on feedback from the FDA or other regulatory agencies or those that have been used for the approval of similar drugs, will be acceptable for future approvals. For example, while we have designed our Phase 3 programs for ribupatide injection and ribupatide oral after receiving input and feedback from the FDA and other regulatory agencies, there can be no assurance that the design of our planned clinical trials will be satisfactory to such agencies or that such agencies will not require us to modify our trials or conduct additional testing, or that completing these trials will result in regulatory approval. For instance, in connection with their review of our Phase 3 programs for ribupatide injection and ribupatide oral, regulatory agencies, particularly those outside of the U.S., may disagree with elements of our clinical trial design, including dose selection and control arms, and

utilization of data collected outside of the applicable territory. We are not currently planning to conduct a global Phase 2 dose-ranging trial or Phase 1 pharmacokinetic bridging trial for ribupatide oral prior to commencing global Phase 3 clinical trials. The FDA and other regulatory agencies may disagree with our clinical development strategy or the designs of our proposed Phase 3 trials for ribupatide oral, including but not limited to dose selection, sample size and utilization of data collected outside of the applicable territory. Even if our Phase 3 clinical trials achieve their primary endpoint, there can be no assurance that the FDA and other regulatory agencies will find them sufficient to support approval.

Our clinical trial results may not support approval of our product candidates. In addition, our product candidates could fail to receive regulatory approval, or regulatory approval could be delayed, for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may not file or accept our NDAs or marketing application for substantive review;
- the FDA or comparable foreign regulatory authorities may disagree with the dosing regimen, design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications;
- the results of our clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from our nonclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of an NDA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may find deficiencies with or fail to approve the manufacturing processes or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Clinical and nonclinical development involves a lengthy and expensive process with an uncertain outcome, and the results of prior clinical trials and studies involving our product candidates are not necessarily predictive of our future results. Our product candidates may not show favorable results in nonclinical studies or clinical trials or receive regulatory approval on a timely basis, if at all.

Pharmaceutical development is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot guarantee that any clinical trials or nonclinical studies will be conducted as planned, including whether we are able to meet expected timeframes for data readouts, or completed on schedule, if at all, and failure can occur at any time during the trial or study process, including due to factors that are beyond our control.

Any of our current or future product candidates in later stages of clinical trials may fail to show the desired characteristics despite having progressed through nonclinical studies and initial clinical trials. The results from nonclinical studies or clinical trials of any of our current and future product candidates, or a competitor's product candidate in the same class, may not predict the results of later clinical trials of any of our current or future product candidates. It is not uncommon to observe results in clinical trials that are unexpected based on nonclinical studies and early clinical trials, and many product candidates fail in later stage clinical trials despite very promising early results. In addition, we do not know whether ribupatide injection will demonstrate weight loss similar to that seen in clinical trials conducted in China by Hengrui. In particular, most of the ribupatide injection clinical data that has been generated to date has been in Chinese patient cohorts based on a maximum dose of 8 mg, however, in our ongoing Phase 3 program of ribupatide injection, we intend to study a dosing regimen of up to 10 mg in populations outside of China. We have limited information as to whether the new dosing regimen will result in a favorable balance between weight loss and tolerability profile and cannot guarantee that we will not need to further optimize the ribupatide injection dosing regimen in the future. A number of companies in the biopharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies. Such setbacks have occurred and may occur for many reasons, including, but not limited to: clinical sites and investigators may deviate from clinical trial protocols, whether due to lack of training or otherwise, and we may fail to detect any such deviations in a timely manner; patients may fail to adhere to any required clinical trial procedures, including any requirements that patients on placebo refrain from using other GLP-1 medications, stay on study treatment or stay in study; our product candidates may fail to demonstrate

safety, purity or potency (or efficacy) in certain patient subpopulations, which has not been observed in earlier trials due to limited sample size, lack of analysis or otherwise; or our clinical trials may not adequately represent the patient populations we intend to treat, whether due to limitations in our trial designs or otherwise, such as where one patient subgroup is overrepresented in the clinical trial. There can be no assurance that we will not suffer similar setbacks despite the data we observed in earlier or ongoing studies. For example, if a higher-than-expected number of patients drop out of clinical trials prior to completion either as a result of their failure to lose weight on placebo or as a result of side effects on an active arm, we may experience difficulties completing trials with adequate numbers of patients to generate sufficient data to support a marketing application. Moreover, nonclinical and clinical data may be susceptible to varying interpretations and analyses. Because ribupatide injection and ribupatide oral are based on the same peptide, if ribupatide injection does not show safety or efficacy in clinical trials, it may negatively impact the development of ribupatide oral, and vice versa. Based upon negative or inconclusive results, we or any current or any future collaborator may decide, or regulators may require us, to conduct additional nonclinical studies or clinical trials, which would cause us to incur additional operating expenses and delays and may not be sufficient to support regulatory approval on a timely basis or at all.

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 will be conducted as planned or completed on schedule, if at all. The clinical development of our initial and potential additional product candidates is susceptible to the risk of failure inherent at any stage of development, including failure to demonstrate efficacy in a clinical trial or across a broad population of patients, the occurrence of adverse events that are severe or medically or commercially unacceptable, failure to comply with protocols or applicable regulatory requirements and determination by the FDA or any comparable foreign regulatory authority that a product candidate may not continue development or is not approvable. It is possible that even if any of our product candidates have 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 such product candidate that is greater than the actual positive effect, if any. Similarly, in our clinical trials we may fail to detect toxicity of, or intolerability caused by, such product candidate, or mistakenly believe that our product candidates are toxic or not well tolerated when that is not in fact the case. Serious adverse events or other adverse events, as well as tolerability issues, could hinder or prevent market acceptance of the product candidate at issue.

For the foregoing reasons, we cannot be certain that our ongoing and planned clinical trials and nonclinical studies will be successful. Any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could have a material adverse effect on our business, financial condition and results of operations.

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

From time to time, we may publicly disclose interim, topline or preliminary data from our clinical trials and nonclinical studies, which is based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We may also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the interim, topline or preliminary results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Topline and preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the topline or preliminary data we previously published. As a result, topline and preliminary data should be viewed with caution until the final data are available. Interim data from clinical trials are further subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse differences between interim, topline or preliminary data and final data could significantly harm our business prospects. In addition, clinical trials with smaller sample sizes can be disproportionately influenced by various biases associated with clinical trial conduct, which limits the ability to generalize the results across a broader population, making the clinical trial results less likely to be replicated than clinical trials with a larger number of patients. For example, in our planned global Phase 3 trials for ribupatide oral, we plan to enroll a larger number of participants than were enrolled in the Phase 2 clinical trial conducted by Hengrui and may not be able to replicate the weight loss seen in the prior Hengrui Phase 2 trial. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock.

In addition, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product, and our company in general. Moreover, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our

disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, product candidate or our business. If the interim, topline or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for and commercialize any of our current or future product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

Any difficulties or delays in the commencement or completion, or the termination or suspension, of our current or planned clinical trials or nonclinical studies could result in increased costs to us, delay or limit our ability to receive approval for and commercialize any product candidates and generate revenue.

Before obtaining approval from regulatory authorities for the sale of any of our current or future product candidates, we must conduct extensive nonclinical studies and clinical trials to demonstrate the safety and efficacy (for small molecule drugs) or safety, purity, and potency (for biologics) of our product candidates. In addition, before we can initiate clinical development for any future nonclinical product candidates, we must submit the results of nonclinical studies to the FDA or comparable foreign regulatory authorities along with other information, including information about product candidate chemistry, manufacturing, and controls, and our proposed clinical trial protocol, as part of an Investigational New Drug, or IND, application, or similar regulatory submission to foreign regulatory authorities for clinical trials outside of the United States. The FDA or comparable foreign regulatory authorities may require us to conduct additional nonclinical studies for any future product candidates before it allows us to initiate clinical trials under any IND or similar foreign regulatory submission, which may lead to delays or increase the costs of developing future product candidates. Moreover, issues may arise that could cause regulatory authorities to suspend or terminate our ongoing or planned clinical trials. Any such delays in the commencement or completion, or the termination or suspension, of our ongoing and planned clinical trials or nonclinical studies could significantly affect our product development timelines and product development costs. We do not know whether our planned clinical trials or nonclinical studies will begin on time or if our ongoing or future trials or studies will be completed on schedule, if at all. The commencement, data readouts and completion of clinical trials and nonclinical studies can be delayed for a number of reasons, including delays related to:

- inability to obtain animals or materials to initiate and generate sufficient nonclinical, toxicology, or other in vitro data to support the initiation or continuation of clinical trials;
- non-acceptance of nonclinical or clinical data generated in China by Hengrui;
- obtaining authorization from regulatory authorities to commence a clinical trial or reaching a consensus with regulatory authorities on trial design;
- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- changes in regulatory requirements, policies, and guidelines;
- any failure or delay in reaching an agreement with contract research organizations, or CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in identifying, recruiting, and training suitable clinical investigators;
- obtaining approval from one or more institutional review boards, or IRBs, or ethics committees, or ECs, at clinical trial sites;
- IRBs/ECs refusing to approve, suspending, or terminating the trial at an investigational site, precluding enrollment of additional patients, or withdrawing their approval of the trial;
- changes to the clinical trial protocol;
- clinical sites deviating from the trial protocol or dropping out of a trial;
- failure by our CROs to perform in accordance with Good Clinical Practice, or GCP, requirements or applicable regulatory requirements or guidelines in other countries;
- obtaining sufficient quantities of any of our current or future product candidates, including in respect of any combination product candidates, and related raw materials or obtaining sufficient quantities of other materials needed for use in clinical trials and nonclinical studies;
- patients failing to enroll or remain in our trials at the rate we expect, or failing to return for post-treatment follow-up;
- patients choosing alternative treatments for the indications for which we are developing any of our current or future product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trials or nonclinical studies or costs being greater than we anticipate;

- patients experiencing severe or serious unexpected drug-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies that could be considered similar to any of our current or future product candidates;
- selection of clinical endpoints that require prolonged periods of clinical observation or extended analysis of the resulting data;
- transfer of manufacturing processes to larger-scale facilities operated by third-party manufacturers, delays or failure by our third-party manufacturers or us to make any necessary changes to such manufacturing process, or failure of such third-party manufacturers to produce clinical trial materials in accordance with current Good Manufacturing Practices, or cGMPs, regulations or other applicable requirements;
- third parties being unwilling or unable to satisfy their contractual obligations in a timely manner;
- third-party actions claiming infringement by our product candidates in clinical trials outside the United States and obtaining injunctions interfering with our progress; and
- business interruptions resulting from geopolitical actions, including war and terrorism, natural disasters including earthquakes, typhoons, floods, and wildfires, or disease.

Clinical trials must be conducted in accordance with the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and ECs or IRBs at the medical institutions where the clinical trials are conducted. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a data safety monitoring board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension, including a clinical hold, or termination due to a number of factors, including, among other reasons, failure to conduct the clinical trial in accordance with GCP and other regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial.

Further, we and Hengrui are currently conducting, and we, Hengrui and any future collaborators may in the future conduct, clinical trials in foreign countries, which presents additional risks that may delay completion of our clinical trials. For example, Hengrui is currently conducting clinical trials in China. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, and political and economic risks relevant to such foreign countries, including war. See "Risks Related to the Development and Regulatory Approval of Our Product Candidates—We currently, and may in the future, conduct certain of our clinical trials for our product candidates outside of the United States. However, the FDA and foreign regulatory authorities may not accept data from such trials, which could materially harm our business."

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

Many of the factors that cause, or lead to, the termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize any of our current or future product candidates. In such cases, our competitors may be able to bring products to market before we do, and the commercial viability of any of our current or future product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition, results of operations and prospects.

As an organization, we have never completed late-stage clinical trials or submitted an NDA, and may be unable to do so for any of our product candidates.

We will need to successfully complete clinical development, including late-stage clinical trials, in order to obtain FDA or comparable regulatory authority approval to market ribupatide injection or any future product candidates. Carrying out late-stage clinical trials and the submission of a successful NDA is a complicated process. As an organization, we are in the process of conducting Phase 3 clinical trials for ribupatide injection and have not yet completed any late-stage clinical trials for ribupatide injection or any other current and future product candidates. We have limited experience as a company in preparing, submitting and prosecuting regulatory filings and have not previously submitted an NDA or other comparable foreign regulatory submission for any product candidate. We also plan to conduct a number of clinical trials for multiple product candidates in parallel over the next several years. This may be a difficult process to manage with our limited resources. In addition, we have had limited interactions with the FDA and cannot be certain how the FDA or comparable foreign regulatory authorities will require such trials to be designed. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that supports a successful regulatory submission and approval of any of our product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in submitting NDAs for and commercializing our product candidates.

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

As product candidates proceed through nonclinical studies to late-stage clinical trials towards potential approval and commercialization, it is common that various aspects of the development program, such as the vendors used to manufacture drug product or manufacturing methods and formulation, are altered along the way in an effort to optimize processes and results. For instance, we are seeking to develop alternative synthesis strategies for certain of our peptide product candidates and conduct formulation development on certain of our oral product candidates. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes.

In addition, when we make formulation or manufacturing changes to any of our current or future product candidates, we may need to conduct additional nonclinical studies or clinical trials to bridge our current versions of any of our current or future product candidates to earlier versions. If we are unable to conduct such studies or trials, or if we otherwise fail to adequately bridge the current versions of our product candidates to earlier versions, then we may be unable to utilize any data we have gathered from studies or trials that evaluated such earlier versions in our planned regulatory submissions, and we could be required to perform additional testing, which could delay our programs. For example, in future studies of ribupatide injection, we currently plan to utilize materials produced by a different third-party manufacturer than the third-party manufacturer that produced ribupatide injection in prior studies and that are formulated as autoinjectors and/or multi-use pens rather than the pre-filled syringes used in prior studies of ribupatide injection, and we may be unable to demonstrate full comparability between lots produced by our current manufacturer and any future supplier. As a result, we may be required to gather additional data before we are able to submit a marketing application for ribupatide injection or any of our other current or future product candidates, if ever. Any delay of clinical trials, the repetition of one or more clinical trials, increases in clinical trial costs or delays in approval of our product candidates could jeopardize our ability to commence sales and generate revenue, if approved.

We may find it difficult to enroll patients in our clinical trials. If we encounter difficulties or delays enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

Successful and timely completion of clinical trials will require that we identify and enroll a specified and sufficient number of eligible patients to participate and remain in the trial until its conclusion for each of our clinical trials. We may not be able to initiate or continue certain clinical trials if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities outside the United States. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and characteristics of the patient population, the process for identifying patients, the proximity and availability of clinical trial sites for prospective patients, the inclusion and exclusion criteria for the trial, the design of the clinical trial, our ability to recruit clinical trial investigators with the appropriate competencies and experience, and competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidates being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating as well as any product candidates under development. We will be required to identify and enroll a sufficient number of patients for each of our clinical trials, obtain and maintain patient consent for each patient enrolled, and monitor such patients adequately during and after treatment. Potential patients for any planned clinical trials may not be adequately diagnosed or identified with the diseases which we are targeting, which could adversely impact the outcomes of our trials and could have safety concerns for the potential patients. Potential patients for any planned clinical trials may also not meet the entry criteria for such trials.

Additionally, other pharmaceutical companies targeting obesity are recruiting clinical trial patients from these patient populations, which may make it more difficult to fully enroll our clinical trials. Our clinical trials will compete with marketed products that are available for use in the same disease areas as our product candidates, and other clinical trials for investigational product candidates in the same disease areas as our product candidates. This competition could reduce the number and types of patients available to us, because some patients who might have opted to enroll in our clinical trials may instead opt to receive an approved therapy or enroll in a trial being conducted by one of our competitors. The timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow-up periods. Moreover, the changing clinical trial landscape in obesity, with increased availability of marketed or compounded obesity management medications that are contraindicated in our clinical trials, may make patient recruitment and retention more difficult. The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants. If patients are unwilling or unable to participate in our trials for any reason, including the existence of concurrent clinical trials for similar target populations, the availability of approved therapies, or the fact that enrolling in our trials may prevent patients from taking a different product, or we otherwise have difficulty enrolling a sufficient number of patients, the timeline for recruiting patients, conducting trials and obtaining regulatory approval of any of our current or future product candidates may be delayed. Our inability to enroll a sufficient number of patients for any of our future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether.

In addition, we rely on, and will continue to rely on, CROs and clinical trial sites to ensure proper and timely conduct of our clinical trials and nonclinical studies. Though we have entered into agreements governing their services, we have limited influence over their actual performance. We cannot be certain that our assumptions used in determining expected clinical trial timelines are correct or that we will not experience delays or difficulties in enrollment, or be required by the FDA or other regulatory authority to increase our enrollment, which would result in the delay of completion of such trials beyond our expected timelines.

Use of any of our current or future product candidates could be associated with side effects, adverse events or other properties or safety risks, which could delay or preclude regulatory approval, cause us to suspend or discontinue clinical trials, abandon any of our current or future product candidates, limit the commercial profile of an approved label or result in other significant negative consequences that could severely harm our business, financial condition, results of operations and prospects.

Results of our, Hengrui's or any future collaborators' clinical trials could reveal a high and unacceptable severity and prevalence of expected or unexpected side effects or unexpected characteristics. Undesirable side effects caused by our product candidates when used alone or in combination with approved or investigational drugs could cause us or regulatory authorities or IRBs to interrupt, delay or halt clinical trials and could result in a more restrictive label, or lead to the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. For example, in clinical trials of ribupatide injection conducted to date, drug-related adverse events including nausea, vomiting, diarrhea and alopecia have been observed. These and any other drug-related side effects could affect patient recruitment or the ability of enrolled patients to complete the trials, lead to poor data, or result in potential product liability claims. Any of these occurrences may harm our business, financial condition, results of operations and prospects significantly.

Moreover, if any of our current or future product candidates are associated with undesirable side effects in clinical trials or demonstrate characteristics that are unexpected, we may elect to abandon their development or limit their development to more narrow 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, which may limit the commercial expectations for such product candidate if approved. Additionally, adverse developments in clinical trials of product candidates conducted by others or adverse events associated with commercial products offered by others may cause the FDA or other regulatory oversight bodies to suspend or terminate our clinical trials or change the requirements for approval of any of our product candidates, or otherwise adversely affect the clinical and commercial development of our product candidates.

We may also be required to modify our development and clinical trial plans based on findings in our ongoing clinical trials or concerns of the FDA or other regulatory authorities.

It is possible that as we, Hengrui or any future collaborators test any of our current or future product candidates in larger, longer and more extensive clinical trials, including with different dosing regimens, or as the use of these product candidates becomes more widespread following any regulatory approval, more illnesses, injuries, discomforts and other adverse events than were observed in earlier trials, as well as new conditions that did not occur or went undetected in previous trials, may be discovered. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition, results of operations and prospects significantly.

In addition, we may study any of our current or future product candidates in combination with other therapies, which may exacerbate adverse events associated with such product candidate. If significant adverse events or other side effects are observed in any of our ongoing or planned clinical trials, we may have difficulty recruiting patients to the clinical trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, other comparable foreign regulatory authorities or

an IRB may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects. Even if the side effects do not preclude the product candidate from obtaining or maintaining regulatory approval, undesirable side effects may inhibit market acceptance due to tolerability concerns as compared to other available therapies. Any of these developments could materially harm our business, financial condition and prospects.

Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result. For example, the FDA could require us to adopt a Risk Evaluation and Mitigation Strategy, or REMS, to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. We, Hengrui or our future collaborators may also be required to adopt a REMS or engage in similar actions, such as patient education, certification of health care professionals or specific monitoring, if we or others later identify undesirable side effects caused by any product that we develop alone. Other potentially significant negative consequences associated with adverse events include:

- IRBs, ECs, or safety monitoring committees may recommend that enrollment or dosing be placed on hold or that additional safety measures be implemented for ongoing clinical trials;
- we may be required to suspend marketing of a product, or we may decide to remove such product from the marketplace;
- regulatory authorities may withdraw or change their approvals of a product;
- regulatory authorities may require additional warnings or contraindications on the label or limit access of a product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment;
- we may be required to create a medication guide outlining the risks of a product for patients, or to conduct post-marketing studies;
- we may be required to change the way a product is dosed, distributed, or administered, or conduct additional clinical trials;
- we may be subject to limitations on how we may promote the product;
- we could be subject to fines, injunctions, or the imposition of criminal or civil penalties, or be sued and held liable for harm caused to subjects or patients; and
- a product may become less competitive, and our reputation may suffer.

Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of our product candidates, if approved by the FDA or other regulatory authorities.

If any of our current or future product candidates receive regulatory approval, they may be subject to stringent labeling requirements, including the potential imposition of a boxed warning. A boxed warning, also known as a “Black Box” warning, is ordinarily used to highlight for prescribers one of the following situations: (1) There is an adverse reaction so serious in proportion to the potential benefit from the drug (e.g., a fatal, life threatening or permanently disabling adverse reaction) that it is essential that it be considered in assessing the risks and benefits of using the drug; (2) or there is a serious adverse reaction that can be prevented or reduced in frequency or severity by appropriate use of the drug (e.g., patient selection, careful monitoring, avoiding certain concomitant therapy, addition of another drug or managing patients in a specific manner, avoiding use in a specific clinical situation); or (3) FDA approved the drug with restrictions to ensure safe use because the FDA concluded that the drug can be safely used only if distribution or use is restricted.

The FDA has required the full prescribing information of approved GLP-1 obesity management medications, such as Wegovy and Zepbound, to carry a boxed warning regarding the risk of thyroid C-cell tumors. The boxed warnings state that semaglutide and tirzepatide, the active ingredients in Wegovy and Zepbound, respectively, cause thyroid C-cell tumors in rodents, but that it is unknown whether Wegovy and Zepbound cause thyroid C-cell tumors in humans. The boxed warnings for both drugs also indicate that they are contraindicated in patients with a personal or family history of medullary thyroid carcinoma or in patients with multiple endocrine neoplasia syndrome type 2. We expect that the label of our GLP-1 monotherapy or any future GLP-1 combination product candidates we may develop, if approved, may carry similar warnings.

If the FDA requires us to include a boxed warning in the prescribing information of any of our current or future product candidates, the inclusion of the boxed warning could adversely affect the market acceptance and commercial success of any of our current or future product candidates. The inclusion of a boxed warning could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of our product candidates, if approved by the FDA or other regulatory authorities.

Further, competitors who are developing products in the obesity management medication field or that utilize a similar mechanism of action as us may experience problems with their products that could indicate or result in class-wide problems or additional requirements that would potentially harm our business. For example, in January 2024, the FDA announced that it was evaluating reports of suicidal thoughts or actions in patients treated with GLP-1 receptor agonists. While the FDA ultimately did not find any association between use of GLP-1 receptor agonists and the occurrence of suicidal thoughts or actions, it did recommend that physicians prescribing GLP-1 receptor agonists should monitor their patients for and advise patients using GLP-1 receptor agonists to report new or worsening depression, suicidal thoughts, or any unusual changes in mood or behavior. Were an association between GLP-1 receptor agonists and suicidal thoughts or actions to be found in the future as additional data become available or other class-wide issues to arise, the FDA may impose additional requirements for product candidates seeking approval or impose labeling requirements the inclusion of which could adversely affect the market acceptance and commercial success of any of our current or future product candidates.

We currently, and may in the future, conduct certain of our clinical trials for our product candidates outside of the United States. However, the FDA and foreign regulatory authorities may not accept data from such trials, which could materially harm our business.

We and Hengrui are currently conducting, and we, Hengrui and any future collaborators may in the future conduct clinical trials for any of our current or future product candidates outside the United States. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. For example, in cases where data from foreign clinical trials are intended to serve as the sole basis for regulatory approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless the data are applicable to the U.S. population and U.S. medical practice; the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means.

In addition, even where the foreign study data are not intended to serve as the sole basis for approval, if the relevant study was not conducted pursuant to an IND, the FDA will not accept the data as support for a marketing application unless the study was conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar requirements for clinical data gathered outside of their respective jurisdictions. For instance, for nonclinical studies submitted to the European Medicines Agency, or EMA, particularly those supporting marketing applications in Europe, China-based testing facilities must adhere to the Organisation for Economic Co-operation and Development, or OECD, Principles of GLP and be part of the OECD Mutual Acceptance of Data system for data to be accepted. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. For example, the data generated by Hengrui on our product candidates in China may not be acceptable to the FDA or other regulatory authorities. In April 2026, the House Appropriations Committee issued a draft, non-binding report accompanying its proposed Fiscal Year 2027 Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act that would bar FDA from accepting, reviewing, or considering any covered clinical data generated by a clinical investigation site in China, Russia, Iran or North Korea in support of an IND, including any amendment or supplement thereto. If the FDA or any comparable foreign regulatory authority does not accept such data from our clinical trials of any of our current or future product candidates, we would need to conduct additional trials, which could be costly and time-consuming, and which may not ultimately support approval in the applicable jurisdiction. Conducting clinical trials outside the United States also exposes us to additional risks, including risks associated with:

- foreign regulatory requirements;
- compliance with foreign manufacturing, customs, shipment, and storage requirements;
- inconsistent standards for reporting and evaluating clinical data and adverse events;
- diminished protection of intellectual property in some countries; and
- public health concerns or political instability, civil unrest, war or similar events that may jeopardize our ability to commence, conduct or complete a clinical trial and evaluate resulting data.

Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize any of our current or future product candidates in foreign markets. We are not permitted to market or promote any of our current or future product candidates before we receive regulatory approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for any of our

current or future product candidates. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, commercial sales, pricing and distribution of any of our current or future product candidates. Approval procedures may be more onerous than those in the United States and may require that we conduct additional nonclinical studies or clinical trials. If we obtain regulatory approval of any of our current or future product candidates and ultimately commercialize our products in foreign markets, we would be subject to additional risks and uncertainties, including:

- different regulatory requirements for approval of drugs in foreign countries;
- reduced protection for intellectual property rights;
- the existence of additional third-party patent rights of potential relevance to our business;
- compliance with export control and import laws and regulations and changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- foreign reimbursement, pricing, and insurance regimes;
- workforce uncertainty in countries where labor unrest is common;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, public health pandemics or epidemics, or natural disasters including earthquakes, typhoons, floods and fires.

Our business is subject to the risks associated with having a collaboration partner located in China.

As a result of our collaboration with Hengrui, located in China, our results of operations, financial condition, and prospects are subject to a significant degree to economic, political, and legal developments in China including government control over capital investments or changes in tax regulations that are applicable to us. China's economy differs from the economies of most developed countries in many respects, including with respect to the amount of government involvement, level of development, growth rate and control of foreign exchange, and allocation of resources. Since we collaborate with an entity located in China, our business is subject to the risks associated with having a collaboration partner located in China, including:

- adverse political and economic conditions, particularly those potentially negatively affecting the trade relationship between the United States and China;
- trade protection measures, such as tariff increases, and import and export licensing and control requirements;
- potentially negative consequences from changes in tax laws;
- difficulties associated with the Chinese legal system, including increased costs and uncertainties associated with enforcing contractual obligations in China;
- historically lower protection of intellectual property rights;
- requirements relating to China's data security rules and regulations;
- requirements relating to China personal information protection laws;
- changes and volatility in currency exchange rates;
- workforce uncertainty;
- unexpected or unfavorable changes in regulatory requirements; and
- difficulties in managing foreign relationships and operations generally.

We are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the U.S. or Chinese governments, political unrest or unstable economic conditions in China. New legislation, regulations or court decisions may impede, delay, limit, or increase the cost of manufacturing our therapeutic candidates. Such events could result in our clinical or commercial supply of drug being interrupted or limited, which could harm our business.

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

The U.S. government has recently made statements and taken certain actions that may lead to potential changes to U.S. and international trade policies, including imposing several rounds of tariffs and export control restrictions affecting certain products manufactured in China, and most recently, proposing legislation that, if enacted would restrict trade with certain Chinese companies that provide biopharmaceutical research, development, and manufacturing services. Recently both China and the United States have each imposed tariffs indicating the potential for further trade barriers. In addition, in the past the U.S. Commerce Department has implemented export controls adding numerous Chinese entities to its "unverified list," which requires U.S. exporters to go through more procedures before exporting goods to such entities. It is unknown whether and to what extent new tariffs, export controls, trade restrictions, or other new laws or regulations will be adopted, or the effect that any such actions would have on us or our industry. Sustained uncertainty about, or the further escalation of, trade and political tensions between the United States and China could result in a disadvantageous research and manufacturing environment in China, particularly for U.S. based companies, including retaliatory restrictions that hinder or potentially inhibit our ability to rely on manufacturing partners and other service providers that operate in China. For example, proposed legislation has been introduced in Congress that could prohibit, among other things, the use of U.S. government executive agency contract, grant, or loan funding to procure or obtain, or enter into, extend or renew contracts involving the use of certain equipment or services produced or provided by certain Chinese companies which could cause us to reevaluate our relationship with certain of our existing manufacturing partners, including Hengrui.

In addition to Hengrui, some of our other suppliers, vendors and service providers are located in China. Trade tensions and conflicts between the United States and China have been escalating in recent years and, as such, we are exposed to the possibility of supply disruptions and increased costs and expenses in the event of changes to the laws, rules, regulations and policies of the governments of the United States or China, or due to geopolitical unrest and unstable economic conditions. Certain Chinese biotechnology companies may become subject to trade restrictions, sanctions, other regulatory requirements or proposed legislation by the U.S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting their supply of material to us. Additionally, third parties may voluntarily require compliance or supply chain requirements that go above and beyond potential legislation to address perceived risk of "pass through," which would make it difficult for us to operate our business.

For example, the U.S. BIOSECURE Act, which was enacted in December 2025, prohibits federal agencies from procuring or using any biotechnology equipment or services from "biotechnology companies of concern", or entering into, extending, or renewing any contracts with entities that use such biotechnology equipment or services from "biotechnology companies of concern". Congress has interpreted a "biotechnology company of concern" as an entity that is under the control of a foreign adversary and that poses a risk to national security based on its research or multiomic data collection (e.g., collection of genomic information). While the U.S. BIOSECURE Act has a grandfathering period of five years for existing contracts, and has carveouts for manufacture of drugs for supply under Medicaid and Medicare Part B, subject to the Secretary of Veteran Affairs' discretion, the impact of the U.S. BIOSECURE Act on the biotechnology industry is uncertain.

It is possible that we or some of our contractual counterparties, including Hengrui, could be impacted by the legislation described above.

Any unfavorable government policies on international trade, such as export controls, capital controls or tariffs, may increase the cost of manufacturing our product candidates and materials, affect the demand for our drug products (if and once approved), the competitive position of our product candidates, and import or export of raw materials and finished product candidate used in our, Hengrui's and our future collaborators' nonclinical studies and clinical trials, particularly with respect to any product candidates and materials that we import from China, including pursuant to the Hengrui License Agreement. If any new tariffs, export controls, legislation and/or regulations are implemented, or if existing trade agreements are renegotiated or, in particular, if either the U.S. or Chinese government takes retaliatory trade actions due to the recent trade tension, such changes could have an adverse effect on our business, financial condition and results of operations.

Even if we or our collaborators obtain approval for any of our product candidates in one jurisdiction, we may never obtain approval for or commercialize such candidates in any other jurisdiction, which would limit our ability to realize their full market potential.

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy. Approval by the FDA in the United States does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. For example, ribupatide injection (being developed as HRS9531 by Hengrui) is currently the subject of a pending NDA in China that has been submitted by Hengrui. If Hengrui fails to obtain approval for ribupatide injection in China, it could negatively impact our ability to obtain approval in the United States or any other jurisdiction. In addition, regulatory approval in one country does not guarantee regulatory approval in any other country.

Approval processes vary among countries and can involve additional product testing and validation, as well as additional administrative review periods. Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional nonclinical studies or clinical trials which could be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

If our product candidates are ultimately regulated as biologics rather than as drugs, we would be required to pursue approval under a different statutory framework than our current plans contemplate, which could delay development, increase costs, alter market exclusivity and competition dynamics, and adversely affect our business.

We are currently developing our product candidates with the expectation of seeking FDA approval through NDAs. There is, however, ongoing litigation challenging whether certain similar products should be regulated as drugs or biologics. The outcome of this litigation could affect how products with attributes comparable to our product candidates are classified. If that litigation, or related FDA actions, result in a determination that product candidates like ours must be regulated as biologics, we could be required to pursue approval via biologics license applications, or BLAs, under the Public Health Service Act.

A change in classification would subject our programs to a different and potentially more burdensome regulatory framework. Among other things, the biologics pathway can entail distinct and complex chemistry, manufacturing, and controls requirements, including expectations around process validation, comparability, and lot-to-lot consistency; expanded facility inspections; differences in quality system requirements; product-specific potency assays; and, potentially, additional nonclinical or clinical data to support a demonstration of safety, purity, and potency. Reclassification could necessitate redesign of our manufacturing processes (for example, to align with biologics quality standards), redevelopment or revalidation of analytical methods, new or supplemental bridging studies, and changes to our clinical development plans. It could also require us to engage different specialized contract manufacturers or to build or qualify new internal capabilities. Any of these changes could materially delay our timelines and substantially increase our costs.

Market entry and competition dynamics would also differ. If approved as biologics, our product candidates' period of reference product exclusivity, biosimilar and interchangeable product competition, and related patent litigation procedures would be governed by the Biologics Price Competition and Innovation Act rather than the generic drug framework under the Drug Price Competition and Patent Term Restoration Act of 1984. While biologics may be eligible for a different statutory regulatory exclusivity period than drugs, the biosimilar and interchangeability standards, naming conventions, and substitution rules are distinct from those applicable to generic drugs approved under abbreviated new drug applications. These differences could change the timing, nature, and intensity of post-approval competition, and affect our pricing and market access strategies.

We have designed our development, regulatory, and manufacturing strategies based on our current understanding that our product candidates will be regulated as drugs subject to the NDA pathway. If FDA were to require that we instead pursue BLAs, we may experience substantial delays to our development programs; incur significant, unplanned costs; need to repeat or augment nonclinical or clinical studies; requalify or replace manufacturing sites and suppliers; and modify our commercial plans. We may also face uncertainty while the scope and implications of any reclassification are implemented by FDA, including how existing guidance, review practices, and user fee commitments apply. Any of these outcomes could adversely affect our ability to obtain timely approval, our competitive position, our potential market opportunity, and our business, financial condition, and results of operations.

Additional time may be required to obtain marketing authorizations for any product candidates that we develop as drug-device combination products.

We expect our current injectable product candidates will be regulated as combination products, as our therapeutic candidates will be administered by the patient using a disposable injector device (pre-filled syringe, autoinjector and/or multi-use pen) marketed together with the therapeutic candidate, if approved. Development of a product candidate as a combination product candidate requires close coordination within the FDA and within comparable regulatory agencies for review of each of the drug and device components that comprise the product and would typically be reviewed by different centers within the FDA if offered for use as standalone products. For example, the FDA's review of a marketing application for a drug-device combination that has a primary mode of action as a drug would likely be subject to an NDA with the Center for Drug Evaluation and Research as the lead center, with coordination with the Center for Devices and Radiological Health for the review of the device component. Although the FDA and comparable foreign agencies have or may have systems in place for the review and approval of such combination products, we may experience additional delays in the development and commercialization of such product candidates due to regulatory timing constraints and uncertainties in the product development and approval process. Furthermore, regulatory bodies like the FDA may require a human factors study, also sometimes referred to as a usability study, to evaluate how people interact with drug-device combination products in real-world settings to ensure

they can be used safely and effectively, and the requirement to conduct a human factors study may delay or prevent approval of a drug-device combination product. Moreover, although we anticipate that the device component of any combination product candidates we develop will be reviewed within the usual time frames expected for the marketing authorization application for underlying therapeutic candidate, and that no separate marketing application for the device components of such product candidates will be required in the United States, the FDA or comparable regulatory authorities may delay approval or require us to conduct additional studies with the device, which may delay the approval of the combination product.

The EU regulates medical devices and medicinal products separately, through different legislative instruments, and the applicable requirements will vary depending on the type of drug-device combination product. For instance, drug-delivery products intended to administer a medicinal product where the medicinal product and the device form a single integral product are regulated as medicinal products in the EU. In such a case, the marketing authorization application must include—where available—the results of the assessment of the conformity of the device part with the EU Medical Devices Regulation contained in the manufacturer's EU declaration of conformity of the device or the relevant certificate issued by a notified body. If the marketing authorization application does not include the results of the conformity assessment and where for the conformity assessment of the device, if used separately, the involvement of a notified body is required, the EMA or the EU member state competent authority must require the applicant to provide a notified body opinion on the conformity of the device. By contrast, in case of drug-delivery products intended to administer a medicinal product where the device and the medicinal product do not form a single integral product (but are e.g. co-packaged), the medicinal product is regulated in accordance with the rules for medicinal products described above while the device part is regulated as a medical device and will have to comply with all the requirements set forth by the Medical Devices Regulation.

Even if we receive regulatory approval for any product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense, and we may be subject to penalties if we fail to comply with regulatory requirements.

For any regulatory approvals that we may receive for our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, sampling, import, export and recordkeeping for our product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, including both federal and state requirements in the United States and requirements of comparable foreign regulatory authorities, as well as ongoing compliance with cGMPs and GCPs for any clinical trials. The holder of an NDA also must submit supplemental applications and obtain prior approval for certain changes to the approved product, product labeling, or manufacturing process.

Manufacturers of drug products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMPs and other applicable regulations and standards. Accordingly, we will need to continue to expend time, money, and effort in all areas of regulatory compliance, including manufacturing, production, and quality control. Manufacturers and other parties involved in the supply chain must also meet chain of distribution requirements and build electronic, interoperable systems for product tracking and tracing and for notifying the FDA of counterfeit, diverted, stolen, and intentionally adulterated products or other products that are otherwise unfit for distribution in the United States.

In addition, any regulatory approvals we may receive will require the submission of periodic reports to regulatory authorities and ongoing surveillance to monitor the safety and efficacy of the product. Such approvals may also contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post-approval study or risk management requirements. For example, the FDA may require a REMS as a condition of approval of our product candidates, which could include requirements for a medication guide, physician training and communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

If we or a regulatory agency discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facilities where the product is manufactured, a regulatory agency may impose restrictions on that product, the manufacturing facility or us, including requiring recall or withdrawal of the product from the market or suspension of manufacturing. This may also result in revisions to the approved labeling to add new safety information, imposition of post-marketing studies or clinical trials to assess new safety risks, or imposition of distribution restrictions or other restrictions under a REMS program. In addition, failure to comply with FDA and other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;
- fines, restitutions, disgorgement of profits or revenues, warning letters, untitled letters or holds on clinical trials;

- refusal by the FDA to approve pending applications or supplements to approved applications submitted, or suspension or revocation of approvals;
- revisions to the labeling, including limitations of use or requirements for additional warnings, contraindications, or other safety information, including boxed warnings;
- product seizures or detentions, or refusal to permit the import or export of our products; and
- injunctions or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay marketing authorization of any product candidates we develop. The U.S. Supreme Court's July 2024 decision to overturn prior established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which the FDA's regulations, policies and decisions may become subject to increasing legal challenges, delays, and/or changes. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

The FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses.

The FDA and other regulatory agencies strictly regulate marketing, labeling, advertising, and the promotional claims that may be made about prescription products, such as any of our current or future product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or other regulatory agencies as reflected in the product's approved labeling. If we receive regulatory approval for any of our current or future product candidates, physicians may prescribe, in their independent professional medical judgment, legally available products for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Physicians may believe that such off-label uses are the best treatment for some patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. Companies may share truthful and not misleading information that is otherwise consistent with a product's FDA-approved labeling, but the FDA does, however, restrict a manufacturer's communications about off-label use of their products. Similar requirements apply in foreign jurisdictions. If we are found to have promoted such off-label uses, we may become subject to significant liability. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The government has also required companies to enter into consent decrees or imposed permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of any of our current or future product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

Disruptions at the FDA, the SEC, and other government agencies caused by funding shortages or staffing limitations 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 have a negative impact on our business.

The ability of the FDA or foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also prolong the time necessary for new drugs or biologics to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years and in the past year, 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. In addition, the current U.S. Presidential administration has issued certain policies and Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities. If a prolonged government shutdown were to occur, or if funding shortages or staffing limitations hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections,

reviews, or other regulatory activities, it could significantly affect the ability of the FDA to review and process our regulatory submissions in a timely manner, which could have a material adverse effect on our business.

Risks Related to Our Reliance on Third Parties

We depend on our license agreement with, and the comprehensiveness of the intellectual property licensed from, Hengrui. Termination of the Hengrui License Agreement, and issues related to intellectual property we license from Hengrui, would have a material adverse effect on our business.

We depend on the patents, know-how and other intellectual property licensed from Hengrui through the Hengrui License Agreement for the development and, if approved, commercialization of our product candidates. If the Hengrui License Agreement is terminated, or found to be unenforceable, it could result in the loss of significant rights and could harm our ability to commercialize our product candidates.

The Hengrui License Agreement imposes certain obligations on us, including obligations to use commercially reasonable efforts to develop and commercialize licensed products in our territory, obligations to achieve certain regulatory milestone obligations within specified timelines, and obligations to pay Hengrui milestone payments, royalties and other fees. If we are unable to meet our obligations, our rights under the License Agreement may be reduced or terminated.

Our rights to our product candidates are subject to the Hengrui License Agreement, which may be terminated in certain circumstances, including in the event of an uncured material breach by us (such as an uncured payment default) or Hengrui. Without rights to the patents and know-how licensed under the Hengrui License Agreement, we may be unable to continue to develop, manufacture or commercialize our product candidates.

Additionally, our ability to realize the full potential of the Hengrui License Agreement may be severely limited by factors involving intellectual property rights, including:

- whether and to what extent our technology and processes may infringe on intellectual property rights of third parties that are not subject to the Hengrui License Agreement;
- whether third parties are entitled to compensation or equitable relief, such as an injunction, for our use of the third parties' intellectual property without their authorization;
- our right to sublicense patent and other intellectual property rights to third parties under collaborative development relationships;
- our compliance with our obligations with respect to the use of the licensed technology in relation to our development and commercialization of product candidates; and
- ownership of specific intellectual property arising under the Hengrui License Agreement.

These issues, if they arise, could reduce or eliminate our rights to the relevant intellectual property or technology, increase what we believe to be our financial or other obligations under the relevant agreement, or increase our costs to develop, manufacture and commercialize products under the Hengrui License Agreement.

We are dependent on Hengrui having accurately generated, collected, interpreted and reported data from certain nonclinical studies and clinical trials that were previously conducted for our product candidates.

We have licensed the rights to substantially all of our current product candidates from Hengrui, for which they undertook prior research and development, including nonclinical studies and clinical trials, primarily in China. We had no involvement with or control over the nonclinical and clinical development of any of our product candidates prior to our entry into the Hengrui License Agreement. In addition, we had no involvement in the development of third-party agents used as comparators or background therapies in such studies. Therefore, we are dependent on these third parties having conducted their research and development in accordance with the applicable protocols, legal and regulatory requirements, and scientific standards; having accurately reported the results of all nonclinical studies and clinical trials conducted with respect to such product candidates and having correctly collected and interpreted the data from these studies and trials. These risks also apply to any additional product candidates that we may acquire or license in the future. To date, we have not completed a comprehensive audit of the data that was generated by Hengrui with respect to our current product candidates. If we were to discover that data previously generated by Hengrui or another third-party was materially inaccurate or that their research and development activities were carried out in a noncompliant manner, we would be unable to rely on such data for our own clinical development, regulatory approval or commercialization purposes, adversely impacting the development of the implicated product candidate(s).

We rely on third parties to conduct our clinical trials and nonclinical studies. If these third parties do not successfully carry out their contractual duties, comply with applicable regulatory requirements, or meet expected deadlines, any of our current or future product candidates and our ability to seek or obtain regulatory approval for or commercialize any of our current or future product candidates may be delayed.

We are dependent on third parties to conduct our clinical trials and nonclinical studies. Specifically, we rely on, and intend to continue to rely on, medical institutions, clinical investigators, CROs and consultants to conduct our nonclinical studies and clinical trials in accordance with our clinical protocols and applicable regulatory requirements. These CROs, investigators and other third parties play a significant role in the conduct and timing of these trials and subsequent collection and analysis of data. In particular, we have licensed our pipeline from Hengrui, which has conducted and is conducting multiple nonclinical studies and clinical trials of our product candidates in China. We intend to leverage the clinical capabilities and data generated by Hengrui to inform and support our global development programs. While we have and will have agreements governing the activities of our third-party contractors, including Hengrui, we have limited influence over their actual performance, and we have no control over the data generated by Hengrui on our product candidates. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards and requirements, and our reliance on our CROs and other third parties does not relieve us of our regulatory responsibilities. In addition, we and our CROs are required to comply with GLP requirements, as applicable, for certain nonclinical studies, as well as GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for any of our current and future clinical trials of product candidates. Regulatory authorities enforce these requirements through periodic inspections of laboratories conducting GLP studies, trial sponsors, principal investigators and trial sites. If we, our investigators, or any of our CROs or trial sites fail to comply with applicable GLP or GCP or other requirements, the clinical data generated in our nonclinical studies or clinical trials may be deemed unreliable, the statistical analysis and robustness of our datasets could be compromised, and the FDA or comparable foreign regulatory authorities may require us to perform additional nonclinical studies or clinical trials before approving our marketing applications, if ever. Further, our clinical trials must be conducted with investigational products produced in accordance with cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the development and regulatory approval process.

Furthermore, these CROs and investigators are not our employees, and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. There is no guarantee that any of our CROs, investigators or other third parties will devote adequate time and resources to such trials or studies or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, or otherwise perform in a substandard manner, our clinical trials may be extended, delayed or terminated. In addition, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other development activities that could harm our competitive position.

Our CROs have the right to terminate their agreements with us in the event of an uncured material breach and under other specified circumstances. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, in a timely manner or at all. Switching or adding additional CROs, investigators and other third parties involves additional cost and requires our management's time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we work to carefully manage our relationships with our CROs, investigators and other third parties, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition, results of operations and prospects.

We rely on the use of third parties, including Hengrui, to manufacture our product candidates, which may increase the risk that we will not have sufficient quantities of our product candidates or products or such quantities at an acceptable time and cost, which could delay, prevent or impair our development or commercialization efforts.

We do not own or operate manufacturing facilities for the production of clinical or commercial supplies of our product candidates. We have limited personnel with experience in drug manufacturing and lack the resources and the capabilities to manufacture any of our product candidates on a clinical or commercial scale. We currently rely on third parties, including Hengrui, for supply of the active pharmaceutical ingredients, or API, drug substance or drug product, in our product candidates. Hengrui supplies us with drug substance and drug product for our clinical trials, but if the Hengrui License Agreement is terminated, then our supply from Hengrui will also be terminated. Our strategy is to outsource all manufacturing of our product candidates and products to third parties.

We have supply arrangements with Hengrui and with other third-party manufacturers for development, validation and manufacturing of our product candidates to support near-term clinical supply and, if approved, potential commercial supply of our future products. We are in the process of further establishing agreements with third party manufacturers for the long-term clinical and commercial supply of our product candidates. We may be unable to conclude agreements for commercial supply with third-party manufacturers, or may be unable to do so on acceptable terms. While we are engaged in a number of efforts to reduce the cost of goods sold of our product

candidates, particularly for ribupatide oral, such efforts may not be successful, which could limit the commercial profitability of such product candidates, if approved. Our efforts to improve the bioavailability of ribupatide oral or reduce the cost of manufacturing ribupatide drug substance may not be successful. We may not be able to enter into commercial manufacturing agreements with third-party manufacturers for drug substance, drug product or fill-finish services on commercially acceptable terms or at all, or may not be able to secure sufficient commercial manufacturing capacity from such third-party manufacturers on a timely enough basis. The third-party manufacturers may not successfully carry out their contractual duties or obligations, the occurrence of which could substantially increase our costs and limit our supply of such product candidates. The demand for third-party manufacturer's services is very high, and such manufacturers could be subject to market transactions including mergers, acquisitions and other market consolidation transactions that limit their ability to provide products and services to us thereby increasing the time and cost it could take us to manufacture our product candidates.

Even if we are able to establish and maintain arrangements with third-party manufacturers, reliance on third-party manufacturers, including Hengrui, entails additional risks, including:

- reliance on the third party for regulatory compliance and quality assurance;
- the possible breach of the manufacturing agreement by the third party;
- the possible diversion of manufacturing capacity to other customers by the third party;
- the possible misappropriation of our proprietary information, including our trade secrets and know-how; and
- the possible termination or non-renewal of the agreement by the third party at a time that is costly or inconvenient for us.

Third-party manufacturers, including Hengrui, may not be able to comply with current good manufacturing practice, or cGMP, regulations or similar regulatory requirements outside the United States. Our failure, or the failure of our third-party manufacturers, including Hengrui, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates. For example, in 2024, Hengrui received a Warning Letter from the FDA that was unrelated to the production of our product candidates. It is possible that Hengrui or other third-party manufacturers may in the future receive similar allegations of noncompliance or regulatory enforcement that may implicate the production of our product candidates, which could significantly and adversely affect supplies of our product candidates.

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

In addition, in order to conduct late-stage clinical trials of our product candidates, we will need to have them manufactured in large quantities. Our third-party manufacturers, including Hengrui, may be unable to successfully increase the manufacturing capacity for any of our product candidates in a timely or cost-effective manner, or at all.

Moreover, if our third-party manufacturers, including Hengrui, are unable to successfully scale up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of those product candidates may be delayed or infeasible, and regulatory approval or commercial launch of such product candidates may be delayed or not obtained, which could significantly harm our business.

In addition, we rely on our licensors and third party manufacturers, including Hengrui, to transfer manufacturing know how, analytical methods, reference standards and any process improvements relating to our product candidates. If we do not receive, retain or are otherwise unable to use such know how, we may incur additional transition costs, need to repeat development or validation activities and experience delays in manufacturing and delivery. Drug substance or drug product supplied by third parties may not comply with regulatory quality requirements or have sufficient stability for commercialization, which could require additional investment, revalidation or process changes and delay our development, approval and commercialization plans. Manufacturing may also depend on raw materials, single source reagents or specialized equipment that may be difficult to secure. Because some supply originates outside the United States, any delay in obtaining or maintaining required import or export licenses or clearances could delay our timelines. Termination, expiration or breach of our supply, manufacturing or technology transfer arrangements could have a material adverse effect on our business.

If the third parties, including Hengrui, that we engage to manufacture product for our nonclinical studies and clinical trials should cease to continue to do so for any reason, including due to outbreaks, geopolitical disruptions, natural disaster, epidemic or pandemic, trade wars, political unrest, economic conditions, changes in legislation or other events beyond their control, we likely would experience

delays in advancing these clinical trials while we identify and qualify replacement suppliers, and we may be unable to obtain replacement supplies on terms that are favorable to us. For example, the passage of the People's Republic of China's Biosecurity law, which became effective on April 15, 2021, and subsequent legislation that China or the United States may adopt in the future, or other events in China could disrupt our ability to continue to rely upon manufacturers located in China, including Hengrui. In addition, if we are not able to obtain adequate supplies of our product candidates or the drug substances used to manufacture them, it will be more difficult for us to develop our product candidates and compete effectively.

Large pharmaceutical companies with greater resources, either through acquisitions, market consolidation or otherwise, may be able to obtain privileged access to manufacturing capacity and supply of material needed for the manufacture of our product candidates or other similar competing drugs. If our competitors are able to use their resources to secure preferential access to the supply capacity of third party manufacturers, or if third party manufacturers elect to terminate their contracts with us in favor of exclusive contracts with other larger pharmaceutical companies, our ability to obtain supply of our product candidates or any other future product candidates may be impacted resulting in significant delays and higher costs for development and commercialization of our product candidates. We may not be able to complete our clinical trials or market our product candidates at scale without stable partnerships with third party manufacturers who produce our product candidates or other drug compounds necessary for our product candidates. Shifting manufacturing relationship to another third-party manufacturer takes significant time and resources, and could delay development and commercialization of our product candidates.

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 advancement of our product candidates and development programs and the potential commercialization of our current and future product candidates will require substantial additional cash to fund expenses. For some of our programs, we may decide to collaborate with other pharmaceutical and biotechnology companies with respect to development and potential commercialization. Likely collaborators may include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. In addition, if we are able to obtain regulatory approval for product candidates from foreign regulatory authorities, we may enter into collaborations with international biotechnology or pharmaceutical companies for the commercialization of such product candidates.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the potential differentiation of our 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 may also consider alternative product candidates or technologies for similar indications that may be available for collaboration and whether such a collaboration could be more attractive than the one with us for our product candidate. 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 our product candidates or bring them to market and generate product revenue.

Collaborations are complex and time-consuming to negotiate and document. Further, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. 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 product candidates. 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.

In addition, if we enter into such collaborations, we will have limited control over the amount and timing of resources that our collaborators will dedicate to the development or commercialization of our 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. 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.

Our employees and independent contractors, including collaborators, principal investigators, CROs, consultants and vendors, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees and independent contractors, including collaborators, principal investigators, CROs, consultants and vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violate: (i) the laws and regulations of the FDA and other comparable foreign regulatory requirements, including those laws that require the reporting of true, complete and accurate information to such authorities; (ii) manufacturing standards, including cGMP requirements, (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad; (iv) laws that require the true, complete and accurate reporting of financial information or data; or (v) laws that prohibit insider trading. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our or our collaborators' nonclinical studies or clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and curtailment of our operations, any of which could adversely affect our business, financial condition, results of operations and prospects.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor or other third party will discover them or that our trade secrets will be misappropriated or disclosed.

Because we currently rely on third parties to manufacture our product candidates and to perform quality testing, we must, at times, share our proprietary technology and confidential information, including trade secrets, with them. We seek to protect our trade secrets, in part, by entering into confidentiality agreements, and, if applicable, material transfer agreements, collaborative research agreements, service agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors or other third parties, are intentionally or inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets and despite our efforts to protect our trade secrets, a competitor's or other third party's discovery of our confidential information or other unauthorized use or disclosure of such information would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations and prospects.

Risks Related to Commercialization of Our Product Candidates

We face significant competition from entities that have made substantial investments into developing novel treatments for patients with obesity, including large pharmaceutical companies with approved therapies in our current indications, and biopharmaceutical, specialty pharmaceutical and biotechnology companies developing novel treatments and technology platforms.

The development and commercialization of therapies for the treatment of obesity is highly competitive. Our product candidates, if approved, will face significant competition, including from well-established, currently marketed therapies that have been developed by large, well-known pharmaceutical companies, and our failure to demonstrate a meaningful improvement to the existing standard of care may prevent us from achieving significant market penetration. In particular, there is intense competition in the obesity field, especially with the advent of GLP-1 weight management medications, such as Wegovy, marketed by Novo Nordisk, and Zepbound, marketed by Eli Lilly. There are numerous other companies that have commercialized or are developing treatments for obesity that we will compete with, including Amgen, AstraZeneca, Boehringer Ingelheim, Merck, Pfizer, Roche, Structure Therapeutics, Viking Therapeutics and Zealand Pharma. We face competition from these companies and other major pharmaceutical and biotechnology companies, including specialty pharmaceutical companies, and academic institutions, governmental agencies and public and private research institutions, among others.

Many of these aforementioned products have been marketed for several years and are well established among physicians, patients, guidelines and third-party payers, creating potential adoption and pricing challenges for new entrants, such as requiring demonstration

of incremental value or benefits and/or reduction of healthcare system costs. These challenges will impact current and future products as they look to enter or expand the market.

We anticipate that we will continue to face increasing competition as new therapies and combinations thereof, and related data, emerge. Competitors, independently or through collaboration, are developing products that potentially directly compete with our current or future product candidates and which may be a longer lasting or a more efficacious treatment, or receive FDA or other applicable regulatory approval more rapidly than any of our current or future product candidates. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other applicable regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Furthermore, established competitors have, and may in the future, pursue aggressive pricing strategies or enter into discounted distribution arrangements to defend or expand their market share, which could intensify pricing pressure and create additional barriers to commercial success for our product candidates. In addition, our ability to compete may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. There are generic products currently on the market for certain of the indications that we are pursuing and additional products are expected to become available on a generic basis over the coming years. If our product candidates are approved, we expect that they will be priced at a significant premium over competitive generic products.

Many of our current or potential competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, manufacturing, nonclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Moreover, many of these aforementioned competing products have been marketed for several years and are well established among physicians, patients and guidelines. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified management and other personnel and establishing clinical trial sites and participants registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

The commercial success of any of our current or future product candidates will depend upon the degree of market acceptance of such product candidates by physicians, patients, healthcare payors and others in the medical community.

Even if any of our current or future product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors or others in the medical community. The commercial success of any of our current or future product candidates will depend significantly on the broad adoption and use of the resulting product by these individuals and organizations for approved indications. The degree of market acceptance of our products will depend on a number of factors, including:

- demonstration of clinical efficacy and safety, including as compared to any more-established products or other alternative products that may later be approved;
- the indications for which any of our current or future product candidates are approved, if any;
- the limitation of our targeted patient population and other limitations or warnings contained in any FDA-approved labeling;
- acceptance of a new drug for the relevant indication by healthcare providers and their patients;
- the pricing and cost-effectiveness of our products, as well as the cost of treatment with our products in relation to alternative treatments and therapies;
- our ability to obtain and maintain sufficient third-party coverage and adequate reimbursement from government healthcare programs, including Medicare and Medicaid, private health insurers and other third-party payors;
- the price concessions required by third-party payors to obtain coverage;
- the willingness of patients to pay all, or a portion of, out-of-pocket costs associated with our products in the absence of sufficient third-party coverage and adequate reimbursement;
- any restrictions on the use of our products, and the prevalence and severity of any adverse effects;
- potential product liability claims;
- the timing of market introduction of our products as well as availability, safety and efficacy of competitive drugs;
- the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies;

- the effectiveness of our or any current or future collaborators' sales and marketing strategies; and
- unfavorable publicity relating to the product, or favorable publicity about competitive products.

If any of our current or future product candidates is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors or patients, we may not generate sufficient revenue from that product and may not become or remain profitable. Our efforts to educate the medical community and third-party payors regarding the benefits of our products may require significant resources and may never be successful.

The successful commercialization of any of our current or future product candidates, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies.

The availability of coverage and the adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as any of our current or future product candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our products by third-party payors will have an effect on our ability to successfully commercialize those products. Accordingly, we will need to successfully implement a coverage and reimbursement strategy for any approved product candidate. Even if we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments or other cost-sharing that patients find unacceptably high.

If we participate in the Medicaid Drug Rebate Program or other governmental pricing programs, in certain circumstances, our products would be subject to ceiling prices, rebates, or other limitations set by such programs, which could reduce the revenue we may generate from any such products. Participation in such programs would also expose us to the risk of significant civil monetary penalties, sanctions and fines should we be found to be in violation of any applicable obligations thereunder.

Third-party payors increasingly are challenging prices charged for biopharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third-party payor may consider our products as substitutable and offer to reimburse patients only for a less expensive competitor product. Even if we are successful in demonstrating improved efficacy or improved convenience of administration with our products, pricing of existing drugs may limit the amount we will be able to charge for our products. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. Statutory constraints, including those limiting use of drugs for weight loss, or agency interpretations of those statutes may limit coverage for certain drug products by governmental payors. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products and may not be able to obtain a satisfactory financial return on products that we may develop.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. Some third-party payors may require pre-approval of coverage or implement prior authorization or step therapy programs for new or innovative devices or drug therapies before they will reimburse patients who use such therapies, which may be time-consuming or costly for patients and lead to a reduction in revenue. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for any of our current or future product candidates. Our success instead could depend on the ability and willingness of patients to pay out-of-pocket for our product candidates, if approved.

Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that reimbursement will be available for any product candidate that we commercialize and, if reimbursement is available, the level of reimbursement. In addition, if we participate in the Medicaid Drug Rebate Program or other federal programs, we would be required to calculate and report certain price reporting metrics to the government, such as best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, programs we participate in may require us to extend mandatory discounts or pay rebates.

Obtaining and maintaining reimbursement status is time-consuming, costly and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage

determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, and, in some cases, at short notice, and we believe that changes in these rules and regulations are likely. For products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization.

Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of any of our current or future product candidates, if approved in these jurisdictions. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with the sale of any of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative and regulatory changes. The downward pressure on healthcare costs in general, and prescription drugs, surgical procedures and other treatments in particular, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. See "Risks Related to Our Business Operations and Industry—Current and future U.S. healthcare reform legislation or regulation may increase the difficulty and cost for us to obtain coverage for and commercialize any of our current or future product candidates and may adversely affect the prices we may set" below for additional related information.

Economic uncertainty may reduce patient demand for any of our current or future product candidates, if approved, which may adversely affect our business, financial condition and results of operations.

To the extent that any of our current or future product candidates are approved for indications that are not covered by or reimbursable through governmental authorities and health insurers, patients will bear the entire cost of our products. The decision to undergo therapy using our products for non-covered indications is thus driven by patient demand, which may be influenced by a number of factors, such as:

- the success of our sales and marketing programs, including our consumer marketing initiatives;
- the extent to which physicians recommend our products, if approved, to their patients;
- consumer sentiment about the benefits and risks of obesity drugs generally and our products, if approved, in particular, including satisfaction of patient expectations;
- the cost, safety and effectiveness of our products, if approved, in comparison to other obesity drugs; and
- general consumer confidence, which may be impacted by economic and political conditions.

Economic downturns in the United States and international markets would likely have an adverse effect on demand for our products, if approved. Our business, financial condition and results of operations will be adversely affected if we cannot generate significant patient demand for our products, if approved.

If we receive regulatory approvals for any of our current or future product candidates, we may face substantial competition from compounding pharmacies.

Under the Federal Food, Drug, and Cosmetic Act, or the FDCA, the FDA has oversight over the compounding of human drug products without an approved drug application. Compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient.

Section 503A of the FDCA establishes conditions under which compounded human drug products are exempt from certain requirements of the FDCA, including prior approval of an NDA, compliance with cGMPs, and labeling requirements, provided that the drug is compounded on the basis of receipt of valid patient-specific prescriptions and meets other requirements. Section 503B of the FDCA

established conditions for a new category of compounders known as outsourcing facilities, which may compound a drug without marketing approval, but are subject to cGMP requirements and other obligations. Subject to these conditions, outsourcing facilities may distribute compounded drugs either pursuant to patient-specific prescriptions or in response to an order from a health care provider, such as a hospital, that is not for an identified individual patient (e.g., for office stock).

Section 503A of the FDCA restricts compounding drugs that are essentially copies of commercially available drugs, but certain amounts are permissible under the law as long as the compounding is not done "regularly or in inordinate amounts." However, all other conditions of Section 503A must be met, including that the compounding is done on the basis of a valid prescription for an individual patient. When a drug is on the FDA's drug shortage list, meaning that the demand or projected demand for the drug within the United States exceeds the supply of the drug, that drug is not considered to be "commercially available" such that the limitation on compounding "essentially copies" is lifted. The FDA intends to consider a compounded drug product to be essentially a copy of a commercially available drug if it has the same API, has the same, similar, or an easily substitutable dosage strength; and can be used by the same route of administration.

Outsourcing facilities registered under Section 503B are also restricted from making essentially a copy of an FDA-approved drug, but this limitation is lifted for identical or nearly identical copies of an FDA-approved drug if that drug is on the FDA's drug shortage list. When a drug is on the FDA's drug shortages list, an outsourcing facility regulated under Section 503B of the FDCA can use a bulk drug substance, also known as an API, to make that drug. The FDA considers a compounded drug to be essentially a copy of a commercially available drug under Section 503B if the compounded drug product and the FDA-approved drug have the same API, route of administration, dosage form, strength, and excipients.

A number of GLP-1 products have previously been identified on the FDA shortage list, allowing for "essentially copies" of these drugs to be compounded by outsourcing facilities, and where applicable, 503A compounders, and sold to meet demand. For example, tirzepatide and semaglutide, the active ingredients in Zepbound and Wegovy, respectively, have previously been on the FDA's drug shortage list, and compounding facilities have and continue to compound these drugs. These compounded formulations of GLP-1 products are generally less expensive than the branded, approved products, so could be a more attractive option for patients, particularly where not covered and reimbursed by third party payors.

The FDA has announced that it has ended enforcement discretion against compounders of both tirzepatide and semaglutide. However, the FDA's removal of these products from the shortage list in March and April 2025 has not yet cleared the market of compounded versions of the products, which could present a competitive threat to us if we obtain approval for our product candidates. Moreover, even if we obtain approval and our products are not on the shortage list, we could nevertheless face competition from compounded, less expensive versions of our product candidates akin to the availability of compounded tirzepatide and semaglutide.

The immediate availability of compounded versions of GLP-1 products may impact our pricing strategy and market penetration, and undermine our ability to establish a strong market position. Furthermore, any adverse events or quality issues associated with compounded versions of these products could negatively impact the perception of our product. These competitive pressures could materially and adversely affect our business and financial condition.

Governments outside the United States tend to impose strict price controls, which may adversely affect our revenues, if any.

In some countries, particularly the EU member states, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced EU member states, can further reduce prices. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidate to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on prices or reimbursement levels within the country of publication and other countries. 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 adversely affected.

If we are unable to develop our sales, marketing and distribution capability on our own or through collaborations with marketing partners, we will not be successful in commercializing our product candidates.

We currently have no marketing, sales or distribution capabilities. We intend to establish a sales and marketing organization, either on our own or in collaboration with third parties, with technical expertise and supporting distribution capabilities to commercialize one or more of our product candidates that may receive regulatory approval in key territories. These efforts will require substantial additional resources, some or all of which may be incurred in advance of any approval of the product candidate. Any failure or delay in the

development of our or third parties' internal sales, marketing and distribution capabilities would adversely impact the commercialization of our product candidates.

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

- our inability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe any future products;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

With respect to our existing and future product candidates, we may choose to collaborate with third parties that have direct sales forces and established distribution systems to serve as an alternative to our own sales force and distribution systems. Our future product revenue may be lower than if we directly marketed or sold our product candidates, if approved. In addition, any revenue we receive will depend in whole or in part upon the efforts of these third parties, which may not be successful and are generally not within our control. If we are not successful in commercializing any approved products, our future product revenue will suffer and we may incur significant additional losses.

If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates.

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

The precise incidence and prevalence for all the conditions we aim to address with our product candidates are unknown. Our projections of both the number of people who have these conditions and their associated diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including sales of our competitors, our own market insights, internal market intelligence and internally generated data and assumptions, scientific literature, surveys of clinics, patient foundations or market research. Market opportunity estimates, whether obtained or derived from third-party sources or developed internally, are subject to significant uncertainty and are based on assumptions and estimates that may not prove to be accurate. Further, new clinical trials may change the estimated incidence or prevalence of these diseases. The total addressable market across all of our product candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final label for each of our product candidates approved for sale for these indications, the ability of our product candidates to improve on the safety, convenience, cost and efficacy of competing therapies or therapies in development, acceptance by the medical community and patients, drug pricing and reimbursement. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our product candidates or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our business, financial condition, results of operations and prospects. Further, even if we obtain significant market share for our product candidates, because some of our potential target populations are very small, we may never achieve profitability despite obtaining such significant market share.

Public opinion and scrutiny of treatments for obesity may impact public perception of our company and product candidates, or may adversely affect our ability to conduct our business and our business plans.

Public perception may be influenced by claims, such as claims that our product candidates are unsafe, unethical or immoral and, consequently, our approach may not gain the acceptance of the public or the medical community. Negative public reaction to treatments for obesity in general could result in greater government regulation and stricter labeling requirements of products to treat these chronic conditions, including our product candidates, if approved, and could cause a decrease in the demand for any product candidates we may develop. For example, there is widespread awareness of gastrointestinal side effects and lean muscle mass loss associated with obesity management medications, and severe adverse events observed with GLP-1-based therapies include, but are not limited to, acute pancreatitis, acute gallbladder disease, acute kidney injury and worsening of diabetic retinopathy. Such side effects associated with GLP-1-based therapies may negatively impact public perception of us or our incretin-based product candidates. Adverse public attitudes may also adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians specializing in the treatment of those diseases that our product candidates target prescribing, and their patients being willing to receive, treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments they are already familiar with and for which greater clinical data may be available. Adverse events in our clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity could result in withdrawal of clinical trial participants, increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing or approval of our product candidates, stricter labeling requirements for those

product candidates that are approved and a decrease in demand for any such product candidates. More restrictive government regulations or negative public opinion could have an adverse effect on our business, financial condition, results of operations and prospects, and may delay or impair the development and, if approved, commercialization of our product candidates or demand for any products we may develop.

Risks Related to Our Business Operations and Industry

Our quarterly and annual operating results may fluctuate significantly or fall below the expectations of investors or securities analysts, each of which may cause our stock price to fluctuate or decline.

Our quarterly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and success or failure of clinical trials for our product candidates or competing product candidates, or any other change in the competitive landscape of our industry;
- our ability to successfully recruit and retain subjects for clinical trials, and any delays caused by difficulties in such efforts;
- our ability to obtain marketing approval for our product candidates and the timing and scope of any such approvals we may receive;
- the timing and cost of, and level of investment in, research and development activities relating to our product candidates, which may change from time to time;
- the cost of manufacturing our product candidates, which may vary depending on the quantity of production and the terms of its agreements with manufacturers;
- our ability to attract, hire and retain qualified personnel;
- expenditures that we will or may incur to develop additional product candidates;
- the level of demand for our product candidates should they receive approval, which may vary significantly;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future therapeutics that compete with our product candidates;
- the changing and volatile U.S. and global economic environments;
- the timing of milestone and royalty payments under the Hengrui License Agreement; and
- future accounting pronouncements or changes in its accounting policies.

The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period-to-period basis may not be meaningful. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our operating results or revenue fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide.

Our success is dependent on our ability to attract and retain highly qualified management and other clinical and medical personnel.

Our success depends in part on our continued ability to attract, recruit, retain, manage and motivate highly qualified management, clinical, and scientific personnel, and we face significant competition for experienced personnel. We are highly dependent upon our executive team, as well as our other employees. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our clinical trials and nonclinical studies, regulatory approvals or the commercialization of any of our current or future product candidates. Although we have executed employment agreements with each of the members of our executive team, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected. We do not currently maintain “key person” life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

In addition, employment candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, either because we are a public company or for other reasons, it may harm our ability to recruit and retain highly skilled employees. Our employees may be more likely to leave us if the shares they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options

that they hold are significantly below the market price of our common stock, particularly after the expiration of the lock-up agreements described herein.

We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be successful in maintaining our unique company culture and continuing to attract or retain qualified management, clinical, and scientific personnel in the future due to the intense competition for qualified personnel among biopharmaceutical, biotechnology and other businesses. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, integrate, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Due to the significant resources required for the development of our pipeline, and depending on our ability to access capital, we must prioritize the development of certain product candidates over others. Moreover, we may fail to expend our limited resources on product candidates or indications that may have been more profitable or for which there is a greater likelihood of success.

We are initially focused on the development of ribupatide injection for obesity, and we have three other product candidates that are at various stages of clinical development. We must seek to maintain a process of prioritization and resource allocation to maintain an optimal balance between aggressively pursuing ribupatide injection, and ensuring the development of additional potential product candidates in our pipeline.

Due to the significant resources required for the development of our product candidates, we are focusing on obesity first and must decide which product candidates to pursue and advance and the amount of resources to allocate to each. Our decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial products and may divert resources away from better opportunities. If we make incorrect determinations regarding the viability or market potential of any of our product candidates or misread trends in the pharmaceutical industry, in particular for obesity treatments, our business, financial condition and results of operations could be materially adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other indications that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing, or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

We are subject to various U.S. federal, state and foreign healthcare laws and regulations, which could increase compliance costs, and our failure to comply with these laws and regulations could harm our reputation, subject us to significant fines and liability or otherwise adversely affect our business.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, marketing personnel, third-party payors, patient organizations and customers expose us to broadly applicable foreign, federal and state fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any products for which we obtain regulatory approval. Such laws include:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, in return for, either the referral of an individual or the purchase, lease, or order, or arranging for or recommending the purchase, lease, or order of any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil monetary penalties (discussed below);
- the federal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making or causing to be made a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. Manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims.

The federal False Claims Act also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the federal False Claims Act and to share in any monetary recovery;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- the federal Physician Payments Sunshine Act, which 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 certain exceptions) to report annually to the Centers for Medicare & Medicaid Services, or CMS, information related to payments and other "transfers of value" made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse-midwives), and teaching hospitals and other healthcare providers, as well as ownership and investment interests held by physicians and their immediate family members; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; some state laws require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; some state laws that require biopharmaceutical companies to report information on the pricing of certain drug products; and some state and local laws that require the registration or pharmaceutical sales representatives.

Efforts to ensure that our current and future business arrangements both internally and with third parties will comply with applicable healthcare laws and regulations will involve ongoing substantial costs. It is possible that governmental authorities will conclude that our business practices, including certain consulting agreements we have entered into with physicians who are paid, in part, in the form of stock or stock options, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws. 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 penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government-funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly and time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws or regulations, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

Current and future U.S. healthcare reform legislation or regulation may increase the difficulty and cost for us to obtain coverage for and commercialize any of our current or future product candidates and may adversely affect the prices we may set.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any of our current or future product candidates for which we obtain regulatory approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, in 2010, the Affordable Care Act, or the ACA, was enacted in the United States. Among other provisions, the ACA established an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; expanded the entities eligible for discounts under the 340B drug pricing program; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare & Medicaid Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, beginning April 1, 2013, Medicare payments to providers were reduced under the sequestration required by the Budget Control Act of 2011, which will remain in effect through the 2032 fiscal year, unless additional Congressional action is taken. Additionally, on January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers. On March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminated the statutory cap on drug manufacturers' Medicaid drug rebate liability, beginning January 1, 2024. The rebate was previously capped at 100% of a drug's average manufacturer price. Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient assistance programs, and reform government program reimbursement methodologies for products.

Most significantly, the Inflation Reduction Act, or the IRA, was enacted in 2022. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare, with prices that can be negotiated subject to a cap (with resulting prices for the initial ten drugs first effective in 2026), imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023), redesigns the Medicare Part D benefit (beginning in 2025), and replaces the Part D coverage gap discount program with a new discounting program (which began on January 1, 2025). Under the IRA, small molecule drugs and biologics that otherwise qualify for selection first become eligible for price negotiation seven and eleven years, respectively, after U.S. FDA approval. The IRA permits the Secretary of Health and Human Services, or HHS, to implement many of these provisions through guidance, as opposed to regulation, for the initial years. CMS published the negotiated prices for the initial ten drugs, which went into effect in January 2026, and for the subsequent 15 drugs, which will first be effective in 2027, as well as the next 15 drugs that will be subject to price negotiation. Each year thereafter, more Part B and Part D products will become subject to the HHS price negotiation program. HHS has issued and will continue to issue guidance implementing the IRA, although the program is currently subject to legal challenges. While the impact of the IRA on us and the pharmaceutical industry cannot yet be fully determined, it is likely to be significant. Additional drug pricing proposals could appear in future legislation.

The One Big Beautiful Bill Act, which was enacted in July 2025, imposes significant reductions in the funding of the Medicaid program. Such reductions are expected to decrease the number of persons enrolled in Medicaid and reduce the services covered by Medicaid, which could adversely affect our sales of any product candidate that we commercialize.

The Trump administration is also pursuing a two-fold strategy to reduce drug costs in the U.S. While it is unclear whether and how the Trump proposals will be implemented, the Trump policies are likely to have a negative impact on the pharmaceutical industry and on our ability to receive adequate revenues for our product candidates, if approved. On the one hand, President Trump has threatened to impose significant tariffs on pharmaceutical manufacturers that do not adopt pricing policies such as most favored nation pricing, which would tie the price for drugs in the U.S. to the lowest price in a group of other countries. In response, multiple manufacturers have reportedly entered into confidential pricing agreements with the federal government. On the other hand, the Trump administration is pursuing traditional regulatory pathways to impose drug pricing policies, although final regulations have not yet been published. Even regulatory proposals or executive actions that are ultimately deemed unlawful could negatively impact the U.S. pharmaceutical sector and our business. In addition, pharmaceutical pricing and marketing has long been the subject of considerable discussion in Congress and among policymakers, and it is possible that Congress could enact additional laws that negatively affect the pharmaceutical industry.

At the state level, state governments have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or reimbursement constraints, discounts, restrictions on certain product access, marketing cost disclosure, drug price reporting and other transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Some states have enacted legislation creating so-called prescription drug affordability boards with the goal of imposing price limits on certain drugs in these states, and at least one state board is imposing an upper payment limit. States are also seeking to implement general, across the board price caps for pharmaceuticals, or are seeking to regulate drug distribution. Legally mandated price controls on payment amounts by third-party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. These measures could reduce the ultimate demand for any of our current and future product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, financial condition, results of operations and prospects.

We expect that these existing laws and other healthcare reform measures both at the federal and state level 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. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. We operate in a highly regulated industry and new laws, regulations or judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery or payment for healthcare products and services could negatively impact our business, operations and financial condition. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our current or future product candidates, if we obtain regulatory approval;
- our ability to set a price that we believe is fair for our products;
- our ability to obtain coverage and reimbursement approval for a product;
- our ability to generate revenue and achieve or maintain profitability;
- the level of taxes that we are required to pay; and
- the availability of capital.

Similar political, economic and regulatory developments are occurring in the EU and may affect the ability of pharmaceutical companies to profitably commercialize their products. In addition to continuing pressure on prices and cost containment measures, legislative developments at the EU or member state level may result in significant additional requirements or obstacles that may increase our operating costs. The delivery of healthcare in the EU, including the establishment and operation of health services and the pricing and reimbursement of medicines, is almost exclusively a matter for national, rather than EU, law and policy. National governments and health service providers have different priorities and approaches to the delivery of health care and the pricing and reimbursement of products in that context. In general, however, the healthcare budgetary constraints in most EU member states have resulted in restrictions on the pricing and reimbursement of medicines by relevant health service providers. Coupled with ever-increasing EU and national regulatory burdens on those wishing to develop and market products, this could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to commercialize our product candidates, if approved. In markets outside of the United States and EU, reimbursement and healthcare payment systems vary significantly by country, and many countries have instituted price ceilings on specific products and therapies.

On December 13, 2021, Regulation No 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted. The Regulation entered into force in January 2022 and has been applicable since January 2025, with phased implementation based on the type of product, i.e. oncology and advanced therapy medicinal products as of 2025, orphan medicinal products as of 2028, and all other medicinal products by 2030. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

Product liability lawsuits against us or any of our future collaborators could divert our resources and attention, cause us to incur substantial liabilities and limit commercialization of our product candidates.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical products. Currently, we have no products that have been approved for commercial sale; however, the use of our product candidates by us and any collaborators in clinical trials, and the sale of these product candidates, if approved, in the future, may expose us to liability claims. We face an inherent risk of product liability lawsuits related to the use of our product candidates in patients and will face an even greater risk if product candidates are approved by regulatory authorities and introduced commercially. Product liability claims may be brought against us by participants enrolled in our clinical trials, patients, health care providers, pharmaceutical companies, our collaborators or others using, administering or selling any of our future approved

products. If we cannot successfully defend ourselves against any such claims, we may incur substantial liabilities or be required to limit commercialization of our product candidates. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for any of our future approved products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- significant litigation costs;
- substantial monetary awards to, or costly settlements with, patients or other claimants;
- product recalls or a change in the indications for which they may be used;
- loss of revenue;
- diversion of management and scientific resources from our business operations; and
- the inability to commercialize our product candidates.

Although the clinical trial process is designed to identify and assess potential side effects, clinical development does not always fully characterize the safety and efficacy profile of a new medicine, and it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If our product candidates were to cause adverse side effects during clinical trials or after approval, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. If any of our product candidates are approved for commercial sale, we will be highly dependent upon consumer perceptions of us and the safety and quality of our products. We could be adversely affected if we are subject to negative publicity associated with illness or other adverse effects resulting from patients' use or misuse of our products or any similar products distributed by other companies.

Although we maintain product liability insurance coverage consistent with industry norms, including clinical trial liability, 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 its favor, could be substantial. We will need to increase our insurance coverage if we commercialize any product that receives regulatory approval. In addition, insurance coverage is becoming increasingly expensive. If we are unable to 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 our product candidates, which could harm our business, financial condition, results of operations and prospects.

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

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include property, general liability, employee benefits liability, commercial automobile, workers' compensation, transportation and storage, cyber liability, clinical trials, directors' and officers' and employment practices insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. No assurance can be given that an insurance carrier will not seek to cancel or deny coverage after a claim has occurred. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our business, financial condition, results of operations and prospects.

We and our service providers may be subject to a variety of ever-evolving state, federal, and foreign data protection, privacy and security obligations, including laws, regulations, and contractual provisions, which could increase compliance costs, and our actual or perceived failure to comply with such laws and obligations could subject us to potentially significant liability, fines or penalties and otherwise harm our business.

We and our service providers receive, maintain, use and otherwise process sensitive information, including confidential business, employee and health-related information, and are subject to laws and regulations governing the privacy and security of such information. The global data protection landscape is rapidly evolving, and we and our service providers may be affected by or subject to existing, amended, or new laws and regulations in the future, including due to expanding operations or if we operate in foreign jurisdictions. These laws and regulations may be subject to differing interpretations, thus creating potentially complex compliance issues for us and our service providers, strategic partners and future customers. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulations, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity,

government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the United States, numerous federal and state laws and regulations, including health information privacy laws, data breach notification laws and consumer protection laws, that govern the collection, use, storage, transfer, disclosure, protection and other processing of health-related and other personal information could apply to our operations or the operations of our collaborators and third-party service providers. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data and CROs) that are subject to privacy and security requirements under HIPAA. Consequently, depending on the facts and circumstances, we could be subject to significant penalties if we knowingly receive individually identifiable health information from a HIPAA-covered healthcare provider, research institution, or CRO that has not satisfied HIPAA's requirements for disclosure of individually identifiable health information. In addition, certain state laws govern the privacy and security of health-related and other personal information, many of which may differ from each other and from HIPAA, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. By way of example, the California Consumer Privacy Act, as amended by the California Privacy Rights Act, or collectively, the CCPA, requires covered businesses that process the personal information of California residents to, among other things: (i) provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; (ii) receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt out of certain disclosures of their personal information; and (iii) enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. Additional compliance investment and potential business process changes may be required. Similar laws have been passed in other states, and are continuing to be proposed at the state and federal level, reflecting a trend toward more stringent privacy legislation in the United States. In addition to these comprehensive consumer privacy laws and proposals, a number of other states have passed or proposed more limited privacy laws that focus on specific privacy issues such as biometric data and the privacy of health and medical information, such as Washington state's My Health My Data Act, which has a private right of action that further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. These various privacy and security 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. State laws are changing rapidly and there is discussion in the U.S. Congress of a new comprehensive federal data privacy law to which we may likely become subject, if enacted. In the event that we are subject to or affected by HIPAA, the CCPA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition.

In 2024, the National Security Division of the U.S. Department of Justice, or the DOJ, issued a new rule—referred to as the "Data Security Program," or DSP, to implement Executive Order 14117 aimed at preventing access to "bulk U.S. sensitive personal data" and "government-related data" by "countries of concern" (including China, Russia, Iran, North Korea, Cuba, and Venezuela) and "covered persons" (as all such terms are defined in the DSP). Effective as of April 8, 2025, and fully enforceable as of July 9, 2025, the DSP imposes stringent obligations on companies within its scope and prohibits or restricts "covered data transactions" that grant countries of concern or covered persons access to bulk U.S. sensitive personal data or any amount of government-related data. The DSP is new, complex and has yet to be enforced, and as such, there is a risk that our interpretation of its applicability, scope, and requirements is incorrect, incomplete, or misapplied. Compliance with the DSP may require us to invest heavily in data security and compliance measures, such as implementing and complying with the Cybersecurity and Infrastructure Security Agency's guidelines and other burdensome recordkeeping, reporting, and auditing requirements. It may also require us to implement new processes, stop or restrict certain data transfers, alter the geographic scope of our operations, cease doing business with certain third parties or using certain tools or vendors, or change how data flows throughout our business, any of which could materially impact our business operations or hinder our ability to grow our business. Finally, non-compliance with the DSP could result in significant civil or criminal penalties, which could materially adversely affect our business, results of operations, and financial condition.

We may in the future be subject to the European Union General Data Protection Regulation and the United Kingdom General Data Protection Regulation, or, together, the GDPR. The GDPR, together with national legislation, regulations and guidelines of the European Economic Area, or EEA, member states and the UK governing the processing of personal data, impose comprehensive data privacy compliance obligations in relation to our collection, processing, sharing, disclosure, transfer and other use of data relating to an identifiable living individual or "personal data", including a principle of accountability and the obligation to demonstrate compliance through policies, procedures, training and audit, as well as regulating cross-border transfers of personal data out of the EEA and the UK. Companies that are subject to the GDPR face compliance obligations and risk, including regulatory enforcement and potential fines for noncompliance of up to £17.5 million (€20 million) or 4% of the annual global revenues of the noncompliant company, whichever is greater.

Among other requirements, the GDPR regulates transfers of personal data subject to the GDPR to third countries that have not been found to provide adequate protection to such personal data, including the United States, and the efficacy and longevity of current transfer mechanisms between the EEA, and the United States remains uncertain. Case law from the Court of Justice of the European Union, or

the CJEU, states that reliance on the standard contractual clauses—a standard form of contract approved by the European Commission as an adequate personal data transfer mechanism—alone may not necessarily be sufficient in all circumstances and that transfers must be assessed on a case-by-case basis. We expect the existing legal complexity and uncertainty regarding international personal data transfers to continue, and international transfers to the United States, China, and to other jurisdictions more generally to continue to be subject to enhanced scrutiny by regulators. As the regulatory guidance and enforcement landscape in relation to data transfers continue to develop, we could suffer additional costs, complaints and/or regulatory investigations or fines, and/or if we are otherwise unable to transfer personal data between and among countries and regions in which we operate, we may have to stop using certain tools and vendors and make other operational changes; we may have to implement alternative data transfer mechanisms under the GDPR and/ or take additional compliance and operational measures; and/or it could otherwise affect the manner in which we operate our business, and could adversely affect our business, operations and financial condition.

We may be subject to data privacy and similar laws in China. China's Personal Information Protection Law, or the PIPL, imposes various requirements on the collection, use processing, sharing and transfer of personal information. The PIPL also sets out data localization requirements for critical information infrastructure operators and personal information processors who process personal information above a certain threshold prescribed by the relevant authorities, unless a security assessment is passed. The PIPL also requires data processors to rely on a data export mechanism and comply with certain requirements prior to the transfer of personal information outside of China, such as compliance with a security assessment, or the Security Assessment, or certification by an agency designated by the relevant authorities, or Certification, or entering into standard form model contracts approved by the relevant authorities, or SCCs, with the overseas recipient, unless an exemption under the Provisions for Promoting and Regulating Cross-Border Data Flows , or the Provisions, applies, such as the transfer being necessary for the performance of a contract which the individual is a party to or necessary for cross-border HR management or the number of individuals' whose personal information is transferred is less than 100,000 since January 1st of the current year. According to the Provisions published by the CAC on March 22, 2024, a data processor must apply for the Security Assessment organized by the CAC under any of the following circumstances and receive an approval from the relevant authorities before the information may be transferred outside of the PRC: (i) where a data processor or a critical information infrastructure operator, or CIIO, provides important data overseas, (ii) where a CIIO transfers personal information overseas (unless an exemption applies) or (iii) where a personal information processor either transfers more than 1 million individuals' personal information or more than 10,000 individuals' sensitive personal information overseas since January 1st of the current year, in each case unless an exemption applies. Additionally, a data processor must enter into the SCCs with the overseas recipient and file this with the local CAC within 10 working days of the contract's effective date or obtain a Certification before transferring information overseas if the data processor either transfers more than 100,000 but less than 1 million individuals' personal information or transfers less than 10,000 individuals' sensitive personal information since January 1st of the current year, unless an exemption applies.

Our business involves cross-border data transfers from or into China, such as the access of certain PRC patient-level information from overseas. We have signed the SCCs regarding certain cross-border data flows and this has been filed with the local CAC. We expect that we have complied with such filing requirements. However, it is possible for the competent PRC government authorities to take a contrary position or adopt different interpretations on the SCCs, in which case we may become subject to penalties or other liabilities under the applicable CAC regulations in relation to our handling of the cross-border transfers.

Failure to comply with PIPL can result in fines of up to RMB 50 million or 5% of the prior year's total annual revenue for the personal information processor and/or a suspension of services or data processing activities. Other potential penalties include a fine of up to RMB 1 million on the person in charge or directly responsible personnel and, in serious cases, individuals and entities may be exposed to criminal liabilities under other local Chinese law, such as the Criminal Law of the People's Republic of China, thus going beyond the penalties imposed under the GDPR. The PIPL also prohibits responsible personnel for violations of the PIPL from holding high level management or data protection officer positions in relevant enterprises.

It is also generally unclear how the laws will be interpreted and enforced in practice by the relevant government authorities as the PIPL and its implementing regulations and measures are drafted broadly, thus leaving great discretion to the relevant government authorities to exercise. As such, our compliance approach towards the PIPL may be subject to further change and we may need to expend significant time and resources in re-evaluating our internal compliance framework to comply with the PIPL.

Compliance with U.S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, store, use, transfer, disclose and otherwise process data, update our data privacy and security policies and procedures, or in some cases, impact our ability to operate in certain jurisdictions. Failure by us or our collaborators and our service providers to comply with U.S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and/or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose such information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations,

even if we are not found liable, could be expensive and time-consuming to defend, could result in adverse publicity and adversely affect our business, financial condition, results of operations and prospects.

Our information technology systems, or those of any of our third-party service providers, may fail or suffer security incidents, breaches, or compromises and other disruptions, which could result in a material disruption of our development programs, compromise sensitive information related to our business or prevent us from accessing critical information, potentially exposing us to liability or otherwise adversely affecting our business.

In the ordinary course of business, we and our third-party service providers collect, store and transmit confidential information (including but not limited to intellectual property, proprietary and confidential business information and personal information). We face numerous and evolving cybersecurity risks that threaten the confidentiality, integrity and availability of our systems and confidential information. Our information technology systems and those of our third-party service providers, strategic partners and other contractors or consultants are vulnerable to attack, damage and interruption from computer viruses and malware (e.g. ransomware), malicious code embedded in open-source software, misconfigurations, "bugs" or other vulnerabilities in commercial software that is integrated into our (or our third-party service providers') systems, products or services, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation-state and nation-state-supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization. In addition, attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. Furthermore, because the techniques (including artificial intelligence) used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we may be unable to anticipate these techniques or implement adequate preventative measures. Any integration of artificial intelligence in our or any third party's operations, products or services is also expected to pose new or unknown cybersecurity risks and challenges. We may also experience security incidents that may remain undetected for an extended period. Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. There can also be no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our IT Systems and Confidential Information.

We and certain of our service providers are from time to time subject to cyberattacks and incidents, and we expect such attacks and incidents to continue in varying degrees. While we do not believe that we have experienced any material system failure, accident or security breach to date, we cannot guarantee that material incidents will not occur in the future. For example, the loss of clinical trial data from clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We also currently rely on a third party to manufacture our product candidates, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any actual or perceived disruption or security incident affects our systems (or those of our third-party service providers) or were to result in a loss of or accidental, unlawful or unauthorized access to, use of, release of, or other processing of personally identifiable information, or damage to, our confidential or proprietary data or applications, or inappropriate disclosure of confidential or proprietary information, it could result in legal claims or proceedings (such as class actions), regulatory investigations and enforcement actions, the further development and commercialization of any of our current or future product candidates could be delayed, negative reputational impacts that cause us to lose existing or future customers, significant incident response, system restoration or remediation and future compliance costs, and we could be subject to significant fines, penalties or liabilities for any noncompliance to certain privacy and security laws. Any or all of the foregoing could materially adversely affect our business, operating results, and financial condition.

We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors may or could have access to our confidential information. If our third-party vendors fail to protect their information technology systems and our confidential and proprietary information, we may be vulnerable to disruptions in service and unauthorized access to our confidential or proprietary information and we could incur liability and reputational damage. If the information technology systems of our third-party vendors and other contractors and consultants become subject to disruptions or security breaches, incidents, or compromises, 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. Some of the federal, state and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular categories of personally identifiable information, which could result from incidents experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. Although we currently hold cybersecurity insurance, the costs related to significant security breaches or disruptions could be material and cause us to incur significant expenses and we cannot guarantee that any costs and liabilities incurred in relation to an attack or incident will be covered by our existing insurance policies or that such

insurance will continue to be available on acceptable terms or in amounts sufficient to cover the potentially significant losses that may result for a security incident or breach.

Our business could be affected by litigation, government investigations and enforcement actions.

We currently operate in a number of jurisdictions in a highly regulated industry and we could be subject to litigation, government investigation and enforcement actions on a variety of matters in the United States or foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, environmental, whistleblower, false claims, privacy, anti-kickback, anti-bribery, securities, commercial, employment and other claims and legal proceedings that may arise from conducting our business. Any determination that our operations or activities are not in compliance with existing laws or regulations could result in the imposition of fines, civil and criminal penalties, exclusion from participation in government-funded healthcare programs, such as Medicare and Medicaid, equitable remedies, including disgorgement, injunctive relief and/or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations.

Legal proceedings, government investigations and enforcement actions can be expensive and time-consuming. An adverse outcome resulting from any such proceedings, investigations or enforcement actions could result in significant damages awards, fines, penalties, exclusion from the federal healthcare programs, healthcare debarment, injunctive relief, product recalls, reputational damage and modifications of our business practices, which could have a material adverse effect on our business, financial condition, results of operations and prospects. Even if such a proceeding, investigation or enforcement action is ultimately decided in our favor, the investigation and defense thereof could require substantial financial and management resources.

Risks Related to Our Intellectual Property

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

We rely, and may in the future rely, upon a combination of patent, trade secret and know-how for any of our current and future product candidates, and proprietary technologies to prevent third parties from exploiting our achievements, thus eroding our competitive position in our market. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property and proprietary information. Our success depends in large part on our ability to obtain, maintain, expand, enforce, and defend the scope, ownership or control, validity and enforceability of our intellectual property protection in the United States and other countries with respect to any of our current and future product candidates and other proprietary technologies we may develop. We generally seek, and may in the future seek, to protect our proprietary position, in part, by filing patent applications in the United States and abroad relating to any of our current and future product candidates and technology, manufacturing processes and methods of use. We may also seek to protect our proprietary position by acquiring or further in-licensing relevant issued patents or pending patent applications from third parties. We will endeavor to seek additional patent protection to cover proprietary features of our product candidates and novel discoveries that are important to our business. Many of our in-licensed patent families were initially drafted, filed, and prosecuted by our licensor, Hengrui, and even where we now control the right to prosecution of such in-licensed patent families, we are and may in the future be required to solicit input and consider comments from Hengrui. Our control of prosecution for such in-licensed patent families is also limited to our territory and Hengrui still controls prosecution outside our territory. Hengrui could potentially make arguments or amendments in their territory that affect the scope or value of our in-licensed patent families in our territory. Additionally, some of our patent families are in an early stage of prosecution and cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents are issued from such applications, and then only to the extent the issued claims cover the third parties' activities. If we are unable to obtain, maintain, expand, enforce and defend the scope, ownership or control, validity and enforceability of our intellectual property protection, our business, financial condition, results of operations and prospects could be materially harmed.

Changes in either the patent laws or their interpretation in the United States and other jurisdictions may diminish our ability to protect our intellectual property, obtain, maintain, expand, enforce and defend our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our protection. We cannot predict whether the patent applications we currently or may in the future pursue or may in-license will issue as patents in any particular jurisdiction, whether the claims of any issued patents will provide sufficient protection against competitors or other third parties, or if these patents are challenged by our competitors, whether the patents will be found to be invalid, unenforceable, or not infringed or not owned or controlled by us. The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, defend or license all necessary or desirable patent applications or patents at a reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we or our current or future licensors will fail, or previously failed, to identify patentable aspects of research and

development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, licensees, third-party collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Consequently, we may not be able to prevent any third party from using any of our technology that is in the public domain to compete with any of our current or future product candidates or technologies. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable in light of the prior art. Furthermore, 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 or our licensors were the first to invent the inventions claimed in any of our owned or licensed patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. If a third party can establish that we or our licensors were not the first to invent or the first to file for patent protection of such inventions, our patents and patent applications may not issue as patents and even if issued, may be challenged and invalidated or rendered unenforceable.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. In particular, the patent position of obesity treatments is particularly uncertain given a significant amount of competition centered around certain specific chemical scaffolds and mechanisms of action, including certain of those associated with our product candidates. As a result, the issuance, scope, validity, enforceability, and commercial value of our owned and in-licensed patent rights are highly uncertain. Our current and future patent applications may not result in patents being issued.

Further, even if patents are granted, they may not afford sufficient protection of any of our current or future product candidates or their intended uses against competitors, nor can there be any assurance that the issued patents cannot be designed around, invalidated by third parties, or effectively prevent others from commercializing any of our current or future product candidates. Furthermore, even if granted, the resulting patents may be difficult to enforce. Obtaining and maintaining our owned and in-licensed patent protection depends on compliance with various procedural, document submission, information disclosure, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements. If we experience noncompliance events that cannot be corrected and we lose our patent rights, competitors could enter the market, which would have a material adverse effect on our business. Further, any issued patents that we own or license or may own or license in the future covering any of our current or future product candidates could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or other countries, including the U.S. Patent and Trademark Office, or USPTO. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of written description or non-enablement. In addition, patent validity challenges may, under certain circumstances, be based upon non-statutory obviousness-type double patenting, which, if successful, could result in a finding that the claims are invalid for obviousness-type double patenting. In certain circumstances, the finding could be cured by filing a retroactive terminal disclaimer over unexpired reference patent(s), which would result in a reduction of patent term, including a reduction or loss of a patent term adjustment granted by the USPTO. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution. Also, patent terms, including any extensions or adjustments that may or may not be available to us, may not protect our competitive position on any of our current or future product candidates for an adequate amount of time, and we may be subject to claims challenging the inventorship, ownership, validity, enforceability of our owned or in-licensed patents and/or other intellectual property. Changes in U.S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect any of our current or future product candidates. Further, if we encounter delays in our development and testing, clinical trials or regulatory review and approval of any of our current or future product candidates, the period of time during which we could market such product candidates under patent protection may be reduced (i.e., patents protecting such product candidates might expire before or shortly after such product candidates are commercialized). Thus, our owned and in-licensed patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or afford us any meaningful competitive advantage.

Moreover, the claim coverage in a patent application can be significantly reduced before the corresponding patent is granted. Even if patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Any patents issuing from our owned and in-licensed patent applications may be challenged, narrowed, circumvented or invalidated by third parties. Consequently, we do not know whether any of our current or future product candidates and other proprietary technology will be protectable or remain protected by valid and enforceable patents. Even if a patent is granted, our competitors or other third parties may be able to circumvent the patent by developing similar or alternative technologies or products in a non-infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects. Furthermore, our competitors or other third parties may avail themselves of safe harbors under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments, to conduct research and clinical trials.

The issuance of a patent is not conclusive as to its inventorship, ownership, scope, validity, or enforceability, and our patent rights may be challenged in the courts or patent offices in the United States and abroad. We may be subject to post-grant proceedings at the USPTO challenging the validity of one or more claims of our owned and in-licensed patents. Third-party submissions may also be made prior to a patent's issuance, precluding the granting of a patent based on our pending patent application. A third party may also claim that our owned and in-licensed patent rights are invalid or unenforceable in a litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In addition, we may become involved in opposition, derivation, revocation, reexamination, reissue, interference, inter partes review, post-grant review proceedings or other similar proceedings in the United States and/or foreign jurisdictions challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, and may allow third parties, including generic drug companies, to commercialize any of our current or future product candidates and use any other proprietary technologies we may develop to compete directly with us.

Moreover, some of our owned and in-licensed patent rights may in the future be co-owned with third parties. In the United States, each co-owner has the freedom to license and exploit the technology. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patent rights, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of such patent rights in order to enforce such patent rights against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

If we or our licensors fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our current or future licensors, or if any of our material license agreements are terminated, we could lose our rights to key intellectual property and components enabling our technologies.

Our rights to our product candidates are subject to the licenses and other terms and conditions of the Hengrui License Agreement, and thus our commercial success will heavily depend on the maintenance of the Hengrui License Agreement. If, for any reason, the Hengrui License Agreement is terminated or we otherwise lose our rights under such agreement, it would adversely affect our business. The Hengrui License Agreement imposes, and future agreements may impose, various development, diligence, commercialization, milestone payment, royalty and other obligations on us, such as the requirement to meet development timelines or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the licenses. If we materially breach any of our obligations under the Hengrui License Agreement, Hengrui may terminate the Hengrui License Agreement, which would have a material adverse effect on us.

The Hengrui License Agreement is complex, and certain provisions may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology or increase what we believe to be our financial or other obligations under the Hengrui License Agreement, which could have a material adverse effect on our business, financial condition, results of operations, and prospects. For example, disputes may arise regarding the payment of the royalties or other payments due to Hengrui in connection with the rights we license from them. Hengrui may contest the basis of such payments, including the royalties we retained and claim that we are obligated to make payments under a broader basis. In addition, disputes may arise between us and our current or future licensors regarding intellectual property subject to a license 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, misappropriate or otherwise violate intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our right to transfer or assign the license;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- our financial or other obligations under the license agreement;
- the priority of invention of patented technology; and
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our current or future licensors and us and our partners.

Such disputes may be costly to resolve and may divert management's attention away from day-to-day activities. In addition to the costs of any litigation we may face, any legal action against us could increase our payment obligations under the respective agreement and require us to pay interest and potentially damages to such licensors. If disputes over intellectual property that we have licensed, or license

in the future, prevent or impair our ability to maintain our licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Despite our best efforts, our current or future licensors might conclude that we materially breached our license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products, if approved, and technology covered by the license agreements. Such termination would result in the ability of the prior licensor to assert the prior licensed patents against us, or the prior licensor could license the patents to a competitor who could assert the prior licensed patents against us. As a result, we may be required to cease our development, manufacture and commercialization of our product candidates and use of our proprietary technologies covered by the patent rights owned by the licensors, which could have a material adverse effect on us. Alternatively, the prior licensor could abandon the patent rights, which would reduce the barrier to entry into the market. If these in-licenses are terminated, or if the licensed patents fail to provide the intended exclusivity, and if competitors circumvent any regulatory exclusivity, competitors would have the freedom to market products identical to ours. These events could have a material adverse effect on our competitive position, business, financial condition, results of operations, and prospects.

Termination of the agreements or reduction or elimination of our rights under the agreements may result in our having to negotiate new or reinstated agreements with less favorable terms or cause us to lose our rights under these agreements, including our rights to important intellectual property or technology. For example, we may agree to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects, and we may be required to identify and license replacement technology from third parties, which may not be available on reasonable terms, if at all.

Further development of our proprietary technology and product candidates may require us to enter into additional license or collaboration agreements. Our future licenses may not provide us with exclusive rights to use the licensed intellectual property and technology, or may not provide us with exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our product candidates and proprietary technology in the future.

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

Filing, prosecuting, maintaining, enforcing and defending patents on any of our current or future product candidates in all countries throughout the world is expensive, and the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. Prosecution of foreign patent applications is often a longer process, and patents may grant at a later date, and with a shorter term, than in the United States. The requirements for patentability differ in certain jurisdictions and countries. Additionally, the patent laws of some countries do not afford intellectual property protection to the same extent as the laws of the United States. For example, other countries may impose substantial restrictions on the scope of claims, including limiting patent protection to specifically disclosed embodiments. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our intellectual property in and into the United States or other jurisdictions. Competitors may use our intellectual property in jurisdictions where we have not pursued and obtained patent protection to develop their own products and, further, may export infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products, and our owned and in-licensed patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets and other intellectual property protection, particularly those relating to biopharmaceutical products, which could make it difficult for us to stop the infringement of our owned and in-licensed patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. In addition, some jurisdictions, such as Europe, Japan, and Korea, may have a heightened standard for patentability than in the United States, including, for example, the requirement of claims having literal support in the original patent filing and the limitation on using supporting data that is not in the original patent filing. Under those heightened patentability requirements, we may not be able to obtain sufficient patent protection in certain jurisdictions even though the same or similar patent protection can be secured in the United States and other jurisdictions.

Proceedings to enforce our owned and in-licensed intellectual property and proprietary rights in the United States or other jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents and any patents we may own or license in the future at risk of being invalidated or interpreted narrowly, could put our owned and in-licensed patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our owned and in-licensed intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop.

Many countries have compulsory licensing laws under which a patent owner or exclusive licensee may be compelled to grant licenses to third parties, including governmental agencies. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner or exclusive licensee may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. In addition, geopolitical actions in the United States and in foreign countries (such as the Russia and Ukraine conflict) could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any current or future licensors and the maintenance, enforcement or defense of our issued patents which could impair our competitive intellectual property position.

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

The USPTO and various non-U.S. government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In some circumstances, we may be dependent on our current or future licensors to take the necessary action to comply with these requirements with respect to any licensed intellectual property. For example, periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our owned and in-licensed patents and applications. In certain circumstances, we may rely on licensing partners to pay these fees due to the U.S. and non-U.S. patent agencies. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non-compliance can cause abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

The USPTO and various non-U.S. government agencies require compliance with certain foreign filing requirements during the patent application process. For example, in some countries, including the United States, China, India and some European countries, a foreign filing license is required before certain patent applications are filed. The foreign filing license requirements vary by country and depend on various factors, including where the inventive activity occurred, citizenship status of the inventors, the residency of the inventors and the invention owner, the place of business for the invention owner and the nature of the subject matter to be disclosed (e.g., items related to national security or national defense). In some, but not all cases, for example in China and India, a foreign filing license cannot be obtained retroactively in accordance with the applicable rules. There are situations, however, in which non-compliance can result in abandonment of a pending patent application or can be grounds for revoking or invalidating an issued patent, resulting in the loss of patent rights in the relevant jurisdiction. Non-compliance events that could result in abandonment or lapse of a patent or patent application include, 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. In such an event, potential competitors might be able to enter the relevant markets with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations and prospects. We may also be dependent on our current or future licensors to take the necessary actions to comply with these requirements with respect to intellectual property that we license.

Public health pandemics (such as the COVID-19 pandemic), geopolitical instability (war and terrorism), natural disasters, or similar events may impair our and our current or future licensors' ability to comply with these procedural, document submission, fee payment, and other requirements imposed by government patent agencies, which may materially and adversely affect our ability to obtain or maintain patent protection for any of our current and future product candidates.

Changes in patent laws or their interpretations could diminish the value of patents in general, thereby impairing our ability to protect our products.

Changes in either the patent laws or interpretation of the patent laws in the United States or in other countries could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us or our current or future licensors could therefore be awarded a patent covering an invention of ours or our licensors even if we or our licensors had made the invention before it was made by such third party. This requires us to be cognizant of the time from invention to filing of a patent application. Since patent

applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our current or future licensors are the first to either (i) file any patent application related to any of our current or future product candidates and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our patents or patent applications.

The America Invents Act also included a number of significant changes that affect the way patent applications are prosecuted and also affect patent litigation. These include allowing third party protests and submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO-administered post-grant proceedings, including post-grant review, inter partes review and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims or any patent claims we may license in the future that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. We cannot predict how decisions by the courts, the U.S. Congress or the USPTO may impact the value of our owned and in-licensed patent rights. For example, the U.S. Supreme Court held in Amgen v. Sanofi (2023) that a functionally claimed genus was invalid for failing to comply with the enablement requirement of the Patent Act. As such, our owned and in-licensed patent rights with functional claims may be vulnerable to third party challenges seeking to invalidate these claims for lacking enablement or adequate support in the specification. Depending on future actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future. In addition to heightened patentability requirements, the Supreme Court and Federal Circuit's interpretation of biosimilar product approval under the BPCIA, has evolved in recent years, affecting the "patent dance" provisions of the statute, which are intended to resolve any patent infringement issues before the approval of a biosimilar. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have or may obtain or license in the future.

In 2012, the European Union Patent Package, or EU Patent Package, regulations were passed with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court, or UPC, for litigation involving European patents. The EU Patent Package was implemented on June 1, 2023. As a result, all European patents, including those issued prior to ratification of the EU Patent Package, now by default automatically fall under the jurisdiction of the UPC, unless otherwise opted out. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries. Our European patents and patent applications, if issued, could be challenged in the UPC. During the first seven years of the UPC's existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We may decide to opt out our future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents and allow for the possibility of a competitor to obtain a pan-European injunction. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and any of our current and future product candidates due to increased competition and, resultantly, on our business, financial condition, results of operations and prospects. The UPC and Unitary Patent are significant changes in European patent practice. As the UPC is a new court system, there is limited precedent for the court, increasing the uncertainty of any litigation in the UPC.

Issued patents covering any of our current or future product candidates could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad.

Our owned and licensed patent rights may be subject to priority, validity, inventorship, ownership and enforceability disputes. Legal proceedings relating to intellectual property claims, with or without merit, are unpredictable and generally expensive and time-consuming and likely to divert significant resources from our core business, including distracting our management and scientific personnel from their normal responsibilities and generally harm our business. If we or any of our current or future licensors are unsuccessful in any of these proceedings, such patents and patent applications may be narrowed, invalidated or held unenforceable. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we initiate legal proceedings against a third party to enforce a patent covering any of our current or future product candidates, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could include an alleged failure

to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, lack of sufficient written description, failure to claim patent-eligible subject matter or obviousness-type double patenting. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading or inconsistent statement, during prosecution. Third parties may raise claims challenging the validity or enforceability of a patent before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, shortening the term of or amendment to our owned or in-licensed patent rights or any patent rights we may obtain or license in the future in such a way that they no longer cover any of our current or future product candidates or prevent third parties from competing with our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection for any of our current or future product candidates. 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 owned and in-licensed patent claims do not cover the invention, or decide that the other party's use of our patented technology falls under the safe harbor to patent infringement under 35 U.S.C. § 271(e). Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional or international patent application filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering any of our current or future product candidates are obtained, once the patent has expired, we may be vulnerable to competition from competitive products, including generics. Given the amount of time required for the development, testing and regulatory review of any of our current or future product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to our product candidates. If we do not have sufficient patent life to protect our products, our business, financial condition, results of operations and prospects will be adversely affected.

If we do not obtain additional protection under the Hatch-Waxman Amendments and similar foreign legislation extending the terms of our licensed patents and any future patents we may own, our business, financial condition and results of operations may be materially and adversely affected.

Depending upon the timing, duration and specifics of FDA regulatory approval for our drug candidates, one or more of our licensed U.S. patents or future U.S. patents that we may license or own may be eligible for limited patent term restoration under the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during drug development and the FDA regulatory review process. This period is generally one-half the time between the effective date of an investigational new drug application (falling after issuance of the patent), and the submission date of an NDA, plus the time between the submission date of an NDA and the approval of that application. Patent term restorations, however, cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval by the FDA, only one patent may be extended, and only claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. The application for patent term extension is subject to approval by the USPTO, in conjunction with the FDA. We may not be granted an extension because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request, including due to failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or failing to satisfy other applicable requirements. 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 will have the right to exclusively market our product will be shortened and our competitors may obtain earlier approval of competing products, and our ability to generate revenues could be materially adversely affected.

We or our current or future licensors may be subject to claims challenging the inventorship or ownership of our owned and in-licensed patents and other intellectual property.

We or our current or future licensors may be subject to claims that former employees, consultants, licensees, collaborators or other third parties have an interest in our owned or in-licensed patent rights, trade secrets, or other intellectual property as an inventor, co-inventor or owner of trade secrets. For example, we or our current or future licensors may have inventorship or ownership disputes arise from

conflicting obligations of consultants or others who are involved in developing any of our current or future product candidates and other proprietary technologies we may develop. We or our current or future licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as from a government entity, such that we or our current or future licensors are not the sole and exclusive owners of the patents we in-licensed. The failure to name the proper inventors on a patent application can result in the patents issuing therefrom being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership of our owned or in-licensed patent rights, trade secrets or other intellectual property. If we or our current or future licensors fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as ownership of, or the right to use intellectual property that is important to any of our current or future product candidates and other proprietary technologies we may develop. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

If we are unable to protect the confidentiality of our and current or future licensors' trade secrets, our business and competitive position would be harmed.

In addition to seeking patent protection for any of our current or future product candidates and proprietary technologies, we may rely on trade secret protection and confidentiality agreements to protect our unpatented know-how, technology, and other proprietary information and to maintain our competitive position. We seek to protect these trade secrets and other proprietary technology, in part, by entering into non-disclosure and confidentiality agreements with parties who have access to them, such as our employees, licensees, third-party collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Trade secrets and know-how can be difficult to protect. We cannot guarantee that we have entered into applicable agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. We cannot guarantee that any potential trade secrets and other proprietary and confidential information will not be disclosed or that competitors will not otherwise gain access to trade secrets. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret (such as through a cybersecurity breach) is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. Furthermore, others may independently discover similar trade secrets and proprietary information. If any of our trade secrets were to be disclosed or misappropriated or if any such information were to be independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed. Additionally, we may need to share our proprietary information, including trade secrets, with future business partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors.

We may be subject to claims that third parties have an ownership interest in our trade secrets. For example, we may have disputes arise from conflicting obligations of our employees, consultants or others who are involved in developing any of our current or future product candidates. Litigation may be necessary to defend against these and other claims challenging ownership of our trade secrets. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable trade secret rights, such as exclusive ownership of, or right to use, trade secrets that are important to any of our current or future product candidates and other proprietary technologies we may develop. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may be subject to claims that our employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Some of our employees, consultants and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors 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 individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer, or that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending

against such claims, litigation could result in substantial costs and be a distraction to our management. In addition, while it is our policy to require our employees and contractors who may be involved in the conception or 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, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market any of our current or future product candidates.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are or will be complete or thorough, nor can we be certain that we have identified or will identify each and every third-party patent and pending patent application in the United States and abroad that is relevant to or necessary for the commercialization of any of our current or future product candidates in any jurisdiction. Patent applications in the United States and elsewhere are not published until approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering any of our current or future product candidates could have been filed by others without our knowledge. The scope of a patent claim is determined by the interpretation of the law, the words of a patent claim, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending patent application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that any of our current or future product candidates are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Alternatively, we may incorrectly determine that the Hatch-Waxman Amendments are a defense for a safe harbor to infringement of a patent we consider relevant to the research or clinical development of any of our current or future product candidates. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and we may incorrectly conclude that a third-party patent is invalid and unenforceable or not infringed. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market any of our current or future product candidates. If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. As the number of competitors in the market grows and the number of patents issued in this area increases, the possibility of patent infringement claims escalates. Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," have purchased patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or "invitations to license," or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing any of our current or future product candidates that are held to be infringing. We might, if possible, also be forced to redesign any of our current or future product candidates or services so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Third-party claims of intellectual property infringement, misappropriation, or other violations against us or our collaborators could be expensive and time-consuming and may prevent or delay the development and commercialization of any of our current or future product candidates.

Our commercial success depends in part on our and our collaborators' ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation, inter partes review, post-grant review, and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions.

Numerous U.S. and foreign-issued patents and pending patent applications owned by third parties exist in the fields in which we plan to commercialize our programs (including obesity, weight loss and maintenance programs) and in which we are developing other proprietary technologies. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our programs and commercializing activities may give rise to claims of infringement of the patent rights of others. We cannot guarantee that our programs and other proprietary technologies we develop will not infringe existing or future patents owned by third parties. We may not be aware of patents that have already been issued for which a third party, such as a competitor in the fields in which we are developing our programs, might assert as infringed by us. It is also possible that patents owned by third parties of which we are aware, but which we do not believe we infringe or that we believe

we have valid defenses to any claims of patent infringement, could be found to be infringed by us. For example, we are aware of certain patent applications and patents in the United States and abroad owned by third parties with patent claims that, if valid and enforceable, may be relevant to safiglipron in the future. We are currently challenging one such granted patent by filing an opposition in the European Patent Office. Our opposition sets forth the grounds for invalidity of the current claims of the granted patent, although the ultimate outcome of the opposition remains uncertain. We may in the future challenge this and other patents or patent applications owned by third parties, including through opposition or other proceedings in the United States and abroad. It is not unusual that corresponding patents issued in different countries have different scopes of coverage, such that in one country a third-party patent does not pose a material risk, but in another country, the corresponding third-party patent may pose a material risk to any of our current or future product candidates. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that we may infringe. For example, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover any of our current or future product candidates or the use of any of our current or future product candidates.

If any third-party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, a court could hold that such patents are valid, enforceable and infringed by us. Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing the infringing products or technologies. In addition, we may be required to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties and/or redesign our infringing products or technologies, which may be impossible or require substantial time and monetary expenditure. Such licenses may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms or at all, we may be unable to commercialize the infringing products or technologies or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business. In addition, we have and may in the future pursue patent challenges with respect to third-party patents, including as a defense against the foregoing infringement claims. The outcome of such challenges is unpredictable.

Even if resolved in our favor, the foregoing proceedings could be very expensive, particularly for a company of our size, and time-consuming. Such proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such proceedings adequately. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Such proceedings may also absorb significant time of our technical and management personnel and distract them from their normal responsibilities. Uncertainties resulting from such proceedings could impair our ability to compete in the marketplace. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects.

We may in the future pursue invalidity proceedings with respect to third-party patents. The outcome following legal assertions of invalidity is unpredictable. Even if resolved in our favor, these legal proceedings may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such proceedings adequately. Some of these third parties may be able to sustain the costs of such proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent proceedings could compromise our ability to compete in the marketplace. If we do not prevail in the patent proceedings the third parties may assert a claim of patent infringement directed at any of our current or future product candidates.

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

Third parties, such as competitors, may infringe our owned or in-licensed patent rights. In an infringement proceeding, a court may decide that a patent we own or license is invalid or unenforceable or may refuse to stop the other party from using the invention at issue. In addition, our owned or in-licensed patent rights may become involved in inventorship, ownership, priority, enforceability, or validity disputes. To counter or defend against such claims can be expensive and time-consuming. An adverse result in any litigation proceeding

could put our patent rights at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation and proceedings, there is a risk that some of our confidential information could be compromised by disclosure during such litigation and proceedings.

Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

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

Our registered or unregistered trademarks or trade names may be challenged, infringed, diluted, circumvented or declared generic or determined to be infringing, misappropriating or violating other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in the markets of interest. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we are given an opportunity to respond to such rejections, we may be unable to overcome them. If our trademarks are successfully challenged or determined to be infringing, misappropriating or violating other marks, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. In addition, at the USPTO and comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, which may not survive such proceedings. Moreover, any name we may propose to use with any of our current or future product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA or an equivalent administrative body in a foreign jurisdiction objects to any of our proposed proprietary product names, we may be required to expend significant additional resources to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe, misappropriate or otherwise violate the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

We may not be able to obtain, protect or enforce our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement, misappropriation, dilution or other claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to obtain, enforce or protect our proprietary rights related to trademarks, trade names, domain name, or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

Intellectual property rights do not necessarily address all potential threats.

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

- others may be able to make products that are similar to any of our current or future product candidates or utilize similar technology but that are not covered by the claims of the patents that we own or license or may own or license in the future;
- we or our current or future licensors or collaborators might not have been the first to make the inventions covered by our current or future patent applications;
- we or our current or future licensors or collaborators might not have been the first to file patent applications covering our or their 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 and future patent applications that we own or license will not lead to issued patents;
- any issued patent that we currently own or license or may own or license in the future may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties;
- others may have access to the same intellectual property rights licensed to us in the future on a non-exclusive basis;
- our competitors or other third parties might conduct research and development activities in countries where we or our current or future licensors 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;
- we may not develop additional proprietary technologies that are patentable;
- we may fail to identify potential patentable subject matter and/or may fail to file on it;
- the patents or other intellectual property rights of others may harm our business; and
- we may choose not to file for patent protection to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property or disclose information resulting in a loss of protection for such trade secret.

Should any of the foregoing occur, it could adversely affect our business, financial condition, results of operations and prospects.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through future acquisitions and in-licenses.

The growth of our business may depend in part on our ability to acquire, in-license or use third-party intellectual property and proprietary rights. For example, any of our current or future product candidates may require specific formulations, delivery devices, or dosing regimens to work effectively and efficiently, we may need to use specific synthetic methods, intermediates or other reagents to efficiently manufacture our current or future product candidates, we may develop product candidates containing our compounds and pre-existing pharmaceutical compounds, we may develop combination therapies with our compounds and third-party compounds, any of which could require us to obtain rights to use intellectual property held by third parties. In addition, with respect to any patent or other intellectual property rights we may co-own with third parties, we may require licenses to such co-owners' interest to such patents. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. In addition, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. Were that to happen, we may need to cease use of the compositions or methods covered by those third-party intellectual property rights and may need to seek to develop alternative approaches that do not infringe, misappropriate or otherwise violate those intellectual property rights, which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we can obtain a license, it may be non-exclusive, which means that our competitors may also receive access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Additionally, we may collaborate with academic institutions to accelerate our research and development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration. Even if we hold such an option, we may be unable to negotiate a license from the institution within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. Even if we can obtain a license, it may be non-exclusive, and our competitors may also receive access to the same technologies licensed to us.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies that may be more established or have greater resources than we do may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive to commercialize any of our current or future product candidates. More established companies may have a competitive advantage over us due to their size, cash resources or greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. There can be no assurance that we will be able to successfully complete these types of negotiations and ultimately acquire the rights to the intellectual property surrounding any of our current or future product candidates that we may seek to develop or market. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of certain programs and our business, financial condition, results of operations, and prospects could suffer."

Risks Related to Ownership of Our Common Stock

An active, liquid and orderly market for our common stock may not develop, or we may in the future fail to satisfy the continued listing requirements of Nasdaq, and you may not be able to resell your common stock at a price that you consider reasonable.

An active trading market for our common stock may not develop or may not be sustained. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses or technologies using our shares as consideration, which, in turn, could materially adversely affect our business.

If we fail to satisfy the continued listing requirements of Nasdaq, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with the listing requirements of Nasdaq.

The trading price of the shares of our common stock could be highly volatile, and purchasers of our common stock could incur substantial losses.

Our stock price is likely to be volatile. The stock market in general and the market for stock of biopharmaceutical 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, investors may not be able to sell their common stock at a price that you consider reasonable. The market price for our common stock may be influenced by those factors discussed in this "Risk Factors" section and many others, including:

- results of our clinical trials and nonclinical studies, and the results of trials of our competitors or those of other companies in our market sector;
- our ability to enroll patients in our future clinical trials;
- our ability to obtain and maintain regulatory approval of any of our current or future product candidates or additional indications thereof, or limitations to specific label indications or patient populations for their use, or changes or delays in the regulatory review process;
- regulatory or legal developments in the United States and foreign countries;
- changes in the structure of healthcare payment systems;
- the success or failure of our efforts to develop, acquire, or license any of our current or future product candidates;
- innovations, clinical trial results, product approvals and other developments regarding our competitors;
- announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, or capital commitments;
- manufacturing, supply, or distribution delays or shortages;
- any changes to our relationship with any manufacturers, suppliers, collaborators or other strategic partners;
- achievement of expected product sales and profitability;
- variations in our financial results or development timelines or those of companies that are perceived to be similar to us, including variations from expectations of securities analysts or investors;
- market conditions in the biopharmaceutical sector and issuance of securities analysts' reports or recommendations;
- trading volume of our common stock;
- an inability to obtain additional funding;
- sales of our stock by us, our insiders or our stockholders, as well as the anticipation of lock-up releases or expiration of market stand-off or lock-up agreements;
- general economic, industry, geopolitical and market conditions, such as military conflict or war, inflation and financial institution instability, or pandemic or epidemic disease outbreaks, many of which are beyond our control;
- additions or departures of senior management, directors or key personnel;

- intellectual property, product liability or other litigation against us or our inability to enforce our intellectual property;
- changes in our capital structure, such as future issuances of securities and the incurrence of additional debt; and
- changes in accounting standards, policies, guidelines, interpretations or principles.

In addition, in the past, stockholders have initiated class action lawsuits against biopharmaceutical companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs, divert our management's attention and resources and damage our reputation, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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

Our executive officers, directors and greater than 5% stockholders, if they choose to act together, will have the ability to significantly influence all matters submitted to our board of directors or stockholders for approval, including the appointment of our management, the election and removal of directors and approval of any significant transaction, as well as our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders.

We do not currently intend to pay dividends on our common stock, so any returns on your investment will be limited to the value of our common stock.

We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, any future debt agreements may preclude us from paying dividends. Any return to stockholders will therefore be limited to the appreciation of their stock. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares.

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

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur could significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity or equity-linked securities.

Our directors and executive officers and substantially all of our securityholders before our initial public offering entered into lock-up agreements in connection with our initial public offering pursuant to which they agreed, with limited exceptions, not to offer, sell or otherwise transfer or dispose of any of our securities, without the prior written consent of two of the representatives of the underwriters, during a period that expired at the close of business on October 13, 2026. As a result of the expiration of the lock-up period, substantially all of our outstanding shares of common stock are eligible for sale in the public market, unless held by one of our directors, executive officers or other affiliates, in which case the resale of those shares will be subject to volume limitations under Rule 144 under the Securities Act. Sales of these shares, or perceptions that they will be sold, could cause the trading price of our common stock to decline.

In addition, we have registered all shares of common stock that we may issue under our equity compensation plans. Such shares of common stock that are subject to outstanding options under our equity compensation plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules. If these additional shares of common stock are sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline.

Furthermore, certain shares of our common stock will be entitled to rights with respect to the registration of their shares under the Securities Act. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restriction under the Securities Act, except for shares held by affiliates, as defined in Rule 144 under the Securities Act. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock.

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

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, or JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the date of our initial public offering, or December 31, 2031. However, if certain events occur prior to the end of such five-year period, including if we become a "large accelerated filer",

as defined under the Exchange Act, our annual gross revenue exceeds $1.235 billion or we issue more than $1.0 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's discussion and analysis of financial condition and results of operations" disclosure;
- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley;
- an exemption from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on the consolidated financial statements;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

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

We have taken advantage of reduced reporting burdens in the Prospectus and in this Quarterly Report on Form 10-Q. In particular, in the Prospectus, we provided only two years of audited financial statements and did not include all of the executive compensation-related information that would be required if we were not an emerging growth company. In addition, in this Quarterly Report on Form 10-Q, we have taken advantage of some of the scaled disclosures permitted, such as excluding quantitative and qualitative disclosures about market risk that would be required if we were not a smaller reporting company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be reduced or more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have irrevocably elected to avail ourselves of this exemption and, therefore, we may not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. We intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404(b) of Sarbanes-Oxley.

Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management.

Our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could significantly reduce the value of our shares to a potential acquiror or delay or prevent changes in control or changes in our management without the consent of our board of directors. The provisions in our charter documents will include the following:

- a classified board of directors with three-year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors;
- no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates;
- the exclusive right of our board of directors, unless the board of directors grants such right to the stockholders, to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors;
- the required approval of at least 66-2/3% of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause;
- the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror;

- the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval;
- the required approval of at least 66-2/3% of the shares entitled to vote to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors;
- a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders;
- an exclusive forum provision providing that the Court of Chancery of the State of Delaware will be the exclusive forum for certain actions and proceedings;
- the requirement that a special meeting of stockholders may be called only by the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and
- advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror's own slate of directors or otherwise attempting to obtain control of us.

We are also subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders and that the federal district courts shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees or the underwriters or any offering giving rise to such claim.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided, that, this provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, our amended and restated certificate of incorporation will also provide that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. These choice of forum provisions may result in increased costs to stockholders to bring a claim, limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, and may generally have the effect of discouraging lawsuits against us and our directors, officers and other employees. By agreeing to this provision, however, stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the choice of forum provisions in our amended and restated 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 adversely affect our business and financial condition.

General Risk Factors

We will incur significant increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives.

As a public company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. We will be subject to the reporting requirements of the Exchange Act, which will require, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, Sarbanes-Oxley and rules subsequently adopted by the SEC and Nasdaq to implement provisions of Sarbanes-Oxley impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and certain corporate governance practices. Further, pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory "say-on-pay" voting requirements that will apply to us when we cease to be an emerging growth company. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate.

We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly. The increased costs will decrease our net income or increase our net loss, and may require us to reduce expenditures in other areas of our business. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain directors and officers liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to comply with these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

We are subject to U.S. and certain foreign export and import controls, sanctions, embargoes, anti-corruption laws and anti-money laundering laws and regulations. We could face criminal liability and other serious consequences for violations, which could harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, and various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Controls and anti-corruption and anti-money laundering laws and regulations, including the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act and other state and national anti-bribery and anti-money laundering laws in the countries in which we conduct activities. Anti-corruption laws are interpreted broadly and prohibit companies and their employees, agents, CROs, contractors and other collaborators and partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, improper payments or anything else of value to or from recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad if and when we enter a commercialization phase, and/or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, CROs, contractors and other collaborators and partners, even if we do not explicitly authorize or have actual knowledge of such activities, and any training or compliance programs or other initiatives we undertake to prevent such activities may not be effective.

Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences.

Furthermore, U.S. export control laws and economic sanctions prohibit the provision of certain products and services to countries, governments, and persons targeted by U.S. sanctions. U.S. sanctions that have been or may be imposed may impact our ability to continue activities at future clinical trial sites within regions covered by such sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and/or denial of certain export privileges. These export and import controls and economic sanctions could also adversely affect our supply chain.

We and any of our third-party manufacturers or suppliers may use potent chemical agents and hazardous materials, and any claims relating to improper handling, storage, or disposal of these materials could be time-consuming or costly.

We and any of our third-party manufacturers or suppliers and our current or any future collaborators may use biological materials, potent chemical agents and hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety of the environment. Our operations and the operations of our third-party manufacturers and suppliers also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, neither we or our third-party manufacturers and suppliers can eliminate the risk of accidental injury or contamination from these materials or wastes. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. In the event of contamination or injury at our, our manufacturers' or our suppliers' sites, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended. Although we maintain workers' compensation insurance for certain costs and expenses we may incur due to injuries to our employees resulting from work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for toxic tort claims that may be asserted against us in connection with the storage or disposal of biologic, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws and regulations, which have tended to become more stringent over time. These current or future laws and regulations may impair our

research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could materially adversely affect our business, financial condition, results of operations and prospects.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses.

Our operations and the operations of our manufacturers, suppliers, collaborators, CROs and clinical sites could be subject to earthquakes, power shortages, telecommunications or infrastructure failures, cybersecurity incidents, physical security breaches, water shortages, floods, hurricanes, typhoons, blizzards and other extreme weather conditions, fires, public health pandemics or epidemics and other natural or manmade disasters, geopolitical actions or business interruptions, for which we are predominantly self-insured. We rely on third-party manufacturers or suppliers in various countries to produce our current or future product candidates and its components and on CROs and clinical sites to conduct our clinical trials, and do not have a redundant source of supply for all components of any of our current or future product candidates. Our ability to obtain clinical or, if approved, commercial, supplies of any of our current or future product candidates could be disrupted if the operations of these suppliers were affected by a man-made or natural disaster, geopolitical action or other business interruption, and our ability to commence, conduct or complete our clinical trials in a timely manner could be similarly adversely affected by any of the foregoing. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

Unstable market and economic conditions and adverse developments with respect to financial institutions and associated liquidity risk may have serious adverse consequences on our business, financial condition and stock price.

From time to time, the global credit and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the conflicts between Russia and Ukraine and in the Middle East, terrorism or other geopolitical events. Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. In addition, in 2023 the closures of financial institutions and their placement into receivership with the FDIC created bank-specific and broader financial institution liquidity risk and concerns. Future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market-wide liquidity shortages, impair the ability of companies to access near-term working capital needs, and create additional market and economic uncertainty. There can be no assurance that future credit and financial market instability and a deterioration in confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, liquidity shortages, volatile business environment or continued unpredictable and unstable market conditions. If the equity and credit markets deteriorate, or if adverse developments are experienced by financial institutions, it may cause short-term liquidity risk and also make any necessary debt or equity financing more difficult, more costly, more onerous with respect to financial and operating covenants and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay, limit, reduce or abandon product development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves. In addition, there is a risk that one or more of our current service providers, financial institutions, manufacturers and other partners may be adversely affected by the foregoing risks, which could directly affect our ability to attain our operating goals on schedule and on budget.

If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

Pursuant to Section 404 of Sarbanes-Oxley, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with the second annual report following the completion of our initial public offering. When we are no longer an "emerging growth company" and do not otherwise qualify as a "smaller reporting company" under the SEC rules, our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for our management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we may need to upgrade our information technology systems; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline.

We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begins its Section 404 reviews, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, even if ultimately decided in our favor, it could result in substantial costs and a diversion of our management's attention and resources, which could harm our business.

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

Recent Sales of Unregistered Equity Securities

None.

Use of Proceeds from our Public Offering of Common Stock

On April 20, 2026, we completed the initial public offering of our common stock pursuant to which we issued and sold 44,921,875 shares of our common stock (inclusive of 5,859,375 shares pursuant to the full exercise of the underwriters' overallotment option) at a price to the public of $16.00 per share.

All shares issued and sold in the initial public offering were registered under the Securities Act pursuant to a Registration Statement on Form S-1 (File No. 333-294690), as amended, declared effective by the SEC on April 16, 2026.

We received net proceeds of $662.0 million from our initial public offering, after deducting commissions, underwriting discounts and other offering costs. None of the expenses associated with the initial public offering were paid to directors, officers, persons owning 10% or more of any class of equity securities, or to our affiliates. J.P. Morgan Securities LLC, Jefferies LLC, Leerink Partners LLC, TD Securities (USA) LLC and Evercore Group L.L.C. acted as joint book-running managers for the offering.

We are holding a significant portion of the balance of the proceeds in a variety of capital preservation investments, including money market funds, U.S. government securities, and corporate bonds. There has been no material change in the expected use of the net proceeds from our initial public offering as described in our Prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the SEC on April 17, 2026.

Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

(a) None.

(b) None.

(c) During the quarter ended September 30, 2026, none of our directors or officers (as defined in Rule 16a-1 under the Exchange Act) adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement" (as those terms are defined in Item 408 of Regulation S-K).

Item 6. Exhibits.

Exhibit Number	Description
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Cover Page Interactive Data File (embedded within the Inline XBRL 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.

Kailera Therapeutics, Inc.

Date: November 4, 2026

By: /s/ Ronald C. Renaud, Jr.
Ronald C. Renaud, Jr.
President, Chief Executive Officer and Director
(principal executive officer)

Date: November 4, 2026

By: /s/ Douglas Pagán
Douglas Pagán
Chief Financial Officer
(principal financial and accounting officer)

Exhibit 31.1

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

I, Ronald C. Renaud, Jr., certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2026 of Kailera 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)) 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) [Omitted];

   (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 4, 2026

By: /s/ Ronald C. Renaud, Jr.
Ronald C. Renaud, Jr.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Douglas Pagán, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q for the period ended September 30, 2026 of Kailera 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)) 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) [Omitted];

   (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 4, 2026

By: /s/ Douglas Pagán
Douglas Pagán
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report of Kailera Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 4, 2026

By: /s/ Ronald C. Renaud, Jr.
Ronald C. Renaud, Jr.
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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

In connection with the Quarterly Report of Kailera Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to the best of my knowledge:

(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 4, 2026

By: /s/ Douglas Pagán
Douglas Pagán
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)