UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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: 001-39269

ORIC PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**47-1787157**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
240 E. Grand Ave, 2nd Floor South San Francisco, CA	**94080**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 388-5600

Not applicable

(Former name, former address, and former fiscal year, if changed since last report)

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

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, $0.0001 par value per share	**ORIC**	**The Nasdaq Global Select Market**

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

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

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

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

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

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

As of November 9, 2026, the registrant had 103,931,597 shares of common stock, $0.0001 par value per share, outstanding.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q contains forward-looking statements. All statements other than statements of historical facts contained in this quarterly report on Form 10-Q, including statements regarding our future results of operations and financial position, business strategy, development plans, planned preclinical studies and clinical trials, future results of clinical trials, expected research and development costs, regulatory strategy, timing and likelihood of success, as well as plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions. Forward-looking statements contained in this quarterly report on Form 10-Q include, but are not limited to, statements about:

- the ability of our clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results;
- the timing, progress and results of preclinical studies and clinical trials for rinzimetostat, enozertinib and other product candidates we may develop, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available, and our research and development programs;
- the timing, scope or likelihood of regulatory filings and approvals;
- the potential benefits of and activity under the company's collaboration, licenses and other third-party agreements;
- our ability to develop and advance our current product candidates and programs into, and successfully complete, clinical studies;
- our manufacturing, commercialization, and marketing capabilities and strategy;
- our plans relating to commercializing our product candidates, if approved, including the geographic areas of focus and sales strategy;
- the need to hire additional personnel and our ability to attract and retain such personnel;
- our expectations regarding the impact of a global pandemic or other public health emergencies on our business;
- the size of the market opportunity for our product candidates, including our estimates of the number of patients who suffer from the diseases we are targeting;
- our expectations regarding the approval and use of our product candidates in combination with other drugs;
- our competitive position and the success of competing therapies that are or may become available;
- our estimates of the number of patients that we will enroll in our clinical trials;
- the beneficial characteristics, safety, efficacy and therapeutic effects of our product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates;
- our plans relating to the further development of our product candidates, including additional indications we may pursue;
- existing regulations and regulatory developments in the United States, Europe and other jurisdictions;
- our intellectual property position, including the scope of protection we are able to establish and maintain for intellectual property rights covering rinzimetostat, enozertinib and other product candidates we may develop, including the extensions of existing patent terms where available, the validity of intellectual property rights held by third parties, and our ability not to infringe, misappropriate or otherwise violate any third-party intellectual property rights;
- our continued reliance on third parties to conduct additional clinical trials of our product candidates, and for the manufacture of our product candidates for preclinical studies and clinical trials;
- our ability to obtain, and negotiate favorable terms of, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- the pricing and reimbursement of rinzimetostat, enozertinib and other product candidates we may develop, if approved;
- the rate and degree of market acceptance and clinical utility of rinzimetostat, enozertinib and other product candidates we may develop, if approved;

- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- our financial performance;
- the period over which we estimate our existing cash, cash equivalents and investments will be sufficient to fund our operating plan;
- the impact of laws and regulations; and
- our anticipated use of our existing resources.

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, and these forward-looking statements are not guarantees of future performance or development. 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. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. 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. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events or otherwise.

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, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain and you are cautioned not to unduly rely upon these statements.

Part I – FINANCIAL INFORMATION

Item 1. Financial Statements.

ORIC PHARMACEUTICALS, INC.
BALANCE SHEETS
(in thousands, except share and per share amounts)

	September 30, 2026	December 31, 2025
	(unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 33,846	$ 45,669
Short-term investments	227,530	235,819
Prepaid expenses and other current assets	13,375	6,978
Total current assets	274,751	288,466
Long-term investments	83,986	110,762
Property and equipment, net	2,085	2,415
Other assets	6,064	7,247
Total assets	$ 366,886	$ 408,890
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,151	$ 3,824
Accrued liabilities	22,625	16,593
Total current liabilities	24,776	20,417
Other long-term liabilities	2,607	4,111
Total liabilities	27,383	24,528
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 200,000,000 shares authorized; no shares issued and outstanding at September 30, 2026 and December 31, 2025	—	—
Common stock, $0.0001 par value; 1,000,000,000 shares authorized; 103,865,706 and 98,528,949 shares issued and outstanding at September 30, 2026 and December 31, 2025, respectively	11	11
Additional paid-in capital	1,158,760	1,075,807
Accumulated deficit	(817,577)	(692,242)
Accumulated other comprehensive (loss) income	(1,691)	786
Total stockholders' equity	339,503	384,362
Total liabilities and stockholders' equity	$ 366,886	$ 408,890

See accompanying notes to unaudited financial statements.

ORIC PHARMACEUTICALS, INC.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)
(in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Operating expenses:				
Research and development	$ 43,358	$ 28,773	$ 111,091	$ 83,962
General and administrative	8,193	7,898	25,375	24,491
Total operating expenses	51,551	36,671	136,466	108,453
Loss from operations	(51,551)	(36,671)	(136,466)	(108,453)
Other income, net	3,475	4,084	11,131	9,490
Net loss	$ (48,076)	$ (32,587)	$ (125,335)	$ (98,963)
Other comprehensive (loss) gain:				
Unrealized (loss) gain on investments	(673)	428	(2,477)	236
Comprehensive loss	$ (48,749)	$ (32,159)	$ (127,812)	$ (98,727)
Net loss per share, basic and diluted	$ (0.44)	$ (0.33)	$ (1.17)	$ (1.20)
Weighted-average shares outstanding, basic and diluted	108,178,078	98,953,331	107,230,989	82,808,969

See accompanying notes to unaudited financial statements.

ORIC PHARMACEUTICALS, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited)
(in thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2025	98,528,949	$ 11	$ 1,075,807	$ (692,242)	$ 786	$ 384,362
Issuance of common stock, net	4,698,400	—	59,888	—	—	59,888
Exercise of common stock options	253,847	—	1,252	—	—	1,252
Issuance of common stock upon vesting of RSUs	5,216	—	—	—	—	—
Stock-based compensation expense	—	—	6,898	—	—	6,898
Unrealized loss on investments	—	—	—	—	(1,076)	(1,076)
Net loss	—	—	—	(35,767)	—	(35,767)
Balance at March 31, 2026	103,486,412	$ 11	$ 1,143,845	$ (728,009)	$ (290)	$ 415,557
Exercise of common stock options	30,976	—	149	—	—	149
Issuance of common stock upon vesting of RSUs	13,093	—	—	—	—	—
Issuance of common stock from ESPP	105,943	—	679	—	—	679
Stock-based compensation expense	—	—	7,091	—	—	7,091
Unrealized loss on investments	—	—	—	—	(728)	(728)
Net loss	—	—	—	(41,492)	—	(41,492)
Balance at June 30, 2026	103,636,424	$ 11	$ 1,151,764	$ (769,501)	$ (1,018)	$ 381,256
Exercise of common stock options	188,290	—	806	—	—	806
Issuance of common stock upon vesting of RSUs	40,992	—	—	—	—	—
Stock-based compensation expense	—	—	6,190	—	—	6,190
Unrealized loss on investments	—	—	—	—	(673)	(673)
Net loss	—	—	—	(48,076)	—	(48,076)
Balance at September 30, 2026	103,865,706	$ 11	$ 1,158,760	$ (817,577)	$ (1,691)	$ 339,503

See accompanying notes to unaudited financial statements.

ORIC PHARMACEUTICALS, INC.
STATEMENTS OF STOCKHOLDERS' EQUITY
(Unaudited)
(in thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance at December 31, 2024	71,021,855	$ 7	$ 805,510	$ (562,774)	$ 379	$ 243,122
Exercise of common stock options	53,009	—	253	—	—	253
Issuance of common stock upon vesting of RSUs	3,647	—	—	—	—	—
Stock-based compensation expense	—	—	6,554	—	—	6,554
Unrealized loss on investments	—	—	—	—	(170)	(170)
Net loss	—	—	—	(30,021)	—	(30,021)
Balance at March 31, 2025	71,078,511	$ 7	$ 812,317	$ (592,795)	$ 209	$ 219,738
Issuance of common stock and pre-funded warrants, net	14,980,313	2	133,267	—	—	133,269
Exercise of common stock options	7,812	—	34	—	—	34
Issuance of common stock upon vesting of RSUs	17,752	—	—	—	—	—
Issuance of common stock from ESPP	102,940	—	757	—	—	757
Stock-based compensation expense	—	—	6,574	—	—	6,574
Unrealized loss on investments	—	—	—	—	(22)	(22)
Net loss	—	—	—	(36,355)	—	(36,355)
Balance at June 30, 2025	86,187,328	$ 9	$ 952,949	$ (629,150)	$ 187	$ 323,995
Issuance of common stock, net	10,930,032	1	108,702	—	—	108,703
Exercise of common stock options	144,301	1	748	—	—	749
Issuance of common stock upon vesting of RSUs	16,371	—	—	—	—	—
Stock-based compensation expense	—	—	5,631	—	—	5,631
Unrealized gain on investments	—	—	—	—	428	428
Net loss	—	—	—	(32,587)	—	(32,587)
Balance at September 30, 2025	97,278,032	$ 11	$ 1,068,030	$ (661,737)	$ 615	$ 406,919

See accompanying notes to unaudited financial statements.

ORIC PHARMACEUTICALS, INC.
STATEMENTS OF CASH FLOWS
(Unaudited)
(in thousands)

	Nine Months Ended September 30,	
	2026	**2025**
Cash flows from operating activities:		
Net loss	$ (125,335)	$ (98,963)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	813	900
Stock-based compensation expense	20,179	18,759
Amortization of premium (accretion of discount) on investments, net	690	(2,060)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(4,490)	(325)
Accounts payable and accrued other liabilities	2,114	(6,798)
Net cash used in operating activities	(106,029)	(88,487)
Cash flows from investing activities:		
Acquisitions of property and equipment	(465)	(485)
Purchases of investments	(143,103)	(354,530)
Maturities of investments	175,000	190,000
Net cash provided by (used in) investing activities	31,432	(165,015)
Cash flows from financing activities:		
Proceeds from issuance of common stock and pre-funded warrants	60,881	244,369
Issuance costs associated with financings	(993)	(2,397)
Proceeds from issuance of common stock under ESPP	679	757
Proceeds from stock option exercises	2,207	1,035
Net cash provided by financing activities	62,774	243,764
Net decrease in cash, cash equivalents and restricted cash	(11,823)	(9,738)
Cash, cash equivalents and restricted cash at beginning of period	46,160	59,897
Cash, cash equivalents and restricted cash at end of period	$ 34,337	$ 50,159

The following table provides a reconciliation of cash, cash equivalents and restricted cash within the balance sheets to the amounts shown in the statements of cash flows above, in thousands:

	September 30,	
	2026	**2025**
Cash and cash equivalents	$ 33,846	$ 49,668
Restricted cash included in other assets	491	491
Total cash, cash equivalents and restricted cash	$ 34,337	$ 50,159

See accompanying notes to unaudited financial statements.

ORIC PHARMACEUTICALS, INC.
NOTES TO UNAUDITED FINANCIAL STATEMENTS

1. Description of the Business

ORIC Pharmaceuticals, Inc. (ORIC or the Company) is a clinical-stage biopharmaceutical company dedicated to improving patients' lives by *Overcoming Resistance In Cancer*. The Company was incorporated in Delaware in August 2014 and has offices in South San Francisco and San Diego, California. The Company's principal operations are in the United States and the Company operates in one segment.

Since inception, the Company has devoted its primary efforts to raising capital, internal research and development activities and business development efforts, and has incurred significant operating losses and negative cash flows from operations. In August 2020, the Company licensed from Mirati Therapeutics, Inc. (Mirati) development and commercialization rights to an allosteric inhibitor program directed towards the polycomb repressive complex 2 (PRC2) and in October 2020, the Company licensed from Voronoi Inc. (Voronoi) development and commercialization rights to a brain-penetrant, orally bioavailable, irreversible inhibitor designed to selectively target epidermal growth factor receptor (EGFR) with high potency against exon 20 insertion mutations.

As of September 30, 2026, the Company had an accumulated deficit of $817.6 million. Through September 30, 2026, all of the Company's financial support has been provided by proceeds from the issuance of common stock and convertible preferred stock.

As the Company continues its expansion, it may seek additional financing and/or strategic investments, however, there can be no assurance that any additional financing or strategic investments will be available to the Company on acceptable terms, if at all. If events or circumstances occur such that the Company does not obtain additional funding, it will most likely be required to reduce its plans and/or certain discretionary spending, which could have a material adverse effect on the Company's ability to achieve its intended business objectives. The accompanying financial statements do not include any adjustments that might be necessary if it were unable to continue as a going concern. Management believes that it has sufficient working capital on hand to fund operations through at least the next twelve months from the date of the issuance of these financial statements.

Strategic Pipeline Prioritization

On August 12, 2025, the Company announced a strategic pipeline prioritization to focus operational and financial resources on the continued advancement of its two lead clinical programs, rinzimetostat and enozertinib. This initiative resulted in a substantial decrease in preclinical research, primarily from the elimination of the Company's discovery research group. This resulted in an approximately 20% workforce reduction and the Company incurred a one-time cost of approximately $1.9 million primarily related to termination benefits, including severance and healthcare-related benefits. The workforce reduction was completed in the fourth quarter of 2025.

At-The-Market Sales Agreement and Offering

The Company previously entered into an "at the market" (ATM) sales agreement with Jefferies LLC as the Company's sales agent, to sell shares of the Company's common stock. On February 23, 2026, pursuant to the terms of the ATM sales agreement, the Company filed a prospectus supplement to its Form S-3ASR filed on March 11, 2024, to allow the Company to sell from time to time up to $200.0 million of shares of the Company's common stock in negotiated transactions or transactions deemed to be an ATM offering. There were no proceeds raised in ATM offerings during the three months ended September 30, 2026. During the nine months ended September 30, 2026, the Company raised net proceeds in ATM offerings, including participation from healthcare specialist funds, of approximately $59.9 million through the sale of 4,698,400 shares at a weighted average purchase price of $12.96. During the three months ended September 30, 2025, the Company raised net proceeds in ATM offerings, including participation from healthcare specialist funds, of approximately $108.7 million through the sale of 10,930,032 shares at a weighted average price of $10.10. During the nine months ended September 30, 2025, the Company raised net proceeds in ATM offerings, including participation from healthcare specialist funds, of approximately $117.6 million through the sale of 11,780,032 shares at a weighted average purchase price of $10.13.

Private Placements

On May 23, 2025, the Company entered into a securities purchase agreement with a select group of institutional and accredited healthcare specialist investors for the private placement of 14,130,313 shares of common stock at a price of $6.50 per share and pre-funded warrants to purchase 5,100,532 shares of common stock at a purchase price of $6.4999 per pre-funded warrant, resulting in gross proceeds of $125.0 million. The purchase price per share represents a premium of approximately 18% to ORIC's 10-day trailing volume-weighted average stock price as of deal signing on May 23, 2025. The pre-funded warrants have an exercise price of $0.0001 per share of common stock, were immediately exercisable and will remain exercisable until exercised in full. After deducting expenses related to the private placement of $0.6 million, the net proceeds to the Company from the private placement were $124.4 million. The private placement closed on May 29, 2025. On June 11, 2025, the Company filed a Form S-3 registering the shares sold in the private placement. The Form S-3 was declared effective by the Securities and Exchange Commission (SEC) on June 20, 2025.

2. Basis of Presentation and Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited financial statements have been prepared in accordance with accounting principles generally accepted in the United States (GAAP) for interim financial information and with the instructions of the SEC on Form 10-Q and Rule 10-01 of Regulation S-X. Certain information and note disclosures normally included in annual financial statements prepared in accordance with GAAP have been omitted. The accompanying unaudited financial statements include all known adjustments necessary for a fair presentation of the results as required by GAAP. These adjustments consist primarily of normal recurring accruals and estimates that impact the carrying value of assets and liabilities. Operating results for the interim period are not necessarily indicative of future results.

The accompanying unaudited financial statements should be read in conjunction with the audited financial statements and the related notes thereto for the year ended December 31, 2025, which are included in the Company's Annual Report on Form 10-K for the year ended December 31, 2025 (the Annual Report). Furthermore, the Company's significant accounting policies are disclosed in the audited financial statements for the periods ended December 31, 2025 and 2024, included in the Annual Report. Since the date of those financial statements, there have been no changes to its significant accounting policies.

Segment Reporting

The Company's chief operating decision maker (CODM) is the Company's Chief Executive Officer. The CODM is assisted in their responsibilities of making decisions regarding resource allocation and performance assessment by the leadership team, consisting of executives, an executive vice president, a senior vice president and a vice president.

The Company views its operations and manages its business as one operating segment, focused on the discovery and development of innovative therapies designed to counter the resistance mechanisms in cancer. Segment profit or loss is measured as the Company's net loss as reported on the Company's Statement of Operations and Comprehensive Loss. The Company monitors its cash and cash equivalents, short-term investments and long-term investments as reported on the Company's Balance Sheets to determine funding for its research and development.

The CODM assesses Company performance through the achievement of pre-clinical and clinical research goals. In addition to the Company's Statement of Operations and Comprehensive Loss, the CODM is regularly provided with budgeted and forecasted expense information which is used to determine the Company's liquidity needs and cash allocation.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued Accounting Standards Update (ASU) 2024-03, *Income Statement - Reporting Comprehensive Income - Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, which is intended to enhance expense disclosures by requiring additional information about specific expense categories in the notes to the financial statements. The standard is effective, as clarified by ASU 2025-01, for annual periods beginning after December 15, 2026, and interim reporting periods within annual reporting periods beginning after December 15, 2027, with early adoption permitted. The standard may be adopted prospectively or retrospectively. The Company is currently evaluating the impact of the standard on its financial statements and related disclosures.

3. License Agreements and Clinical Development Collaborations

Bayer collaborations

On July 7, 2026, the Company entered into a clinical trial collaboration and supply agreement with Bayer Consumer Care AG (Bayer) to provide their androgen receptor (AR) inhibitor, Nubeqa® (darolutamide), at no cost for use in the Himalayas-1 global Phase 3 registrational trial. The Company will conduct and sponsor the Himalayas-1 trial and maintain full economic ownership and control of rinzimetostat.

On May 14, 2024, the Company entered into a clinical trial collaboration and supply agreement with Bayer, as amended effective October 23, 2024, to evaluate rinzimetostat in combination with darolutamide. The Company will continue to conduct and sponsor the ongoing Phase 1b clinical trial, and Bayer will provide darolutamide for the trial. The Company maintains full economic ownership and control of rinzimetostat.

Johnson & Johnson collaborations

On August 29, 2024, the Company entered into a clinical supply agreement with Janssen Research & Development, LLC, a Johnson & Johnson company (Johnson & Johnson), to evaluate enozertinib in combination with subcutaneous (SC) amivantamab, Johnson & Johnson's fully-human EGFR-MET bispecific antibody. The Company will continue to conduct and sponsor the ongoing Phase 1b clinical trial, and Johnson & Johnson will provide SC amivantamab for the trial. The Company maintains full economic ownership and control of enozertinib.

On July 10, 2024, the Company entered into a clinical trial collaboration and supply agreement with Johnson & Johnson, to evaluate rinzimetostat in combination with Erleada® (apalutamide), Johnson & Johnson's AR inhibitor. The Company will continue to conduct and sponsor the ongoing Phase 1b clinical trial, and Johnson & Johnson will provide apalutamide for the trial. The Company maintains full economic ownership and control of rinzimetostat.

Voronoi License Agreement

On October 19, 2020, the Company entered into a license and collaboration agreement (Voronoi License Agreement) with Voronoi. The Voronoi License Agreement gives the Company access to Voronoi's preclinical stage EGFR exon 20 insertion mutation program, including a lead product candidate now designated as enozertinib. Under the Voronoi License Agreement, Voronoi granted the Company an exclusive, sublicensable license under Voronoi's rights to certain patent applications directed to certain small molecule compounds that bind to EGFR with one or more exon 20 insertion mutations and certain related know-how, in each case, to develop and commercialize certain licensed compounds and licensed products incorporating any such compound in the ORIC Territory, defined as worldwide other than in the People's Republic of China, Hong Kong, Macau and Taiwan. Pursuant to an amendment to the Voronoi License Agreement that the Company entered into with Voronoi on March 20, 2024, the Company also obtained the right to conduct and control certain clinical trials for the licensed products at specified clinical sites within Voronoi's territory to support the development and commercialization of licensed products in the ORIC Territory. Under the Voronoi License Agreement, Voronoi had the right to perform certain mutually agreed upon development activities. Except for Voronoi's right to participate in such development activities, the Company is wholly responsible for development and commercialization of licensed products in the ORIC Territory. In addition, the Company is obligated to use commercially reasonable efforts to develop and commercialize at least one licensed product in certain major markets in the ORIC Territory.

The Company's financial obligations under the Voronoi License Agreement included an upfront payment of $5.0 million in cash and the issuance to Voronoi of 283,259 shares of the Company's common stock, valued at approximately $6.8 million, issued pursuant to a stock issuance agreement entered into between the parties on October 19, 2020. The number of shares issued pursuant to the stock issuance agreement was based on a price of $28.24 per share, representing a premium of 25% to the 30-day trailing volume weighted average trading price of the Company's common stock. The shares were issued in a private placement in reliance on Section 4(a)(2) of the Securities Act of 1933, as amended (Securities Act), for transactions by an issuer not involving any public offering.

Under the Voronoi License Agreement, Voronoi was responsible for certain research and development costs up to a predetermined threshold. Upon achievement of the predetermined threshold in the second quarter of 2022, Voronoi chose to opt out of participation in and funding of future development activities. The Company is also obligated to make milestone payments to Voronoi upon the achievement of certain events. Upon the achievement of certain development and regulatory milestones with respect to the first licensed product, the Company is obligated to pay Voronoi up to a maximum of $111.0 million. Upon the achievement of certain commercial milestones with respect to the first licensed product, the Company is obligated to pay Voronoi up to a maximum of $225.0 million. If the Company pursues a second licensed product, the Company could pay Voronoi up to an additional $272.0 million in success-based milestones. In addition, the Company is obligated to pay royalties on net sales of licensed products in the ORIC Territory. In the third quarter of 2022, the Company made a development milestone payment to Voronoi in the amount of $5.0 million, which was recorded in acquired in-process research and development expense.

Unless earlier terminated, the Voronoi License Agreement will continue in effect until the expiration of all royalty payment obligations. Following the expiration of the Voronoi License Agreement, the Company will retain its licenses under the intellectual property Voronoi licensed to it on a royalty-free basis. The Company and Voronoi may each terminate the Voronoi License Agreement if the other party materially breaches the terms of such agreement, subject to specified notice and cure provisions, or enters into bankruptcy or insolvency proceedings. Voronoi may also terminate the agreement if the Company discontinues development of licensed products for a specified period of time. The Company also has the right to terminate the Voronoi License Agreement without cause by providing prior notice to Voronoi.

If Voronoi terminates the Voronoi License Agreement for cause, or if the Company terminates the Voronoi License Agreement without cause, then the Company is obligated to grant a nonexclusive license to Voronoi under certain of the Company's patents and know-how and to assign to Voronoi certain of its regulatory filings for licensed compounds and licensed products.

Mirati License Agreement

On August 3, 2020, the Company entered into a license agreement (Mirati License Agreement) with Mirati. Under the Mirati License Agreement, Mirati granted the Company a worldwide, exclusive, sublicensable, royalty-free license under Mirati's rights to certain patents and patent applications directed to certain small molecule compounds that bind to and inhibit PRC2 and certain related know-how, in each case, to develop and commercialize certain licensed compounds and licensed products incorporating any such compounds. Under the Mirati License Agreement, the Company is wholly responsible for development and commercialization of licensed products. In addition, the Company is obligated to use commercially reasonable efforts to develop and commercialize at least one licensed product in certain major markets.

The Company's financial obligation under the Mirati License Agreement was an upfront payment of 588,235 shares of ORIC common stock, valued at approximately $13.0 million based upon the closing price of the Company's common stock on the acquisition date. The number of shares issued was based on a price of $34.00 per share, representing a premium of 10% to the 60-day trailing volume-weighted average trading price of the Company's common stock. The shares were issued in a private placement in reliance on Section 4(a)(2) of the Securities Act for transactions by an issuer not involving any public offering. During the eighteen-month period following the date of the agreement, Mirati was subject to certain transfer restrictions, and the parties agreed to negotiate and enter into a registration rights agreement, with respect to the shares. The Company is not obligated to pay Mirati milestones or royalties.

Unless earlier terminated, the Mirati License Agreement will continue in effect on a country-by-country and licensed product-by-licensed product basis until the later of (a) the expiration of the last valid claim of a licensed patent covering such licensed product in such country or (b) ten years after the first commercial sale of such licensed product in such country. Following the expiration of the Mirati License Agreement, the Company will retain its licenses under the intellectual property Mirati licensed to it on a royalty-free basis. ORIC and Mirati may each terminate the Mirati License Agreement if the other party materially breaches the terms of such agreement, subject to specified notice and cure provisions, or enters into bankruptcy or insolvency proceedings. Mirati may terminate the agreement if the Company challenges any of the patent rights licensed to the Company by Mirati or it discontinues development of licensed products for a specified period of time. The Company also has the right to terminate the Mirati License Agreement without cause by providing prior notice to Mirati.

On October 8, 2023, Bristol Myers Squibb (BMS) and Mirati announced that they entered into a definitive merger agreement under which BMS through a subsidiary will acquire all of the outstanding shares of Mirati common stock. The Mirati License Agreement continued in effect upon consummation of the transaction, which closed on January 23, 2024.

4. Property and Equipment, net

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

	September 30, 2026	December 31, 2025
Lab equipment	$ 7,270	$ 7,012
Leasehold improvements	2,097	2,065
Computer hardware and software	485	292
Furniture and fixtures	697	697
Total property and equipment, gross	10,549	10,066
Less accumulated depreciation	(8,464)	(7,651)
Total property and equipment, net	$ 2,085	$ 2,415

5. Accrued Liabilities

Accrued liabilities consisted of the following (in thousands):

	September 30, 2026	December 31, 2025
Accrued clinical and manufacturing costs	$ 10,177	$ 4,303
Accrued compensation	7,333	8,094
Operating lease liabilities - short-term	3,352	3,330
Other accruals	1,763	866
Total accrued liabilities	$ 22,625	$ 16,593

6. Investments

The Company's available-for-sale investments consisted of the following (in thousands):

September 30, 2026	Amortized Cost	Unrealized Gains	Unrealized Losses	Estimated Fair Value
Short-term				
U.S. treasury securities	$ 228,411	$ —	$ (881)	$ 227,530
Short-term investments	$ 228,411	$ —	$ (881)	$ 227,530
Long-term				
U.S. treasury securities	$ 84,796	$ —	$ (810)	$ 83,986
Long-term investments	$ 84,796	$ —	$ (810)	$ 83,986
December 31, 2025				
Short-term				
U.S. treasury securities	$ 235,263	$ 556	$ —	$ 235,819
Short-term investments	$ 235,263	$ 556	$ —	$ 235,819
Long-term				
U.S. treasury securities	$ 110,532	$ 234	$ (4)	$ 110,762
Long-term investments	$ 110,532	$ 234	$ (4)	$ 110,762

The Company has determined that there were no material declines in fair value of its investments due to credit-related factors as of September 30, 2026 and December 31, 2025. Credit loss is limited due to the nature of the investments.

7. Fair Value Measurements

The accounting guidance defines fair value, establishes a consistent framework for measuring fair value and expands disclosure for each major asset and liability category measured at fair value on either a recurring or nonrecurring basis. Fair value is defined as an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the accounting guidance establishes a three-tier fair-value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1: Observable inputs such as quoted prices in active markets;

Level 2: Inputs, other than the quoted prices in active markets, that are observable either directly or indirectly; and

Level 3: Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

The carrying amounts of the Company’s interest receivable, included in prepaid expenses and other current assets, accounts payable and accrued liabilities are generally considered to be representative of their fair value because of their short-term nature. The Company’s investments, which may include money market funds and available-for-sale investments consisting of U.S. treasury securities, certificates of deposit and high-quality, marketable debt instruments of corporations and government sponsored enterprises, are measured at fair value in accordance with the fair value hierarchy.

Following are the major categories of assets measured at fair value on a recurring basis (in thousands):

		Fair Value Measurements			
	Fair Value	Level 1	Level 2	Level 3	Total
September 30, 2026					
Money market funds [1]	$ 33,846	$ 33,846	$ —	$ —	$ 33,846
U.S. treasury securities	311,516	311,516	—	—	311,516
Total	$ 345,362	$ 345,362	$ —	$ —	$ 345,362
December 31, 2025					
Money market funds [1]	$ 45,669	$ 45,669	$ —	$ —	$ 45,669
U.S. treasury securities	346,581	346,581	—	—	346,581
Total	$ 392,250	$ 392,250	$ —	$ —	$ 392,250

(1) Included in cash and cash equivalents in accompanying balance sheets.

No transfers between levels occurred during either of the reporting periods presented.

8. Stockholders' Equity and Stock-Based Compensation

As of September 30, 2026, there were 1,276,961 shares available for future issuance under the 2020 Equity Incentive Plan and 1,030,875 shares available for future issuance under the 2022 Inducement Equity Incentive Plan. The 2020 Equity Incentive Plan provides for the grants of stock options and other equity-based awards to employees, non-employee directors and consultants of the Company. The 2022 Inducement Equity Incentive Plan provides for the grants of equity-based awards to individuals not previously employees or non-employee directors of the Company.

The table below summarizes the total stock-based compensation expense included in the Company's statements of operations and comprehensive loss for the periods presented (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Research and development	$ 3,164	$ 2,434	$ 9,913	$ 8,245
General and administrative	3,026	3,197	10,266	10,514
Total stock-based compensation expense	$ 6,190	$ 5,631	$ 20,179	$ 18,759

Stock Options

The following table summarizes the stock option activity for the nine months ended September 30, 2026:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2025	13,902,239	$ 6.49		
Granted	3,896,158	$ 8.60		
Exercised	(473,113)	$ 4.67		
Forfeited and cancelled	(186,928)	$ 8.65		
Outstanding at September 30, 2026	17,138,356	$ 6.99	7.0	$ 112,494
Exercisable at September 30, 2026	10,494,572	$ 5.94	5.9	$ 80,484

The fair value of stock option awards to employees, executives, directors, and other service providers was estimated at the date of grant using the Black-Scholes-Merton option pricing model with the following assumptions:

	Nine Months Ended September 30,	
	2026	2025
Risk-free interest rate	3.73% - 4.61%	3.87% - 4.43%
Expected volatility	84.89% - 87.57%	83.11% - 85.76%
Expected term (in years)	5.50 - 6.08	5.50 - 6.08
Expected dividend yield	0%	0%

The Company recognized stock-based compensation expense related to the vesting of stock options of $4.7 million and $4.7 million during the three months ended September 30, 2026 and 2025, respectively, and $16.1 million and $15.7 million during the nine months ended September 30, 2026 and 2025, respectively. Total unrecognized compensation expense related to outstanding unvested stock-option awards as of September 30, 2026, was $37.4 million, which is expected to be recognized over a weighted-average remaining service period of 2.7 years.

Restricted Stock Units

The following table summarizes the restricted stock unit activity for the nine months ended September 30, 2026:

	Number of Shares	Weighted-Average Grant-Date Fair Value
Outstanding at December 31, 2025	582,533	$ 8.96
Granted	614,949	$ 8.61
Vested	(59,301)	$ 9.67
Forfeited	(25,929)	$ 8.79
Outstanding at September 30, 2026	1,112,252	$ 8.73

The Company recognized stock-based compensation expense related to the vesting of restricted stock units of $1.1 million and $0.7 million during the three months ended September 30, 2026 and 2025, respectively, and $3.3 million and $2.5 million during the nine months ended September 30, 2026 and 2025, respectively. Total unrecognized compensation expense related to restricted stock units as of September 30, 2026, was $6.5 million, which is expected to be recognized over a weighted-average remaining service period of 1.7 years.

Employee Stock Purchase Plan

The Company recognized stock-based compensation expense related to the Employee Stock Purchase Plan (ESPP) of $0.4 million and $0.2 million during the three months ended September 30, 2026 and 2025, respectively, and $0.8 million and $0.6 million during the nine months ended September 30, 2026 and 2025, respectively.

Pre-funded Warrants

In May 2025, the Company completed a private placement in which it sold 14,130,313 shares of common stock together with pre-funded warrants to purchase 5,100,532 shares of common stock with an exercise price of $0.0001 per share of common stock. Each pre-funded warrant was immediately exercisable and will remain exercisable until exercised in full. The Company performed an assessment upon issuance of the pre-funded warrants to determine proper classification in the financial statements based on the specific terms of the pre-funded warrants. The Company determined the pre-funded warrants met all the criteria for equity classification and recorded them in additional paid-in capital. There were 4,463,636 pre-funded warrants that remained outstanding and unexercised as of September 30, 2026.

Net Loss per Share

The following outstanding shares of potentially dilutive securities were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented because including them would have been anti-dilutive:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
Options to purchase common stock	17,138,356	14,130,668	17,138,356	14,130,668
Non-vested restricted stock units	1,112,252	945,945	1,112,252	945,945
Total	18,250,608	15,076,613	18,250,608	15,076,613

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

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited financial statements and related notes included elsewhere in this quarterly report on Form 10-Q and 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, both of which are contained in our Annual Report on Form 10-K for the year ended December 31, 2025, filed with the SEC on February 23, 2026. This discussion contains forward-looking statements that involve risks and uncertainties, including those described in the section titled "Special Note Regarding Forward-Looking Statements." Our actual results and the timing of selected events could differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those set forth under the section titled "Risk Factors" included elsewhere in this report.

Overview

ORIC Pharmaceuticals is a clinical-stage biopharmaceutical company dedicated to improving patients' lives by *Overcoming Resistance In Cancer.*

Our fully integrated research and development team is advancing a diverse pipeline of innovative clinical therapies designed to counter resistance mechanisms in cancer by leveraging our expertise within three specific areas: hormone-dependent cancers, precision oncology and key tumor dependencies.

Our clinical stage product candidates include:

Rinzimetostat

Rinzimetostat is an orally bioavailable, allosteric inhibitor of the PRC2 via the embryonic ectoderm development (EED) subunit, for which we licensed development and commercialization rights from Mirati under the Mirati License Agreement. We filed and cleared an Investigational New Drug application (IND) with the Food and Drug Administration (FDA) for rinzimetostat in the fourth quarter of 2021. We completed a Phase 1b trial of rinzimetostat as a single-agent, in patients with advanced prostate cancer and reported initial Phase 1b data from this trial in January 2024, demonstrating potential best-in-class drug properties, including an approximate 20-hour clinical half-life, robust target engagement and a favorable safety profile. In the first half of 2024, we initiated dosing of rinzimetostat in combination with apalutamide as well as in combination with darolutamide, as part of the ongoing Phase 1b trial in patients with metastatic castration resistant prostate cancer (mCRPC). We also announced that we entered into clinical trial collaboration and supply agreements with Johnson & Johnson and Bayer, to evaluate rinzimetostat in combination with Erleada® (apalutamide), Johnson & Johnson's AR inhibitor, and Nubeqa® (darolutamide), Bayer's AR inhibitor.

In November 2025, we announced the completion of the dose exploration portion of the Phase 1b trial and the selection of provisional recommended Phase 2 doses (RP2Ds) of rinzimetostat to be tested in combination with the approved doses of darolutamide and apalutamide in the dose optimization portion of the Phase 1b trial: 400 mg and 600 mg QD of rinzimetostat in combination with 600 mg BID of darolutamide; and 600 mg, 800 mg and 1,200 mg QD of rinzimetostat in combination with 240 mg QD of apalutamide. Also, in November 2025, we reported Phase 1b dose exploration data in 20 patients with mCRPC, who were treated with rinzimetostat in combination with 240 mg QD of apalutamide or with 600 mg BID of darolutamide. As of the November 2025 data presentation cutoff date, rinzimetostat demonstrated PSA responses and circulating tumor DNA (ctDNA) reductions across all rinzimetostat dose levels and at comparable rates in combination with apalutamide or with darolutamide. Both combination regimens demonstrated a safety profile compatible with long-term dosing, with the vast majority of treatment-related adverse events (TRAEs) Grade 1 or 2 in severity and consistent with PRC2 and AR inhibition. As of the November 2025 data presentation cutoff date, only one patient experienced a Grade 3 TRAE, and there were no Grade 4 or Grade 5 AEs attributed to rinzimetostat, apalutamide or darolutamide.

In March 2026, we reported Phase 1b dose optimization data in 18 mCRPC patients previously treated with abiraterone and the selection of 400 mg QD rinzimetostat in combination with darolutamide as the recommended Phase 3 dose (RP3D). As of the March 2026 data presentation cutoff dates, at a median follow-up of approximately 5 months, landmark 5-month radiographic progression-free survival (rPFS) of 84% was consistent with a competitor PRC2 inhibitor benchmark, and better than the benchmarks for standard of care therapies in post-androgen receptor pathway inhibitor (ARPI) mCRPC. Importantly, the data demonstrated a highly differentiated, potential best-in-disease safety profile, with significantly lower frequency and severity of adverse events, nearly all Grade 1 or 2, and fewer treatment modifications than competitor regimens. In March 2026, we also reported Phase 1b dose optimization data in 19 patients with mCRPC previously treated with an androgen receptor (AR) inhibitor. These patients were treated with 400 mg QD rinzimetostat in combination with darolutamide. As of the March 2026 data presentation cutoff dates, at a median follow-up of approximately 5 months, landmark 5-month rPFS of 85% was consistent with a competitor PRC2 inhibitor benchmark, and better than the benchmarks for standard of care therapies in post-ARPI mCRPC.

In July 2026, we announced that we initiated our first global Phase 3 registrational trial for rinzimetostat in combination with darolutamide, named Himalayas-1, in patients with mCRPC previously treated with abiraterone. We also announced that we entered into a clinical trial collaboration and supply agreement with Bayer to provide darolutamide at no cost for use in the Himalayas-1 trial.

In October 2026, we completed a pre-planned biannual Periodic Safety Review (PSR). The review was based on a data extraction conducted on August 14, 2026, consisting of all entered data for the ongoing Phase 1b dose-optimization cohorts evaluating 400 mg QD rinzimetostat in combination with darolutamide in patients with mCRPC previously treated with abiraterone and in patients with mCRPC previously treated with an AR inhibitor. As of August 14, 2026, with a median follow-up of approximately 8 months, the safety profile across both patient populations was consistent with the March 2026 data disclosure. The vast majority of TRAEs were Grade 1 in severity and consistent with PRC2 and AR inhibition. The most common TRAEs were fatigue (32%; 11% Grade 1, 16% Grade 2, and 5% Grade 3), diarrhea (24%; 19% Grade 1 and 5% Grade 2), and nausea (22%; 19% Grade 1 and 3% Grade 2), which are similar rates and grades to the March 2026 data disclosure. Consistent with the March 2026 data disclosure, there were no Grade 4 or 5 AEs attributed to rinzimetostat or darolutamide. These data continue to demonstrate a highly differentiated safety profile, with significantly lower frequency and severity of adverse events, nearly all Grade 1 or 2, and fewer treatment modifications than competitor regimens.

In parallel with the October 2026 PSR, longer-term durability was also evaluated across both patient populations.

- Post-abiraterone cohort: At the time of the previous data disclosure (March 6, 2026 data cutoff), of 18 efficacy-evaluable patients in this cohort, 7 remained on treatment without radiographic progression. As of the August 14, 2026 data cutoff, 2 of these 7 patients discontinued treatment due to radiographic progression (one at more than 13 months and one at more than 11 months), and 5 patients remained on treatment without radiographic progression, with the longest ongoing at nearly 17 months. While still preliminary with 28% of patients ongoing, landmark rPFS rates continue to demonstrate meaningful and durable clinical benefit for rinzimetostat in combination with darolutamide compared to competitor data and historical outcomes with approved therapies. With a median follow-up of 7.8 months, landmark rPFS rates of 59% at each of 8, 9, and 10 months are consistent with the competitor PRC2 inhibitor currently in multiple Phase 3 trials in prostate cancer (mevrometostat in combination with enzalutamide demonstrated estimated landmark rPFS rates of 63% at each of 8, 9, and 10 months, in a post-abiraterone patient population). These rinzimetostat landmark rPFS rates are superior to reported outcomes for available standard-of-care therapies, including Xtandi®, Jevtana®, Taxotere®, and Pluvicto®. For reference, the estimated 10-month landmark rPFS for these approved therapies ranges from approximately 35% to 50%.
- Post-AR inhibitor cohort: At the time of the previous data disclosure (March 6, 2026 data cutoff), of 19 efficacy-evaluable patients in this cohort, 8 remained on treatment without radiographic progression. As of the August 14, 2026 data cutoff, 2 of these 8 patients discontinued treatment (one at nearly 10 months due to clinical progression; one at more than 8 months due to an adverse event), and 6 patients remained on treatment without radiographic progression, 4 of whom are ongoing at between 12 to 16 months. While still preliminary with 32% of patients ongoing, landmark rPFS rates continue to demonstrate meaningful and durable clinical benefit for rinzimetostat in combination with darolutamide compared to competitor data and historical outcomes with approved therapies. With a median follow-up of 7.6 months, landmark rPFS rates of 71%, 59%, and 59% at 8, 9, and 10 months, respectively, are consistent with the competitor PRC2 inhibitor currently in multiple Phase 3 trials in prostate cancer (mevrometostat in combination with enzalutamide demonstrated estimated landmark rPFS rates of 58%, 54%, and 54% at 8, 9 and 10 months, respectively, in a post-AR inhibitor patient population). These rinzimetostat landmark rPFS rates are superior to reported outcomes for available standard-of-care therapies, including Zytiga®, Jevtana®, Taxotere®, and Pluvicto®. For reference, the estimated 10-month landmark rPFS for these approved therapies ranges from approximately 15% to 50%.

Enozertinib

Enozertinib is a brain-penetrant, orally bioavailable, irreversible inhibitor targeting EGFR exon 20 insertion and EGFR atypical mutations, for which we licensed development and commercialization rights from Voronoi under the Voronoi License Agreement. In the fourth quarter of 2021, we filed a Clinical Trial Application (CTA) in South Korea for enozertinib, which was cleared in the first quarter of 2022. We also filed and cleared an IND with the FDA for enozertinib in the third quarter of 2022. Enozertinib is being evaluated in Phase 1b trials in EGFR exon 20 insertion and P-loop and alpha C-helix compressing (PACC) mutated non-small cell lung cancer (NSCLC), which allow enrollment of patients with CNS metastases that are either treated or untreated but asymptomatic. We reported initial Phase 1b data with enozertinib as a monotherapy in patients with EGFR exon 20 insertion mutations at the European Society for Medical Oncology (ESMO) Congress in October 2023, which demonstrated both systemic and intracranial activity across multiple dose levels in a heavily pre-treated patient population. In April 2024, we announced the selection of two provisional monotherapy RP2Ds of enozertinib at 80 mg and 120 mg QD. In January 2025, we announced that we entered into a clinical trial and supply agreement with Johnson & Johnson to evaluate enozertinib in combination with amivantamab and hyaluronidase-lpuj subcutaneous injection (SC) amivantamab for the first line treatment of patients with advanced NSCLC with EGFR exon 20 insertion mutations, and we initiated a Phase 1b trial in the first quarter of 2025.

In December 2025, we reported additional Phase 1b data at the 2025 ESMO Asia Congress in treatment-naïve and in previously treated NSCLC patients with EGFR exon 20 insertion and EGFR atypical mutations. EGFR atypical mutations are a heterogeneous group of non-classical mutations, with PACC mutations comprising the largest subset. Enozertinib achieved highly competitive systemic response rates as well as profound antitumor activity in the CNS in EGFR exon 20 insertion and EGFR PACC patients. Enozertinib also demonstrated a well-tolerated safety profile in EGFR exon 20 insertion and EGFR atypical patients, with no significant off-target toxicity and manageable on-target toxicity, resulting in low rate of discontinuations. Based on these data, 80 mg QD oral enozertinib has been selected as the monotherapy dose for potential Phase 3 development.

In October 2026, we reported additional Phase 1b data at the 2026 ESMO Congress in treatment-naïve NSCLC patients with EGFR atypical mutations, consisting of PACC and L861Q mutations. Despite enrolling patients with more than double the rate of baseline CNS disease as competitor datasets, including previously untreated CNS metastases, enozertinib achieved a meaningful systemic response and a compelling CNS response, including an 84% confirmed systemic ORR and a 70% confirmed intracranial ORR by investigator. These findings were supported by similar response rates utilizing the more stringent blinded independent central review (BICR), with a systemic ORR of 80% (RECIST 1.1) and an intracranial ORR of 67% (RANO-BM). While median PFS and duration of response data were immature as of the October 2026 data presentation cutoff date, a majority of patients remain on treatment and the 6-month landmark PFS of 88% compares favorably to reported benchmarks for currently used therapies and for late-stage investigational therapies. Enozertinib also demonstrated a well-tolerated safety profile, with no significant off-target toxicity and manageable on-target toxicity, resulting in no treatment-related discontinuations. Supported by these data and based on End-of-Phase 1 interactions with FDA, we plan to initiate Redwood-1, a global Phase 3 registrational trial in treatment-naïve NSCLC patients with EGFR atypical mutations in the first half of 2027.

Dosing and follow-up continues in NSCLC patients with exon 20 insertion mutations, including as a monotherapy, in combination with SC amivantamab and in combination with chemotherapy, as well as in NSCLC patients with EGFR atypical mutations as a monotherapy. We expect to report data in mid-2027 in 1L NSCLC patients with EGFR exon 20 insertion mutations as a monotherapy, in combination with SC amivantamab, and in combination with chemotherapy.

Beyond these clinical stage product candidates, we have historically engaged in the research and development of multiple discovery stage precision medicines targeting other hallmark cancer resistance mechanisms. On August 12, 2025, we announced a strategic pipeline prioritization to focus operational and financial resources on the continued advancement of our two lead clinical programs, rinzimetostat and enozertinib. This initiative resulted in a substantial decrease in preclinical research, primarily from the elimination of our discovery research group.

In October 2026, we announced that we entered into an agreement with Cancer Research UK, under which Cancer Research UK will fully fund, sponsor, design and execute CTA-enabling studies and Phase 1/2 clinical development of ORIC-259, a potential first-in-class small molecule targeting CIP2A. We retain an option to reacquire rights to ORIC-259 following Phase 1/2 data, and Cancer Research UK is eligible to receive downstream milestone payments and royalties.

We have incurred significant losses since the commencement of our operations. Our net loss for the nine months ended September 30, 2026, was $125.3 million and we had an accumulated deficit of $817.6 million as of September 30, 2026. Our losses and accumulated deficit have resulted primarily from costs incurred in connection with research and development activities including in-licensing and to a lesser extent from general and administrative costs associated with our operations. We expect to incur significant losses for the foreseeable future, and we anticipate these losses will increase significantly as we continue our development of rinzimetostat and enozertinib and any future product candidates through preclinical development and into clinical trials as we seek regulatory approval for these product candidates. Our net losses may fluctuate significantly from period to period, depending on the timing of and expenditures on our planned research and development activities.

Components of Operating Results

Research and Development Expenses

Research and development expenses account for a significant portion of our operating expenses and consist primarily of external and internal costs incurred in connection with the discovery and development of our product candidates.

External expenses include:

- payments to third parties in connection with the clinical development of our product candidates, including contract research organizations (CROs) and consultants;
- the cost of manufacturing products for use in our preclinical studies and clinical trials, including payments to contract manufacturing organizations (CMOs) and consultants;
- payments to third parties in connection with the preclinical development of our product candidates, including outsourced professional scientific development services, consulting research fees and sponsored research arrangements with third parties;

- laboratory supplies; and
- allocated facilities, depreciation and other expenses, which include direct or allocated expenses for IT, rent and maintenance of facilities.

We may also incur in-process research and development expense as we acquire or in-license assets from other parties. Technology acquisitions are expensed or capitalized based upon the asset achieving technological feasibility in accordance with management's assessment regarding the ultimate recoverability of the amounts paid and the potential for alternative future use. Acquired in-process research and development costs that have no alternative future use are immediately expensed.

Internal expenses include employee-related costs such as salaries, related benefits and non-cash stock-based compensation expense for employees engaged in research and development functions.

We expense research and development costs in the periods in which they are incurred. External expenses are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers or our estimate of the level of service that has been performed at each reporting date. We track external costs by program, clinical or preclinical. We do not track internal costs by program because these costs are deployed across multiple programs and, as such, are not separately classified.

Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages, 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 in the foreseeable future as we continue to invest in research and development activities related to developing our product candidates, including investments in manufacturing, advance our programs into later stages of development, conduct additional clinical trials, maintain, expand, protect and enforce our intellectual property portfolio, and hire additional personnel.

The successful development of our product candidates is highly uncertain, and we do not believe it is possible at this time to accurately project the nature, timing and estimated costs of the efforts necessary to complete the development of, and obtain regulatory approval for, any of our product candidates. To the extent our product candidates continue to advance into clinical trials, as well as advance into larger and later-stage clinical trials, our expenses will increase substantially and may become more variable. We are also unable to predict when, if ever, we will generate revenue from our product candidates to offset these expenses. Our expenditures on current and future preclinical and clinical development programs are subject to numerous uncertainties in timing and cost to completion. The duration, costs and timing of preclinical studies and clinical trials and development of our product candidates will depend on a variety of factors, including:

- the timing and progress of preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- our ability to maintain our current research and development programs and to establish new ones;
- establishing an appropriate safety profile with IND-enabling toxicology studies;
- successful patient enrollment in, and the initiation and completion of, clinical trials;
- the successful completion of clinical trials with safety, tolerability and efficacy profiles that are satisfactory to the FDA or any comparable foreign regulatory authority;
- the receipt of regulatory approvals from applicable regulatory authorities;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- our ability to establish licensing or collaboration arrangements;
- the performance of our future collaborators, if any;
- obtaining and retaining research and development personnel;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- development and timely delivery of commercial-grade product formulations that can be used in our planned clinical trials and for commercial launch;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;

- launching commercial sales of our product candidates, if approved, whether alone or in collaboration with others; and
- maintaining a continued acceptable safety profile of our products following approval.

Any changes in the outcome of any of these factors could significantly impact the costs, timing and viability associated with the development of our product candidates.

On August 12, 2025, we announced a strategic pipeline prioritization to focus operational and financial resources on the continued advancement of our two lead clinical programs, rinzimetostat and enozertinib. This initiative resulted in a substantial decrease in preclinical research, primarily from the elimination of our discovery research group. This resulted in an approximately 20% workforce reduction and we incurred a one-time cost of approximately $1.9 million primarily related to termination benefits, including severance and healthcare-related benefits. The workforce reduction was completed in the fourth quarter of 2025.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, related benefits and stock-based compensation expense for personnel in executive, finance and administrative functions. General and administrative expenses also include allocated facilities, depreciation and other expenses, which include direct or allocated expenses for rent and maintenance of facilities and insurance, not otherwise included in research and development expenses, as well as professional fees for legal, patent, consulting, investor and public relations, accounting and audit services. We expect that our general and administrative expenses will increase substantially in the foreseeable future as we increase our headcount to support the continued research and development of our programs and the growth of our business.

Other Income, Net

Other income, net primarily consists of interest income generated from our interest-bearing money market accounts and investments.

Results of Operations

Comparison of the Three and Nine Months Ended September 30, 2026 and 2025

The following table summarizes our results of operations (in thousands):

	Three Months Ended September 30,			Nine Months Ended September 30,		
	2026	2025	Change	2026	2025	Change
Operating expenses:						
Research and development	$ 43,358	$ 28,773	$ 14,585	$ 111,091	$ 83,962	$ 27,129
General and administrative	8,193	7,898	295	25,375	24,491	884
Total operating expenses	51,551	36,671	14,880	136,466	108,453	28,013
Loss from operations	(51,551)	(36,671)	(14,880)	(136,466)	(108,453)	(28,013)
Other income, net	3,475	4,084	(609)	11,131	9,490	1,641
Net loss	$ (48,076)	$ (32,587)	$ (15,489)	$ (125,335)	$ (98,963)	$ (26,372)

Research and Development Expenses

Research and development expenses were $43.4 million for the three months ended September 30, 2026, compared to $28.8 million for the same period in 2025, an increase of $14.6 million. The increase was primarily driven by an increase in external expenses related to the advancement of rinzimetostat, offset by lower enozertinib costs due to timing of manufacturing and clinical costs.

For the nine months ended September 30, 2026, research and development expenses were $111.1 million, compared to $84.0 million for the same period in 2025, an increase of $27.1 million. The increase was primarily driven by an increase in external expenses related to the advancement of rinzimetostat, offset by lower enozertinib costs due to timing of manufacturing and clinical costs as well as lower preclinical costs.

The following table summarizes our external and internal costs 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	Change	2026	2025	Change
External costs:						
rinzimetostat	$ 21,170	$ 5,559	$ 15,611	$ 49,222	$ 17,613	$ 31,609
enozertinib	7,647	9,031	(1,384)	20,232	24,204	(3,972)
Preclinical, other unallocated and discontinued costs	3,934	3,839	95	10,676	12,037	(1,361)
Total external costs	32,751	18,429	14,322	80,130	53,854	26,276
Internal costs	10,607	10,344	263	30,961	30,108	853
Total research and development expenses	$ 43,358	$ 28,773	$ 14,585	$ 111,091	$ 83,962	$ 27,129

General and Administrative Expenses

General and administrative expenses were $8.2 million for the three months ended September 30, 2026, compared to $7.9 million for the same period in 2025, an increase of $0.3 million. The increase was primarily due to higher professional services costs.

For the nine months ended September 30, 2026, general and administrative expenses were $25.4 million, compared to $24.5 million for the same period in 2025, an increase of $0.9 million. The increase was primarily due to higher professional services costs.

Liquidity and Capital Resources

Sources of Liquidity

We previously entered into an ATM sales agreement with Jefferies LLC as our sales agent, to sell shares of our common stock. On February 23, 2026, pursuant to the terms of the ATM sales agreement, we filed a prospectus supplement to our Form S-3ASR filed on March 11, 2024, to allow us to sell from time to time up to $200.0 million of shares of our common stock in negotiated transactions or transactions deemed to be an ATM offering. There were no proceeds raised in ATM offerings during the three months ended September 30, 2026. During the nine months ended September 30, 2026, we raised net proceeds in ATM offerings, including participation from healthcare specialist funds, of approximately $59.9 million through the sale of 4,698,400 shares at a weighted average purchase price of $12.96. During the three months ended September 30, 2025, we raised net proceeds in ATM offerings, including participation from healthcare specialist funds, of approximately $108.7 million through the sale of 10,930,032 shares at a weighted average price of $10.10. During the nine months ended September 30, 2025, we raised net proceeds in ATM offerings, including participation from healthcare specialist funds, of approximately $117.6 million through the sale of 11,780,032 shares at a weighted average purchase price of $10.13.

On May 23, 2025, we entered into a securities purchase agreement with a select group of institutional and accredited healthcare specialist investors for the private placement of 14,130,313 shares of common stock at a price of $6.50 per share and pre-funded warrants to purchase 5,100,532 shares of common stock at a purchase price of $6.4999 per pre-funded warrant, resulting in gross proceeds of $125.0 million. The private placement closed on May 29, 2025.

Future Funding Requirements

To date, we have not generated any revenue. We do not expect to generate any meaningful revenue unless and until we obtain regulatory approval of and commercialize any of our product candidates, and we do not know when, or if at all, that will occur. We will continue to require substantial additional capital to develop our product candidates and fund operations for the foreseeable future. Moreover, we expect our expenses to increase in connection with our ongoing activities, particularly as we continue the development of and seek regulatory approvals for our product candidates. Further, we are subject to all the risks incident in the development of new pharmaceutical products, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may harm our business. Our expenses will increase if, and as, we:

- advance our product candidates through preclinical and clinical development;
- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- seek to develop additional product candidates;
- establish a sales, marketing, medical affairs and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval and intend to commercialize on our own or jointly;

- expand our operational, financial and management systems and increase personnel, including personnel to support our development, manufacturing and commercialization efforts and our operations as a public company;
- maintain, expand, protect and enforce our intellectual property portfolio; and
- acquire or in-license other product candidates and technologies.

We expect our current cash, cash equivalents and investments will be sufficient to fund our current operating plan into the second half of 2028. However, our forecast of the period of time through which our financial resources will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. In order to complete the development of our product candidates and to build the sales, marketing and distribution infrastructure that we believe will be necessary to commercialize our product candidates, if approved, we will require substantial additional funding. Until we can generate a sufficient amount of revenue from the commercialization of our product candidates, we may seek to raise any necessary additional capital through the sale of equity, debt financings or other capital sources, which could include income from collaborations, strategic partnerships or marketing, distribution or licensing arrangements with third parties or from grants. 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 preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, including restricting our operations and limiting our ability to incur liens, issue additional debt, pay dividends, repurchase our common stock, make certain investments or engage in merger, consolidation, licensing or asset sale transactions. If we raise funds through collaborations, strategic partnerships and other similar arrangements with third parties, we may be required to grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves. We may be unable to raise additional funds or to enter into such agreements or arrangements on favorable terms, or at all. If we are unable to raise additional funds when needed, we may be required to delay, reduce or eliminate our product development or future commercialization efforts.

We have based our projections of operating capital requirements on our current operating plan, which is based on several assumptions that may prove to be incorrect and we may use all of our available capital resources sooner than we expect. Because of the numerous risks and uncertainties associated with research, development and commercialization of product candidates, we are unable to estimate the exact amount and timing of our working capital requirements. Our future funding requirements will depend on many factors, including:

- the scope, progress, results and costs of researching and developing our product candidates, and conducting preclinical studies and clinical trials;
- the costs, timing and outcome of regulatory review of our product candidates;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the costs of manufacturing commercial-grade products and sufficient inventory to support commercial launch;
- the revenue, if any, received from commercial sale of our products, should any of our product candidates receive marketing approval;
- the cost and timing of hiring new employees to support our continued growth;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the ability to establish and maintain collaborations on favorable terms, if at all;
- the extent to which we acquire or in-license other product candidates and technologies; and
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future product candidates, if any.

A change in the outcome of any of these or other factors 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. Furthermore, our operating plan may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plan.

Cash Flows

The following table summarizes the sources and uses of our cash (in thousands):

	Nine Months Ended September 30,	
	2026	2025
Net cash used in operating activities	$ (106,029)	$ (88,487)
Net cash provided by (used in) investing activities	31,432	(165,015)
Net cash provided by financing activities	62,774	243,764
Net decrease in cash, cash equivalents and restricted cash	$ (11,823)	$ (9,738)

Operating Activities

Net cash used in operating activities during the nine months ended September 30, 2026, of $106.0 million was attributable to our net loss of $125.3 million and $2.4 million in changes to working capital, offset by non-cash expenses of $21.7 million, which were primarily driven by stock-based compensation.

Net cash used in operating activities during the nine months ended September 30, 2025, of $88.5 million was attributable to our net loss of $99.0 million and $7.1 million in changes to working capital, offset by non-cash expenses of $17.6 million, which were primarily driven by stock-based compensation offset by accretion of discount on investments.

Investing Activities

Net cash provided by investing activities during the nine months ended September 30, 2026, of $31.4 million was primarily attributable to maturities of investments partially offset by purchases of investments.

Net cash used in investing activities during the nine months ended September 30, 2025, of $165.0 million was primarily attributable to purchases of investments, net of maturities.

Financing Activities

Net cash provided by financing activities during the nine months ended September 30, 2026, of $62.8 million was attributable to net proceeds received from our ATM offerings and proceeds received from stock option exercises and common stock issued under our ESPP.

Net cash provided by financing activities during the nine months ended September 30, 2025, of $243.8 million was attributable to net proceeds received from our private placement in May 2025 of $124.4 million, net proceeds from our ATM offerings of $117.6 million and proceeds received from stock option exercises and common stock issued under our ESPP.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States (US GAAP). The preparation of these financial statements in conformity with US GAAP requires management to make estimates and assumptions that impact the reported amounts of assets, liabilities, expenses, and the disclosure of contingent assets and liabilities in our financial statements and accompanying notes. These estimates and assumptions are based on current facts, historical experience and various other factors believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses. Actual results may differ materially from these estimates under different assumptions or conditions. There have been no significant changes in our critical accounting policies as discussed in our Annual Report on Form 10-K for the year ended December 31, 2025.

Transition from Emerging Growth Company Status and Smaller Reporting Company Status

On December 31, 2025, we ceased to be an "emerging growth company" (EGC), as defined in the Jumpstart Our Business Startups Act of 2012, due to the occurrence of the fifth anniversary of our initial public offering. Accordingly, we may no longer take advantage of EGC-related reduced reporting requirements that are otherwise applicable to public companies. EGC status also exempted us from having to provide an auditor attestation of internal control over financial reporting under Sarbanes-Oxley Act Section 404(b).

On December 31, 2025, we also ceased to be a "smaller reporting company" as defined in the Exchange Act because the market value of our stock held by non-affiliates exceeded $700 million as of June 30, 2025. Beginning with our Quarterly Report on Form 10-Q for the quarter ended March 31, 2026, we are no longer permitted to take advantage of the reduced reporting requirements applicable to smaller reporting companies, but will remain a non-accelerated filer through 2026. Due to the loss of smaller reporting company status, we expect our public company compliance costs to increase.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

Interest Rate Risk

The primary objective of our investment activities is to preserve principal and liquidity while at the same time maximizing the income we receive without significantly increasing risk. To achieve this objective, we may invest in money market funds, U.S. Treasury notes, and high-quality marketable debt instruments of corporations and government sponsored enterprises with contractual maturity dates of generally less than two years, in accordance with an investment policy approved by our audit committee. Some of the financial instruments that we invest in could be subject to market risk, meaning that a change in prevailing interest rates may cause the value of the instruments to fluctuate. For example, if we purchase a security that was issued with a fixed interest rate and the prevailing interest rate later rises, the value of that security will probably decline. To minimize this risk, we intend to maintain a portfolio which may include a variety of securities, including money market funds, government debt securities, certificates of deposit and commercial paper, all with various maturity dates. As of September 30, 2026, we had cash, cash equivalents and investments of $345.4 million, consisting of interest-bearing money market funds and securities issued by the U.S. Treasury. Due to the nature of our cash equivalents and investments, an immediate 100 basis point change in interest rates would not have a material effect on their fair market value.

Inflation generally affects us by increasing our cost of labor, clinical trial and manufacturing costs. We do not believe that inflation, interest rate changes or exchange rate fluctuations had a significant impact on our results of operations for any periods presented herein.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is recorded, processed, summarized and reported within the time period specified in the SEC's rules and forms, and that such information is accumulated and communicated to management including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. As of September 30, 2026, we carried out an evaluation under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of 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. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of September 30, 2026.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation required by Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the 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.

From time to time, we may become involved in litigation or other legal proceedings arising in the ordinary course of our business. We are not currently a party to any material litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, negative publicity, reputational harm and other factors.

Item 1A. Risk Factors.

Risk factors

You should carefully consider the risks described below, as well as the other information in this quarterly report on Form 10-Q, including our financial statements and related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," and in our other public filings in evaluating our business. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations and the market price of our common stock.

Risk factor summary

The following summarizes the most material risks that make an investment in our securities risky or speculative. If any of the following risks occur or persist, our business, financial condition, results of operations and prospects could be materially harmed and the market price of our common stock could significantly decline:

Risks related to our financial position and need for additional capital

- our limited operating history;
- our past and anticipated future net losses;
- uncertainty related to our ability to generate revenue and achieve profitability; and
- our need for substantial additional capital to finance our operations.

Risks related to development and commercialization of our product candidates

- our substantial dependence on our product candidates;
- our challenges in developing and commercializing additional product candidates;
- limitations in regulatory approval processes and product candidate approvals;
- our clinical trials that may fail to satisfactorily demonstrate safety and efficacy;
- our product candidates that may cause significant adverse events, toxicities or other undesirable side effects;
- potentially negative clinical trial results and challenges related to FDA, European Medicines Agency (EMA) and other regulatory requirements;
- deficiencies in audits and verification procedures of our clinical trial data;
- adverse effects due to third parties investigating the same product candidates as us in the same or different territories or indications;
- potential delays or difficulties in enrollment and/or maintenance of patients in clinical trials;
- the impact of global pandemics or other public health emergencies on our operations;
- our inability to develop effective companion diagnostic tests for our product candidates, if necessary;
- unexpected difficulties in developing our potential programs;
- profitability challenges related to our focus on developing our product candidates for particular indications;
- significant competition in the markets in which we operate;
- production difficulties encountered by our third-party manufacturers;
- changes in methods of product candidate manufacturing or formulation;
- market unacceptance of our product candidates in the medical community;
- limited market opportunities for our product candidates;
- our inability to augment our product pipeline through acquisitions and in-licenses;
- potential for unfavorable third-party coverage and reimbursement practices of our product candidates; and
- limitations of our product liability and insurance coverage.

Risks related to regulatory, legal and other compliance matters

- difficulties in our ability to obtain regulatory approval of our product candidates;
- FDA, EMA and other regulatory authorities' unacceptance of data from trials conducted outside their jurisdiction;
- our inability to obtain and maintain regulatory approval of our product candidates in various jurisdictions;

- burdens related to post-marketing regulatory requirements and oversight of our product candidates;
- impacts of regulatory authorities' enforcement of laws and regulations prohibiting promotion of off-label uses;
- challenges related to FDA approval of required companion diagnostic tests;
- challenges related to our ability to obtain Fast Track designation from the FDA for our product candidates;
- limitations to our ability to obtain orphan drug designation or maintain orphan drug exclusivity for our product candidates;
- any delays or barriers to secure approval for accelerated registration pathways;
- changes to current regulations and future legislation that impact us adversely;
- inadequate funding of regulatory agencies that may hinder timely product development or commercialization;
- potential misconduct or noncompliance with regulatory standards by our employees and certain third parties;
- limitations on our ability to use overseas vendors and service providers;
- any potential incompliance with U.S. healthcare laws and requirements;
- any potential incompliance with environmental, health and safety laws and regulations;
- any potential incompliance with anti-bribery, anti-corruption, export (including data export), trade sanctions and import laws or regulations; and
- any potential incompliance with enhanced trade tariffs, import restrictions, export restrictions, Chinese regulations or other trade barriers.

Risks related to employee matters, managing our growth and other risks related to our business

- challenges to our ability to attract and retain highly skilled executive officers and employees;
- difficulties in our ability to sell or market our product candidates;
- our potential inability to grow and manage growth of our organization;
- security or data privacy breaches or incidents impacting our internal systems or those of commercial third parties;
- rapid developments in AI technologies and related laws and regulations that could increase our costs and expose us to compliance, privacy and security risks, including through our vendors;
- natural disasters and other catastrophic events that may cause damage or disruption;
- the SEC civil enforcement action against one of our officers;
- our potential inability to use our net operating losses and tax credits to offset future taxable income;
- changes in tax laws and additional effort and expenses incurred as a result;
- complexities related to contracting with foreign third parties or international marketing of our product candidates;
- international military conflicts, and any resulting trade war, could result in increased manufacturing costs; and
- inflation may adversely affect us by increasing our costs.

Risks related to intellectual property

- challenges to our ability to protect our intellectual property and proprietary technologies;
- the potentially narrow scope of patent protection we receive;
- potential threats to our competitive advantage;
- our ability to operate without infringing intellectual property rights and claims of infringement by third parties;
- our potential inability to obtain or maintain rights to our product candidates through acquisitions and in-licenses;
- costs associated with protecting or enforcing our patents and our licensors' patents;
- intellectual property litigation that may lead to unfavorable publicity;
- unfavorable outcomes from necessary derivation proceedings;
- patent reform legislation and related uncertainties and costs;
- changes in U.S. and international intellectual property laws and related challenges;
- claims challenging ownership of our intellectual property, including internationally;
- patent terms and access to extensions that may not adequately protect our competitive position;
- our patent protection and dependence on compliance with various regulations;
- potentially limited name recognition in our markets that depend on protection of our trademarks and trade names;
- difficulties in protecting confidentiality of our trade secrets;
- risks to our intellectual property and confidential information arising from the use of AI, including generative AI;
- claims of wrongful disclosure of our confidential information or trade secrets;
- claims of wrongful hiring or disclosure or use of competitors' confidential information or trade secrets;
- our product development and commercialization rights that are subject to unfavorable terms and conditions of licensors;
- potential business relationship disruptions due to failure to comply with license agreement obligations;
- our patent protection and prosecution that may be dependent on third parties; and
- intellectual property discovered through government funding and potential limits on our exclusive rights.

Risks related to dependence on third parties

- our dependence on third-party suppliers and the loss of these third-party suppliers or their inability to supply us could harm our business;
- our dependence on third parties for production, preclinical studies and clinical trials of our product candidates;
- acquisitions or strategic partnerships that may increase capital requirements, dilution and debt;
- failure to establish commercially reasonable collaborations; and
- difficulties related to collaborations for development and commercialization of product candidates.

Risks related to the securities markets and ownership of our common stock

- market conditions and price that may limit your ability to sell our common stock;
- the volatility of our stock price;
- adverse or misleading industry analyst publications regarding our business or market;
- significant fluctuations in our operating results;
- principal stockholders and management that may exert significant control over stockholder approval matters;
- large sales of our stock that could cause our stock price to fall;
- failure of our internal controls that could impair our ability to produce accurate financial statements;
- limitations of our disclosure controls and procedures;
- liabilities related to securities litigation;
- our intention not to pay dividends;
- provisions of our certificate of incorporation and bylaws that may prevent or delay a change in control; and
- exclusive forum provisions in our bylaws that may limit stockholder ability to obtain a favorable judicial forum.

Risks related to our financial position and need for additional capital

We have a limited operating history, have not completed any large-scale or pivotal clinical trials, and have no products approved for commercial sale, which may make it difficult for you to evaluate our current business and likelihood of success and viability.

We are a clinical-stage biopharmaceutical company with a limited operating history upon which you can evaluate our business and prospects. We commenced operations in 2014, have no products approved for commercial sale and have not generated any revenue. Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We have initiated clinical trials for a limited number of our product candidates. To date, we have devoted substantially all of our resources to research and development activities, including with respect to the preclinical and clinical development of rinzimetostat, enozertinib and our other product candidates, in-licensing of external programs, business planning, establishing and maintaining our intellectual property portfolio, hiring personnel, raising capital and providing general and administrative support for these operations.

We have not yet demonstrated our ability to successfully complete any large-scale or pivotal clinical trials, obtain marketing approvals, manufacture a commercial-scale product or arrange for a third party to do so on our behalf, or conduct sales and marketing activities necessary for successful product commercialization. As a result, it may be more difficult for you to accurately predict our likelihood of success and viability than it could be if we had a longer operating history.

In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known and unknown factors and risks frequently experienced by clinical-stage biopharmaceutical companies in rapidly evolving fields. We also may need to transition from a company with a research and development focus to a company capable of supporting commercial activities. We have not yet demonstrated an ability to successfully overcome such risks and difficulties, or to make such a transition. If we do not adequately address these risks and difficulties or successfully make such a transition, our business will suffer.

We have incurred significant net losses since our inception, and we expect to continue to incur significant net losses for the foreseeable future.

We have incurred significant net losses since our inception, have not generated any revenue from product sales to date and have financed our operations principally through public offerings and private placements of our common stock and other derivative securities. Our net loss was $125.3 million for the nine months ended September 30, 2026, and as of September 30, 2026, we had an accumulated deficit of $817.6 million. We expect that it will be several years, if ever, before we have a commercialized product and generate revenue from product sales. Even if we succeed in receiving marketing approval for and commercializing one or more of our product candidates, we expect that we will continue to incur substantial research and development and other expenses in order to develop and market additional potential products.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an

adverse effect on our working capital, our ability to fund the development of our product candidates and our ability to achieve and maintain profitability and the performance of our stock.

Our ability to generate revenue and achieve profitability depends significantly on our ability to achieve several objectives relating to the development and commercialization of our product candidates.

Our business depends entirely on the successful development and commercialization of product candidates. We have no products approved for commercial sale and do not anticipate generating any revenue from product sales for the next several years, if ever. Our ability to generate revenue and achieve profitability depends significantly on our ability, or any current or future collaborator's ability, to achieve several objectives, including:

- successful and timely completion of preclinical and clinical development of rinzimetostat, enozertinib and our other future product candidates;
- establishing and maintaining relationships with CROs and clinical sites for the clinical development of rinzimetostat, enozertinib and our other future product candidates;
- timely receipt of marketing approvals from applicable regulatory authorities for any product candidates for which we successfully complete clinical development;
- developing an efficient and scalable manufacturing process for our product candidates, including obtaining finished products that are appropriately packaged for sale;
- establishing and maintaining commercially viable supply and manufacturing relationships with third parties that can provide adequate, in both amount and quality, products and services to support clinical development and meet the market demand for our product candidates, if approved;
- successful commercial launch following any marketing approval, including the development of a commercial infrastructure, whether in-house or with one or more collaborators;
- a continued acceptable safety profile following any marketing approval of our product candidates;
- commercial acceptance of our product candidates by patients, the medical community and third-party payors;
- satisfying any required post-marketing approval commitments to applicable regulatory authorities;
- identifying, assessing and developing new product candidates;
- obtaining, maintaining and expanding patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- protecting our rights in our intellectual property portfolio;
- defending against third-party interference or infringement claims, if any;
- entering into, on favorable terms, any collaboration, licensing or other arrangements that may be necessary or desirable to develop, manufacture or commercialize our product candidates;
- obtaining coverage and adequate reimbursement by third-party payors for our product candidates;
- addressing any competing therapies and technological and market developments; and
- attracting, hiring and retaining qualified personnel.

We may never be successful in achieving our objectives and, even if we do, may never generate revenue that is significant or large enough to achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would decrease the value of our company and could impair our ability to maintain or further our research and development efforts, raise additional necessary capital, grow our business and continue our operations.

We will require substantial additional capital to finance our operations. If we are unable to raise such capital when needed, or on acceptable terms, we may be forced to delay, reduce and/or eliminate one or more of our research and drug development programs or future commercialization efforts.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. Our operations have consumed substantial amounts of cash since inception, and we expect our expenses to increase in connection with our ongoing activities, particularly as we conduct clinical trials of, and seek marketing approval for our product candidates and advance our other programs. Even if one or more of the product candidates that we develop is approved for commercial sale, we anticipate incurring significant costs associated with sales, marketing, manufacturing and distribution activities. Our expenses could increase beyond expectations if we are required by the FDA, the EMA

or other regulatory agencies to perform clinical trials or preclinical studies in addition to those that we currently anticipate. Other unanticipated costs may also arise. Because the design and outcome of our planned and anticipated clinical trials are highly uncertain, we cannot reasonably estimate the actual amount of resources and funding that will be necessary to successfully complete the development and commercialization of any product candidate we develop. We are not permitted to market or promote our product candidates before we receive marketing approval from the FDA. Accordingly, we will need to obtain substantial additional funding in order to continue our operations.

As of September 30, 2026, we had $345.4 million in cash, cash equivalents and investments. Based on our current operating plan, we believe that our existing cash, cash equivalents and investments will be sufficient to fund our operations into the second half of 2028. Our estimate as to how long we expect our existing cash, cash equivalents, and investments, to be able to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

We will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources, which may dilute our stockholders or restrict our operating activities. We do not have any committed external source of funds. Adequate additional financing may not be available to us on acceptable terms, or at all. 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 may include liquidation or other preferences that adversely affect your rights as a stockholder. Debt financing may result in the imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through upfront payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Our failure to raise capital as and when needed or on acceptable terms would have a negative impact on our financial condition and our ability to pursue our business strategy, and we may have to delay, reduce the scope of, suspend or eliminate one or more of our research-stage programs, clinical trials or future commercialization efforts.

Market conditions and changing circumstances, some of which may be beyond our control, could impair our ability to access our existing cash, cash equivalents and investments and to timely pay key vendors and others.

Market conditions and changing circumstances, some of which may be beyond our control, could impair our ability to access our existing cash, cash equivalents and investments and to timely pay key vendors and others. For example, on March 10, 2023, Silicon Valley Bank (SVB), where we maintained certain accounts, was placed into receivership with the Federal Deposit Insurance Corporation (FDIC), which resulted in all funds held at SVB being temporarily inaccessible by SVB's customers. If other banks and financial institutions with whom we have banking relationships enter receivership or become insolvent in the future, we may be unable to access, and we may lose, some or all of our existing cash, cash equivalents and investments to the extent those funds are not insured or otherwise protected by the FDIC. In addition, in such circumstances we might not be able to timely pay key vendors and others. We regularly maintain cash balances that are not insured or are in excess of the FDIC's insurance limit. Any delay in our ability to access our cash, cash equivalents and investments (or the loss of some or all of such funds) or to timely pay key vendors and others could have a material adverse effect on our operations and cause us to need to seek additional capital sooner than planned.

Risks related to the development and commercialization of our product candidates

We are substantially dependent on the success of our product candidates, rinzimetostat and enozertinib. If we are unable to complete development of, obtain approval for and commercialize our product candidates for one or more indications in a timely manner, our business will be harmed.

We allocate the majority of our efforts and financial resources to the development of rinzimetostat and enozertinib. Our future success is dependent on our ability to timely and successfully complete clinical trials, obtain marketing approval for and successfully commercialize rinzimetostat and enozertinib.

These product candidates will require additional clinical development, expansion of manufacturing capabilities, marketing approval from government regulators, substantial investment and significant marketing efforts before we can generate any revenues from product sales. We are not permitted to market or promote rinzimetostat, enozertinib or any other product candidate, before we receive marketing approval from the FDA and comparable foreign regulatory authorities, and we may never receive such marketing approvals.

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

- the successful and timely completion of our ongoing clinical trials of our product candidates;
- addressing any delays in our clinical trials and additional costs incurred as a result of a global pandemic or other public health emergencies, including those resulting from preclinical study delays and adjustment to our clinical trials;

- the initiation and successful patient enrollment and completion of additional clinical trials of our product candidates on a timely basis;
- maintaining and establishing relationships with CROs and clinical sites for the clinical development of our product candidates both in the United States and internationally;
- the frequency and severity of adverse events in clinical trials;
- demonstrating efficacy, safety and tolerability profiles that are satisfactory to the FDA, EMA or any comparable foreign regulatory authority for marketing approval;
- the timely receipt of marketing approvals for our product candidates from applicable regulatory authorities;
- the timely identification, development and approval of companion diagnostic tests, if required;
- the extent of any required post-marketing approval commitments to applicable regulatory authorities;
- the maintenance of existing or the establishment of new supply arrangements with third-party drug product suppliers and manufacturers for clinical development and, if approved, commercialization of our product candidates;
- obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- the protection of our rights in our intellectual property portfolio;
- the successful launch of commercial sales following any marketing approval;
- a continued acceptable safety profile following any marketing approval;
- commercial acceptance by patients, the medical community and third-party payors; and
- our ability to compete with other therapies.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. If we are not successful with respect to one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our product candidates, which would materially harm our business. If we do not receive marketing approvals for our product candidates, we may not be able to continue our operations.

In addition to rinzimetostat and enozertinib, our prospects depend in part upon developing and commercializing additional product candidates, which may fail in development or suffer delays that adversely affect their commercial viability.

Our future operating results are dependent on our ability to successfully develop, obtain regulatory approval for and commercialize product candidates. All of our current programs other than rinzimetostat and enozertinib, are in research or preclinical development. A product candidate can unexpectedly fail at any stage of preclinical and/or clinical development. The historical failure rate for product candidates is high due to risks relating to safety, efficacy, clinical execution, changing standards of medical care and other unpredictable variables. The results from preclinical testing or early clinical trials of a product candidate may not be predictive of the results that will be obtained in later stage clinical trials of the product candidate.

The success of other product candidates we may develop will depend on many factors, including the following:

- generating sufficient data to support the initiation or continuation of clinical trials;
- addressing any delays in our research programs resulting from factors related to a global pandemic or other public health emergencies;
- obtaining regulatory permission to initiate clinical trials;
- contracting with the necessary parties to conduct clinical trials;
- successful enrollment of patients in, and the completion of, clinical trials on a timely basis;
- the timely manufacture of sufficient quantities of a product candidate for use in clinical trials; and
- adverse events in clinical trials.

Even if we successfully advance product candidates into clinical development, their success will be subject to all of the clinical, regulatory and commercial risks described elsewhere in this “Risk Factors” section. Accordingly, we cannot assure you that

we will ever be able to develop, obtain regulatory approval of, commercialize or generate significant revenue from any product candidates.

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

Obtaining approval by the FDA, EMA and other comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the type, complexity and novelty of the product candidates involved. 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, which may cause delays in the approval or the decision not to approve an application. For example, FDA's Oncology Center of Excellence initiated Project Optimus to reform the dose optimization and dose selection paradigm in oncology drug development and Project FrontRunner to help develop and implement strategies to support approvals in the early clinical setting, among other goals. How the FDA plans to implement these goals and their impact on specific clinical programs and the industry are unclear. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical or other data. Even if we eventually complete clinical testing and receive approval for our product candidates, the FDA, EMA and other comparable foreign regulatory authorities may approve our product candidates for a more limited indication or a narrower patient population than we originally requested or may impose other prescribing limitations or warnings that limit the product's commercial potential. We have not submitted for, or obtained, regulatory approval for any product candidate, and it is possible that none of our product candidates will ever obtain regulatory approval. Further, development of our product candidates and/or regulatory approval may be delayed for reasons beyond our control.

Applications for our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA, EMA or other comparable foreign regulatory authorities may disagree with the design, implementation or results of our clinical trials;
- the FDA, EMA or other comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, are only moderately effective or have undesirable or unintended side effects, toxicities or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval;
- the FDA, EMA or other comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- we may be unable to demonstrate to the FDA, EMA or other comparable foreign regulatory authorities that our product candidate's risk-benefit ratio for its proposed indication is acceptable;
- the FDA, EMA or other comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications or facilities of third-party manufacturers with which we contract for clinical and commercial supplies;
- the FDA, EMA or other comparable regulatory authorities may fail to approve companion diagnostic tests that are required for our product candidates; and
- the approval policies or regulations of the FDA, EMA or other 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 the results of clinical trials, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations and prospects.

The clinical trials of our product candidates may not demonstrate safety and efficacy to the satisfaction of the FDA, EMA or other comparable foreign regulatory authorities or otherwise produce positive results.

Before obtaining marketing approval from the FDA, EMA or other comparable foreign regulatory authorities for the sale of our product candidates, we must complete preclinical development and extensive clinical trials to demonstrate with substantial evidence the safety and efficacy of such product candidates. Clinical testing is expensive, difficult to design and implement, can take many years to complete and its ultimate outcome is uncertain. A failure of one or more clinical trials can occur at any stage of the process. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have

believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs.

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

- receipt of feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- negative or inconclusive clinical trial results that may require us to conduct additional clinical trials or abandon certain drug development programs;
- the number of patients required for clinical trials being larger than anticipated, enrollment in these clinical trials being slower than anticipated or participants dropping out of these clinical trials at a higher rate than anticipated;
- third-party contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- the suspension or termination of our clinical trials for various reasons, including non-compliance with regulatory requirements or a finding that our product candidates have undesirable side effects or other unexpected characteristics or risks;
- the cost of clinical trials of our product candidates being greater than anticipated;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates being insufficient or inadequate; and
- regulators revising the requirements for approving our product candidates.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing in a timely manner, if the results of these trials or tests are not positive or are only modestly positive or if there are safety concerns, we may incur unplanned costs, be delayed in seeking and obtaining marketing approval, if we receive such approval at all, receive more limited or restrictive marketing approval, be subject to additional post-marketing testing requirements or have the drug removed from the market after obtaining marketing approval.

Our product candidates may cause significant adverse events, toxicities or other undesirable side effects when used alone or in combination with other approved products or investigational new drugs that may result in a safety profile that could prevent regulatory approval, prevent market acceptance, limit their commercial potential or result in significant negative consequences.

If our product candidates are associated with undesirable side effects or have unexpected characteristics in preclinical studies or clinical trials when used alone or in combination with other approved products or investigational new drugs we may need to interrupt, delay or abandon their development or limit 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. Treatment-related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Any of these occurrences may prevent us from achieving or maintaining market acceptance of the affected product candidate and may harm our business, financial condition and prospects significantly.

Patients in our ongoing and planned clinical trials may in the future suffer other significant adverse events or other side effects not observed in our preclinical studies or previous clinical trials. Our product candidates may be used in populations for which safety concerns may be particularly scrutinized by regulatory agencies. Patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments, which can cause side effects or adverse events that are unrelated to our product candidate but may still impact the success of our clinical trials. The inclusion of critically ill patients in our clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the gravity of such patients' illnesses. For example, it is expected that some of the patients enrolled in our clinical trials will die or experience major clinical events either during the course of our clinical trials or after participating in such trials, which has occurred in the past.

If further significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to the clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of that product candidate altogether. We, the FDA, EMA, other comparable 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. Some potential therapeutics developed in the biotechnology industry that initially showed therapeutic promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining marketing approval, undesirable side effects may inhibit market acceptance due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition and prospects. Further, if any of our product candidates obtains marketing approval, toxicities associated with such product candidates previously not seen during clinical testing may also develop after such approval and

lead to a requirement to conduct additional clinical safety trials, additional contraindications, warnings and precautions being added to the drug label, significant restrictions on the use of the product or the withdrawal of the product from the market. We cannot predict whether our product candidates will cause toxicities in humans that would preclude or lead to the revocation of regulatory approval based on preclinical studies or early-stage clinical trials.

The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and the results of our clinical trials may not satisfy the requirements of the FDA, EMA or other comparable foreign regulatory authorities.

We will be required to demonstrate with substantial evidence through well-controlled clinical trials that our product candidates are safe and effective for use in a diverse population before we can seek marketing approvals for their commercial sale. Success in preclinical studies and early-stage clinical trials does not mean that future clinical trials will be successful. For instance, we do not know whether rinzimetostat or enozertinib will perform in current or future preclinical studies or future clinical trials as they have in prior preclinical studies or clinical trials. Product candidates in later-stage clinical trials may fail to demonstrate sufficient safety and efficacy to the satisfaction of the FDA, EMA and other comparable foreign regulatory authorities despite having progressed through preclinical studies and early-stage clinical trials. Regulatory authorities may also limit the scope of later-stage trials until we have demonstrated satisfactory safety, which could delay regulatory approval, limit the size of the patient population to which we may market our product candidates, or prevent regulatory approval.

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dose and dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. Patients treated with our product candidates may also be undergoing surgical, radiation and chemotherapy treatments and may be using other approved products or investigational new drugs, which can cause side effects or adverse events that are unrelated to our product candidates. As a result, assessments of efficacy can vary widely for a particular patient, and from patient to patient and site to site within a clinical trial. This subjectivity can increase the uncertainty of, and adversely impact, our clinical trial outcomes.

We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain approval to market any of our product candidates.

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

From time to time, we may publicly disclose preliminary, interim or topline data from our clinical trials. These interim updates are 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. For example, we may report tumor responses in certain patients that are unconfirmed at the time and which do not ultimately result in confirmed responses to treatment after follow-up evaluations. We 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 topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. In addition, we may report interim analyses of only certain endpoints rather than all endpoints. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Adverse changes between interim data and final data could significantly harm our business and prospects. Further, additional disclosure of interim data by us or by our competitors in the future could result in volatility in the price of our common stock.

In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically selected from a more extensive amount of available information. You or others may not agree with what we determine is the 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 product candidate or our business. If the preliminary or topline data that we report differ from late, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, any product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects.

Adverse results of clinical trials conducted by third parties investigating the same class of product candidates as us in the same or different territories or indications could adversely affect our development of such product candidate.

Lack of efficacy, adverse events, undesirable side effects or other adverse results may emerge in clinical trials conducted by third parties investigating the same class of product candidates as us in the same or different territories or indications. For example, pursuant to the Voronoi License Agreement, Voronoi retains the right to develop and commercialize the same compounds licensed to

us, after a certain period, as specified in the Voronoi License Agreement, including the compound we refer to as enozertinib, in the People's Republic of China, Hong Kong, Macau and Taiwan and, subject to certain restrictions, to collaborate with others for such development and commercialization. We do not have control over Voronoi's clinical trials or development program, and adverse findings from Voronoi's conduct of clinical trials could adversely affect our development of enozertinib or even the viability of enozertinib as a product candidate. We may be required to report Voronoi's adverse events or unexpected side effects to the FDA or comparable foreign regulatory authorities, which could, among other things, order us to cease further development of enozertinib.

Reports of adverse results, including side effects or safety concerns, in other companies' clinical trials of the same or similar class of products or of products sharing the same mechanism of action as our product candidates could delay or prevent us from obtaining regulatory approval for our product candidates or negatively impact public perception and market acceptance of our product candidates.

There are a number of clinical trials being conducted by other pharmaceutical companies involving compounds similar to, or potentially competitive with, our product candidates, including compounds of the same or similar class of products or sharing the same mechanism of action as our product candidates. Adverse results reported by these other companies in their clinical trials could delay or prevent our receipt of regulatory approval or our ability to commercialize our product candidates or could negatively impact public perception and market acceptance of our product candidates, which could harm our business, financial condition and results of operations.

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

We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials to such trial's conclusion as required by the FDA, EMA or other comparable foreign regulatory authorities. Often done through biomarker testing, patient identification and enrollment are significant factors in the timing of clinical trials. Our ability to identify and enroll eligible patients may be limited or may result in slower enrollment than we anticipate. If patient identification proves unsuccessful, we may have difficulty enrolling or maintaining patients appropriate for our product candidates. Similarly, enrollment in trials for our product candidates may be limited or slower than we anticipated if any required laboratory biomarker tests are not available due to shortages of staff or reagents.

Enrollment of patients in our clinical trials and maintaining patients in our ongoing clinical trials may be delayed or limited if our clinical trial sites limit their onsite staff or temporarily close as a result of a global pandemic or other public health emergencies. For instance, certain of our clinical trial sites in 2020 temporarily stopped or delayed enrolling new patients in response to the COVID-19 pandemic. In addition, patients may not be able to visit clinical trial sites for dosing or data collection purposes due to limitations on travel and physical distancing imposed or recommended by federal or state governments or patients' reluctance to visit the clinical trial sites during a pandemic. These factors could delay the anticipated readouts from our clinical trials and our regulatory submissions.

Patient enrollment may be affected if our competitors have ongoing clinical trials for programs that are under development for the same indications as our product candidates, and patients who would otherwise be eligible for our clinical trials instead enroll in clinical trials of our competitors' programs. Patient enrollment for our current or any future clinical trials may be affected by other factors, including:

- size and nature of the patient population;
- severity of the disease under investigation;
- availability and efficacy of approved drugs for the disease under investigation;
- patient eligibility criteria for the trial in question as defined in the protocol;
- perceived risks and benefits of the product candidate under study;
- clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new products that may be approved or other product candidates being investigated for the indications we are investigating;
- clinicians' willingness to screen their patients for biomarkers to indicate which patients may be eligible for enrollment in our clinical trials;
- patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment;
- proximity and availability of clinical trial sites for prospective patients; and

- the risk that patients enrolled in clinical trials will drop out of the trials before completion or, because they may be late-stage cancer patients, will not survive the full terms of the clinical trials.

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates and jeopardize our ability to obtain marketing approval for the sale of our product candidates. Furthermore, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining participation in our clinical trials through the treatment and any follow-up periods.

Our operations and financial results could be adversely impacted by global pandemics or other public health emergencies in the United States and the rest of the world.

We may experience disruptions that could severely impact our business and clinical trials due to global pandemics or other public health emergencies, including:

- interruption of key research and development or other activities related to any impact of disease contraction by or transmission among our employees, including those that are essential workers and work within our laboratory;
- delays or difficulties in enrolling patients in our clinical trials, or those conducted by third parties, and further incurrence of additional costs as a result of preclinical study and clinical trial delays and adjustments;
- challenges related to ongoing and increased operational expenses related to a global pandemic or other public health emergency;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- delays in the manufacturing supply chain, which could delay or otherwise impact procurement of materials for certain of our ongoing or planned clinical studies;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- limitations in resources that would otherwise be focused on the conduct of our business or our clinical trials, including because of sickness or the desire to avoid contact with large groups of people or as a result of government-imposed “shelter in place” or similar working restrictions;
- delays in receiving approval from local regulatory authorities to initiate our planned clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials;
- interruption in global shipping that may affect the transport of clinical trial materials, such as investigational drug product used in our clinical trials;
- changes in regulations as part of a response to a global pandemic or other public health emergency which may require us to change the ways in which our clinical trials are conducted, or to discontinue the clinical trials altogether, or which may result in unexpected costs;
- delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources or forced furlough of government or contractor personnel; and
- refusal of the FDA to accept data from clinical trials in affected geographies outside the United States.

We will continue to assess the impact that any public health emergencies may have on our ability to effectively conduct our business operations as planned and there can be no assurance that we will be able to avoid a material impact on our business from such public health emergencies or their consequences, including disruption to our business and downturns in business sentiment generally or in our industry.

To the extent a global pandemic or other public health emergency adversely affects our business, financial condition and operating results, it may also have the effect of heightening many of the risks described in this “Risk Factors” section.

If we are unable to successfully develop any required companion diagnostic tests for our product candidates, experience significant delays in doing so, or rely on third parties in the development of such companion diagnostic tests, we may not realize the full commercial potential of our product candidates.

We are exploring predictive biomarkers to determine patient selection for certain of our clinical trials and to evaluate whether a companion diagnostic test will be required for any of our product candidates. In general, the FDA expects to review and approve simultaneously NDA and pre-market approval submissions for a therapeutic and its companion diagnostic, respectively, so any delay in diagnostic approval could delay drug approval. On April 13, 2020, the FDA issued new guidance on developing and labeling companion diagnostics for a specific group of oncology therapeutic products, including recommendations to support a broader labeling claim rather than individual therapeutic products. In June 2023, the FDA announced a new voluntary pilot program through which drug manufacturers can provide to the FDA the diagnostic test performance information used to enroll patients into clinical trials for drug approval. Based on assessment of the performance information, the FDA will publish the minimum performance characteristics recommended for similar tests that may be used to select patients for treatment with the approved drug to help laboratories identify specific biomarkers for their development of laboratory-developed tests (LDTs), and to ensure more consistent performance of these tests for drug selection and improved cancer patient care. In May 2024, the FDA published a final rule that phases out its enforcement discretion for LDTs, unless exempt, and amends the FDA's regulations to make explicit that in vitro diagnostics are medical devices under the Federal Food, Drug, and Cosmetic Act, including when the manufacturer of the diagnostic product is a laboratory. The American Clinical Laboratory Association and a private laboratory have initiated litigation against the agency to challenge the implementation of this final rule. On March 31, 2025, U.S. District Court in Texas ruled that FDA exceeded its authority and vacated and set aside this LDT final rule in its entirety. We will continue to evaluate the impact of this litigation, as well as any future lawsuits brought against the FDA, and future legislative and administration actions on our companion diagnostic development and strategy. Future guidance documents from the FDA and other regulatory authorities may impact our development of a companion diagnostic for our product candidates and result in delays in regulatory approval. To the extent other approved diagnostics are able to broaden their labeling claims to include our approved drug products, we may be forced to abandon any of our companion diagnostic development plans or we may not be able to compete effectively upon approval, which could adversely impact our ability to generate revenue from the sale of our approved products and our business operations.

We may rely on third parties for the design, development and manufacture of companion diagnostic tests for our product candidates that require such tests. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. If we or such third parties are unable to successfully develop companion diagnostics, or experience delays in doing so, we may be unable to enroll enough patients for our current and planned clinical trials, the development of our product candidates may be adversely affected or we may not obtain marketing approval, and we may not realize the full commercial potential of our product candidates.

We may develop our programs in combination with other therapies, which exposes us to additional risks.

We may develop our programs in combination with one or more currently approved cancer therapies or therapies in development. Patients may not be able to tolerate our product candidates in combination with other therapies or dosing of our product candidates in combination with other therapies may have unexpected consequences. Even if any of our product candidates were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA, EMA or other comparable foreign regulatory authorities could revoke approval of the therapy used in combination with any of our product candidates, or safety, efficacy, manufacturing or supply issues could arise with these existing therapies. In addition, it is possible that existing therapies with which our product candidates are approved for use could themselves fall out of favor or be relegated to later lines of treatment. This could result in the need to identify other combination therapies for our product candidates or our own products being removed from the market or being less successful commercially.

We may also evaluate our product candidates in combination with one or more other cancer therapies that have not yet been approved for marketing by the FDA, EMA or comparable foreign regulatory authorities. We will not be able to market and sell any product candidate in combination with any such unapproved cancer therapies that do not ultimately obtain marketing approval.

If the FDA, EMA or other comparable foreign regulatory authorities do not approve or revoke their approval of these other therapies, or if safety, efficacy, commercial adoption, manufacturing or supply issues arise with the therapies we choose to evaluate in combination with our product candidates, we may be unable to obtain approval of or successfully market any one or all of the product candidates we develop.

Additionally, if the third-party providers of therapies or therapies in development used in combination with our product candidates are unable to produce sufficient quantities for clinical trials or for commercialization of our product candidates, or if the costs of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

We have limited resources and are focusing our efforts on developing rinzimetostat and enozertinib. As a result, we may fail to capitalize on other indications or product candidates that may ultimately have proven to be more profitable.

We are focusing our resources and efforts on developing rinzimetostat and enozertinib. As a result, because we have limited resources, we may forgo or delay pursuit of opportunities for other indications or with other product candidates that may have greater commercial potential. For example, we completed a Phase 1b trial of ORIC-533 as a single-agent, in patients with relapsed/refractory multiple myeloma, and intend to evaluate strategic partnerships to develop ORIC-533 in combination with other immune-based antimyeloma therapies. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future research and development activities may not yield any commercially viable drugs. If we do not accurately evaluate the commercial potential or target markets for rinzimetostat, enozertinib or any of our other future programs, we may relinquish valuable rights to that product candidate or program through collaboration, licensing or other strategic arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate or program.

We face significant competition, and if our competitors develop and market technologies or products more rapidly than we do or that are more effective, safer or less expensive than the products we develop, our commercial opportunities will be negatively impacted.

The biotechnology and pharmaceutical industries are characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates.

Our competitors have developed, are developing or may develop products, product candidates and processes competitive with our product candidates. Any product candidates that we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of conditions for which we may attempt to develop product candidates. In addition, our products may need to compete with drugs physicians use off-label to treat the indications for which we seek approval. This may make it difficult for us to replace existing therapies with our products.

In particular, there is intense competition in the field of oncology. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies, emerging and start-up companies, universities and other research institutions. We also compete with these organizations to recruit management, scientists and clinical development personnel, which could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites, enrolling subjects for clinical trials and in identifying and in-licensing new product candidates. We expect to face competition from existing products and products in development for each of our programs.

For rinzimetostat, we are aware of several companies developing inhibitors against PRC2 via EZH2 inhibition that are currently in clinical trials, including Ipsen, Novartis, Daiichi Sankyo, Pfizer, Shanghai HaiHe Pharmaceutical, Treeline Biosciences in collaboration with Jiangsu HengRui Medicine Co., Evopoint Biosciences and Hanmi Pharmaceutical. To our knowledge, Ascentage Pharma has an allosteric PRC2 inhibitor in clinical trials for patients with cancer.

For enozertinib, we are aware that Johnson & Johnson and Dizal Pharmaceuticals have FDA-approved products for patients with EGFR exon 20 insertion mutations. We are also aware of several companies developing small molecule inhibitors against EGFR exon 20 insertion mutations and EGFR atypical mutations that are currently in clinical trials, including Cullinan Therapeutics in collaboration with Taiho Pharmaceutical, ArriVent BioPharma in collaboration with Allist Pharmaceuticals, Black Diamond Therapeutics, Scorpion Therapeutics in collaboration with Pierre Fabre, BlossomHill Therapeutics, Avistone Biotechnology, BeBetter Med, Suzhou Puhe Pharmaceutical Technology Co. and Yuhan Corporation.

Many of these current and potential competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources, and commercial expertise than we do. Large pharmaceutical and biotechnology companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and manufacturing biotechnology products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical and biotechnology companies may also invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make the product candidates that we develop obsolete. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies, as well as in acquiring technologies complementary to, or necessary for, our programs. As a result of all of these factors, our competitors may obtain approval from the FDA, EMA or other comparable foreign regulatory authorities or develop or commercialize products in our field before we do. In

addition, we are facing increasing competition from companies utilizing artificial intelligence, or AI, in their research and development efforts or other business processes, which could create a competitive advantage that we would find difficult to match. Although we have made a third-party generative AI platform available to our employees for general business use, our use of AI-based platforms or tools in the discovery and development of our product candidates is limited, while many of our competitors have begun utilizing AI tools to aid in the development of pharmaceutical products. Our more limited use of AI in research and development may put us at a competitive disadvantage in comparison to competitors who currently use them in the development of pharmaceutical products or other business processes, which could impair our ability to compete effectively and adversely affect our results of operations. As we expand our use of AI, we may be subject to significant risks related to developing and deploying AI platforms or tools, and there can be no assurance that the use of AI will enhance the development of our product candidates or be beneficial to our business. For a discussion of these and other risks related to AI, see the risk factors in this section under "Risks related to employee matters, managing our growth and other risks related to our business" and "Risks related to our intellectual property."

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer side effects, are more convenient, have a broader label, are marketed more effectively, are more widely reimbursed or are less expensive than any products that we may develop. Our competitors also may obtain marketing approval from the FDA, EMA or other comparable foreign regulatory authorities 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. Even if the product candidates we develop achieve marketing approval, they may be priced at a significant premium over competitive products if any have been approved by then, resulting in reduced competitiveness. Technological advances or products developed by our competitors may render our technologies or product candidates obsolete, less competitive or uneconomical. If we are unable to compete effectively, our opportunity to generate revenue from the sale of our products we may develop, if approved, could be adversely affected.

The manufacture of drugs is complex, and our third-party manufacturers may encounter difficulties in production or supply chain. If any of our third-party manufacturers encounter such difficulties, our ability to provide adequate supply of our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.

Manufacturing drugs, especially in large quantities, is complex and may require the use of innovative technologies. Each lot of an approved drug product must undergo thorough testing for identity, strength, quality, purity and potency. Manufacturing drugs requires facilities specifically designed for and validated for this purpose, as well as sophisticated quality assurance and quality control procedures. Slight deviations anywhere in the manufacturing process, including filling, labeling, packaging, storage and shipping and quality control and testing, may result in lot failures, product recalls or spoilage. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our manufacturer, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business. The use of biologically derived ingredients can also lead to allegations of harm, including infections or allergic reactions, or closure of product facilities due to possible contamination. Additionally, we may experience supply chain disruptions or slowdowns, including related manufacturing, logistics, labor supply or other factors related to the supply chains of products and materials that we use. If our third-party manufacturers are unable to produce sufficient quantities for clinical trials or for commercialization as a result of these challenges, or otherwise, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and growth prospects.

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

As product candidates progress through preclinical and clinical trials to marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize yield and manufacturing batch size, minimize costs and achieve consistent quality and results. Such changes carry the risk that they will not achieve these intended objectives. Any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the altered materials. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates, if approved, and generate revenue.

Our product candidates may not achieve adequate market acceptance among physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

Even if our product candidates receive regulatory approval, they may not gain adequate market acceptance among physicians, patients, third-party payors and others in the medical community. The degree of market acceptance of any of our approved product candidates will depend on a number of factors, including:

- the efficacy and safety profile as demonstrated in clinical trials compared to alternative treatments;
- the timing of market introduction of the product candidate as well as competitive products;
- the clinical indications for which a product candidate is approved;
- restrictions on the use of product candidates in the labeling approved by regulatory authorities, such as boxed warnings or contraindications in labeling, or a Risk Evaluation and Mitigation Strategy (REMS), if any, which may not be required of alternative treatments and competitor products;
- the potential and perceived advantages of our product candidates over alternative treatments;
- the cost of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement by third-party payors, including government authorities;
- the availability of an approved product candidate for use as a combination therapy;
- relative convenience and ease of administration;
- the willingness of the target patient population to try new therapies and undergo required diagnostic screening to determine treatment eligibility and of physicians to prescribe these therapies and diagnostic tests;
- the effectiveness of sales and marketing efforts;
- unfavorable publicity relating to our product candidates; and
- the approval of other new therapies for the same indications.

If any of our product candidates are approved but do not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors and patients, we may not generate or derive sufficient revenue from that product candidate and our financial results could be negatively impacted.

The market opportunities for our product candidates we develop, if approved, may be limited to certain smaller patient subsets.

Cancer therapies are sometimes characterized as first-line, second-line or third-line, and the FDA often approves new therapies initially only for a particular line of use. When cancer is detected early enough, first-line therapy, such as chemotherapy, hormone therapy, surgery, radiation therapy or a combination of these, is sometimes adequate to cure the cancer or prolong life without a cure. Second- and third-line therapies are administered to patients when prior therapy is not effective. There is no guarantee that product candidates we develop, even if approved, would be approved for first-line therapy, and, prior to any such approvals, we may have to conduct additional clinical trials that may be costly, time-consuming and subject to risk.

The number of patients who have the cancers we are targeting may turn out to be lower than expected. Additionally, the potentially addressable patient population for the product candidates we develop may be limited or may not be amenable to treatment with our product candidates. Regulatory approval may limit the market of a product candidate to target patient populations when biomarker-driven identification and/or highly specific criteria related to the stage of disease progression, or progression on or after certain therapies, are utilized.

Even if we obtain significant market share for any approved product, if the potential target populations are small, we may never achieve profitability without obtaining marketing approval for additional indications.

We may not be successful in augmenting our product pipeline through acquisitions and in-licenses.

We believe that accessing external innovation and expertise is important to our success; and while we plan to leverage our leadership team's prior business development experience as we evaluate potential in-licensing and acquisition opportunities to further expand our portfolio, we may not be able to identify suitable licensing or acquisition opportunities, and even if we do, we may not be able to successfully secure such licensing and acquisition opportunities. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire

third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment, or at all. If we are unable to successfully license or acquire additional product candidates to expand our portfolio, our pipeline, competitive position, business, financial condition, results of operations, and prospects may be materially harmed.

Any product candidates we develop may become subject to unfavorable third-party coverage and reimbursement practices, as well as pricing regulations.

The availability and extent of coverage and adequate reimbursement by third-party payors, including government health administration authorities, private health coverage insurers, managed care organizations and other third-party payors is essential for most patients to be able to afford expensive treatments. Sales of any of our product candidates that receive marketing approval will depend substantially, both in the United States and internationally, on the extent to which the costs of such product candidates will be covered and reimbursed by third-party payors. If reimbursement is not available, or is available only to limited levels, we may not be able to successfully commercialize our product candidates. Even if coverage is provided, the approved reimbursement amount may not be high enough to allow us to establish or maintain pricing sufficient to realize an adequate return on our investment. Coverage and reimbursement may impact the demand for, or the price of, any product candidate for which we obtain marketing approval. If coverage and reimbursement are not available or reimbursement is available only to limited levels, we may not successfully commercialize any product candidate for which we obtain marketing approval.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, for example, principal decisions about reimbursement for new products are typically made by the Centers for Medicare & Medicaid Services (CMS), an agency within the U.S. Department of Health and Human Services (HHS). CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare, and private third-party payors often follow CMS's decisions regarding coverage and reimbursement to a substantial degree. However, one third-party payor's determination to provide coverage for a product candidate does not assure that other payors will also provide coverage for the product candidate. As a result, the coverage determination process is often time-consuming and costly. This process will require us to provide scientific and clinical support for the use of our products to each third-party payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance.

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. Further, such payors are increasingly challenging the price, examining the medical necessity and reviewing the cost effectiveness of medical product candidates. There may be especially significant delays in obtaining coverage and reimbursement for newly approved drugs. Third-party payors may limit coverage to specific product candidates on an approved list, known as a formulary, which might not include all FDA-approved drugs for a particular indication. We may need to conduct expensive pharmaco-economic studies to demonstrate the medical necessity and cost effectiveness of our products. Nonetheless, our product candidates may not be considered medically necessary or cost effective. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be.

Most significantly, in August 2022, then-President Biden signed the Inflation Reduction Act of 2022 (IRA) into law. 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 2024); and replaces the Part D coverage gap discount program with a new discounting program (beginning in 2025). The IRA permits the Secretary of the HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years. On August 29, 2023, HHS announced the list of the first ten drugs that will be subject to price negotiations. HHS has issued and will continue to issue and update guidance implementing the IRA, although the Medicare drug price negotiation program is currently subject to legal challenges. While the impact of the IRA on the pharmaceutical industry cannot yet be fully determined, it is likely to be significant.

Further, in June 2024, the U.S. Supreme Court overruled the Chevron doctrine, which gives deference to regulatory agencies' statutory interpretations in litigation against federal government agencies, such as the FDA, where the law is ambiguous. This landmark Supreme Court decision may invite various stakeholders to bring lawsuits against the FDA and other federal agencies to challenge longstanding decisions and policies, which could lead to uncertainty in the industry and disrupt federal agencies' normal operations. Changes to the leadership of federal agencies like HHS, CMS and FDA under the current administration can lead to new policies and regulations that can have a material impact on our industry and business operations.

In addition, companion diagnostic tests require coverage and reimbursement separate and apart from the coverage and reimbursement for their companion pharmaceutical or biological products. Similar challenges to obtaining coverage and reimbursement, applicable to pharmaceutical or biological products, will apply to companion diagnostics. Additionally, if any companion diagnostic provider is unable to obtain reimbursement or is inadequately reimbursed, that may limit the availability of such companion diagnostic, which would negatively impact prescriptions for our product candidates, if approved.

Outside the United States, the commercialization of therapeutics is generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of therapeutics such as our product candidates. In many countries, particularly the countries of the EU, medical product prices are subject to varying price control mechanisms as part of national health systems. In these countries, pricing negotiations with governmental authorities can take considerable time after a product receives marketing approval. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost-effectiveness of our product candidate to other available therapies. In general, product prices under such systems are substantially lower than in the United States. Other countries allow companies to fix their own prices for 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 product candidates. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits.

If we are unable to establish or sustain coverage and adequate reimbursement for any product candidates from third-party payors, the adoption of those products and sales revenue will be adversely affected, which, in turn, could adversely affect the ability to market or sell those product candidates, if approved. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Our business entails a significant risk of product liability and if we are unable to obtain sufficient insurance coverage such inability could have an adverse effect on our business and financial condition.

Our business exposes us to significant product liability risks inherent in the development, testing, manufacturing and marketing of therapeutic treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in an FDA, EMA or other regulatory authority investigation of the safety and effectiveness of our products, our manufacturing processes and facilities or our marketing programs. FDA, EMA or other regulatory authority investigations could potentially lead to a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our products, injury to our reputation, costs to defend the related litigation, a diversion of management's time and our resources and substantial monetary awards to trial participants or patients. We currently have product liability insurance that we believe is appropriate for our stage of development and may need to obtain higher levels prior to marketing any of our product candidates, if approved. Any insurance we have or may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could have an adverse effect on our business and financial condition.

Information obtained from expanded access studies may not reliably predict the efficacy of our product candidates in our clinical trials and may lead to adverse events that could materially harm our business.

Expanded access studies that we may support are likely to be uncontrolled, carried out by individual investigators and not conducted in strict compliance with good clinical practices (GCPs), all of which can lead to a treatment effect which may differ from that in our clinical trials. These studies provide only anecdotal evidence of efficacy for regulatory review. Patient data from these studies are not designed to be aggregated or reported as study results and may be highly variable.

Expanded access studies provide supportive safety information for regulatory review. Physicians conducting these studies may use our product candidates in a manner inconsistent with the protocol, including in children and in individuals with conditions beyond those being studied in our clinical trials. In addition, patients who receive access to unapproved drugs through expanded access studies have life-threatening illnesses and generally have exhausted all other available therapies. The risk for serious adverse events in this patient population is high and may be attributed to our product candidates. This could have a negative impact on the safety profile of our product candidates, which could cause significant delays or an inability to successfully commercialize our product candidates and could materially harm our business.

Risks related to regulatory approval and other legal compliance matters

We may be unable to obtain U.S. or foreign regulatory approval and, as a result, may be unable to commercialize our product candidates.

Our product candidates are and will continue to be subject to extensive governmental regulations relating to, among other things, research, testing, development, manufacturing, safety, efficacy, approval, recordkeeping, reporting, labeling, storage, packaging, advertising and promotion, pricing, marketing and distribution of drugs. Rigorous preclinical testing and clinical trials and an extensive regulatory approval process must be successfully completed in the United States and in many foreign jurisdictions before a new drug can be approved for marketing. Satisfaction of these and other regulatory requirements is costly, time consuming, uncertain and subject to unanticipated delays. We cannot provide any assurance that any product candidate we may develop will progress through required clinical testing and obtain the regulatory approvals necessary for us to begin selling them.

We have not conducted, managed or completed large-scale or pivotal clinical trials nor managed the regulatory approval process with the FDA or any other regulatory authority. The time required to obtain approvals from the FDA and other regulatory authorities is unpredictable and requires successful completion of extensive clinical trials which typically takes many years, depending upon the type, complexity and novelty of the product candidate. The standards that the FDA and its foreign counterparts use when evaluating clinical trial data can, and often does, change during drug development, which makes it difficult to predict with any certainty how they will be applied. We may also encounter unexpected delays or increased costs due to new government regulations, including future legislation or administrative action, or changes in FDA policy during the period of drug development, clinical trials and FDA regulatory review.

Any delay or failure in seeking or obtaining required approvals would have a material and adverse effect on our ability to generate revenue from any particular product candidates we are developing and for which we are seeking approval. Furthermore, any regulatory approval to market a drug may be subject to significant limitations on the approved uses or indications for which we may market, promote and advertise the drug or the labeling or other restrictions. In addition, the FDA has the authority to require a REMS plan as part of approving an NDA, or after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. These requirements or restrictions might include limiting prescribing to certain physicians or medical centers that have undergone specialized training, limiting treatment to patients who meet certain safe-use criteria and requiring treated patients to enroll in a registry. These limitations and restrictions may significantly limit the size of the market for the drug and affect reimbursement by third-party payors.

We are also subject to numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries, and generally includes all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval may differ from that required to obtain FDA approval.

Further, under the new leadership at the HHS under the current administration, departures and retirements of high-profile regulators at the FDA, layoffs due to the reduction in force initiative, government shutdown, and a lapse in U.S. government appropriations may impact the normal operations at the FDA as well as other federal agencies, which can materially delay our timelines. FDA may lack adequate staff and resources to meet current review, approval, and inspection schedules, which could delay our anticipated timelines. Recent developments at the FDA include implementation of Elsa, a generative AI tool, across all centers at the agency, announcement of a plan to phase out animal testing for monoclonal antibodies and certain other drugs, and the announcement of a new Commissioner's National Priority Voucher program to companies supporting certain U.S. national health priorities and interests. FDA has also increased its scrutiny of foreign drug manufacturing facilities and other contractors based in China, especially with respect to the transfer of biological materials, genetic data, and other health data of American patients to parties located in China. Further, FDA's "real-time" release of newly issued Complete Response Letters associated with withdrawn or abandoned applications, if applicable to any of our product candidates, can materially impact our competitive advantage and intellectual property. It is unclear how our industry and our clinical programs will be impacted by policies and regulations implemented under the current administration and the new FDA commissioner or other executive orders. There is significant uncertainty in the industry and how federal agencies like the FDA will change in the coming years under the current administration. To the extent changes lead to disruptions in FDA's operations, including changes resulting from executive orders; freeze on hiring, federal funding for research, and external communications; layoffs; government shutdown; return-to-office policies, and changes in funding for certain programs at the FDA, correspondence and regulatory review processes with the FDA may be materially delayed.

The FDA, EMA and other comparable foreign regulatory authorities may not accept data from trials conducted in locations outside of their jurisdiction.

We have conducted and still conduct clinical trials in the United States. We may choose to conduct additional clinical trials internationally, including our current Phase 1b trials in Asia, Australia and Europe. The acceptance of study data by the FDA, EMA or other comparable foreign regulatory authority from clinical trials conducted outside of their respective jurisdictions may be subject to certain conditions. In cases where data from United States clinical trials are intended to serve as the basis for marketing approval in

the foreign countries outside the United States, the standards for clinical trials and approval may be different. There can be no assurance that any United States or foreign regulatory authority would accept data from trials conducted outside of its applicable jurisdiction. If the FDA, EMA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

Brexit and uncertainty in the regulatory framework as well as future legislation in the United Kingdom (UK), EU and other jurisdictions can lead to disruption in the execution of international multi-center clinical trials, the monitoring of adverse events through pharmacovigilance programs, the evaluation of the benefit-risk profiles of new medicinal products, and determination of marketing authorization across different jurisdictions. Uncertainty in the regulatory framework could also result in disruption to the supply and distribution as well as the import/export both of active pharmaceutical ingredients and finished product. Such a disruption could create supply difficulties for ongoing clinical trials. The cumulative effects of the disruption to the regulatory framework, uncertainty in future regulation, and changes to existing regulations may increase our development lead time to marketing authorization and commercialization of products in the EU and/or the UK and increase our costs. We cannot predict the impact of such changes and future regulation on our business or the results of our operations.

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

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

Obtaining foreign regulatory approvals and establishing and maintaining compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we or any future collaborator fail to comply with the regulatory requirements in international markets or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of our potential product candidates will be harmed.

Even if our product candidates receive regulatory approval, they will be subject to significant post-marketing regulatory requirements and oversight.

Any regulatory approvals that we may receive for our product candidates will require the submission of reports to regulatory authorities and on-going surveillance to monitor the safety and efficacy of the product candidate, may 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 and regulatory inspection. For example, the FDA may require a REMS in order to approve our product candidates, which could entail 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 the FDA finds that the clinical data used to support approval do not sufficiently represent the diversity of the real-world patient population, the FDA may require additional data on underrepresented populations post-approval, including as a post-marketing requirement, or the FDA may enter into a written agreement with the applicant to collect additional data as a post-marketing commitment. In addition, if the FDA or foreign regulatory authorities approve our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, 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, as well as on-going compliance with current good manufacturing practices (cGMPs) and GCPs for any clinical trials that we conduct post-approval. In addition, 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 regulations and standards. 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. In addition, failure to comply with FDA, EMA and

other comparable foreign regulatory requirements may subject our company to administrative or judicially imposed sanctions, including:

- delays in or the rejection of product approvals;
- restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials;
- restrictions on the products, manufacturers or manufacturing process;
- warning or untitled letters;
- civil and criminal penalties;
- injunctions;
- suspension or withdrawal of regulatory approvals;
- product seizures, detentions or import bans;
- voluntary or mandatory product recalls and publicity requirements;
- total or partial suspension of production; and
- imposition of restrictions on operations, including costly new manufacturing requirements.

Moreover, the FDA strictly regulates the promotional claims that may be made about drug products. In particular, a product may not be promoted for uses that are not approved by the FDA as reflected in the product's approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant civil, criminal and administrative penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates, if approved, and generate revenue.

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

If any of our product candidates are approved and we are found to have improperly promoted off-label uses of those products, we may become subject to significant liability. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as our product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product's approved labeling. 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 FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of our product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition.

If we are required by the FDA to obtain approval of a companion diagnostic test in connection with approval of any of our product candidates or a group of therapeutic products, and we do not obtain or we face delays in obtaining FDA approval of a diagnostic test, we will not be able to commercialize the product candidate and our ability to generate revenue will be materially impaired.

In connection with the development of our potential product candidates, we may develop or work with collaborators to develop or obtain access to companion diagnostic tests to identify patient subsets within a disease category who may derive selective and meaningful benefit from our programs. Such companion diagnostics would be used during our clinical trials as well as in connection with the commercialization of our product candidates. To be successful in developing and commercializing product candidates in combination with these companion diagnostics, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. According to FDA guidance, if the FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, the FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic is not also approved or cleared at the same time the product candidate is approved. To date, the FDA has required marketing approval of all companion diagnostic tests for cancer therapies. Various foreign regulatory authorities also regulate in vitro companion diagnostics as medical devices and, under those regulatory frameworks, will likely require the conduct of clinical trials to demonstrate the safety and effectiveness of our current diagnostics and any future diagnostics we may develop, which we expect will require separate regulatory clearance or approval prior to commercialization.

The approval of a companion diagnostic as part of the therapeutic product's labeling limits the use of the therapeutic product to only those patients who express certain biomarkers or the specific genetic alteration that the companion diagnostic was developed to detect. If the FDA, EMA or a comparable regulatory authority requires approval of a companion diagnostic for any of our product

candidates, whether before or concurrently with approval of the product candidate, we, and/or future collaborators, may encounter difficulties in developing and obtaining approval for these companion diagnostics. Any delay or failure by us or third-party collaborators to develop or obtain regulatory approval of a companion diagnostic could delay or prevent approval or continued marketing of our related product candidates. Further, in April 2020, the FDA issued new guidance on developing and labeling companion diagnostics for a specific group of oncology therapeutic products, including recommendations to support a broader labeling claim rather than individual therapeutic products. In May 2024, the FDA published a final rule that phases out its enforcement discretion for LDTs, unless exempt, and amends the FDA's regulations to make explicit that in vitro diagnostics are medical devices under the Federal Food, Drug, and Cosmetic Act, including when the manufacturer of the diagnostic product is a laboratory. On March 31, 2025, U.S. District Court in Texas ruled that FDA exceeded its authority and vacated and set aside this LDT final rule in its entirety. The full impact of this litigation as well as any future lawsuits brought against the FDA, and future legislative and administration actions on our companion diagnostic development and strategy is unclear. To the extent other approved diagnostics are able to broaden their labeling claims to include our approved drug products, we may be forced to abandon our companion diagnostic development plans or we may not be able to compete effectively upon approval, which could adversely impact our ability to generate revenue from the sale of our approved products and our business operations. Additionally, we may rely on third parties for the design, development and manufacture of companion diagnostic tests for our product candidates that may require such tests. If we enter into such collaborative agreements, we will be dependent on the sustained cooperation and effort of our future collaborators in developing and obtaining approval for these companion diagnostics. It may be necessary to resolve issues such as selectivity/specificity, analytical validation, reproducibility, or clinical validation of companion diagnostics during the development and regulatory approval processes. Moreover, even if data from preclinical studies and early clinical trials appear to support development of a companion diagnostic for a product candidate, data generated in later clinical trials may fail to support the analytical and clinical validation of the companion diagnostic. We and our future collaborators may encounter difficulties in developing, obtaining regulatory approval for, manufacturing and commercializing companion diagnostics similar to those we face with respect to our product candidates themselves, including issues with achieving regulatory clearance or approval, production of sufficient quantities at commercial scale and with appropriate quality standards, and in gaining market acceptance. If we are unable to successfully develop companion diagnostics for our product candidates, or experience delays in doing so, the development of our product candidates may be adversely affected, our product candidates may not obtain marketing approval, and we may not realize the full commercial potential of any of our product candidates that obtain marketing approval. As a result, our business, results of operations and financial condition could be materially harmed. In addition, a diagnostic company with whom we contract may decide to discontinue selling or manufacturing the companion diagnostic test that we anticipate using in connection with development and commercialization of product candidates or our relationship with such diagnostic company may otherwise terminate. We may not be able to enter into arrangements with another diagnostic company to obtain supplies of an alternative diagnostic test for use in connection with the development and commercialization of our product candidates or do so on commercially reasonable terms, which could adversely affect and/or delay the development or commercialization of our product candidates.

We may seek Fast Track designation from the FDA for one or more of our product candidates. Even if one or more of our product candidates receive Fast Track designation, we may be unable to obtain or maintain the benefits associated with the Fast Track designation.

Fast Track designation is designed to facilitate the development and expedite the review of therapies for serious conditions and fill an unmet medical need. Programs with Fast Track designation may benefit from early and frequent communications with the FDA, potential priority review and the ability to submit a rolling application for regulatory review. Fast Track designation applies to both the product candidate and the specific indication for which it is being studied. If any of our product candidates receive Fast Track designation but do not continue to meet the criteria for Fast Track designation, or if our clinical trials are delayed, suspended or terminated, or put on clinical hold due to unexpected adverse events or issues with clinical supply, we will not receive the benefits associated with the Fast Track program. Furthermore, Fast Track designation does not change the standards for approval. Fast Track designation alone does not guarantee qualification for the FDA's priority review procedures.

We may not be able to obtain orphan drug designation or obtain or maintain orphan drug exclusivity for our product candidates and, even if we do, that exclusivity may not prevent the FDA, EMA or other comparable foreign regulatory authorities, from approving competing products.

Regulatory authorities in some jurisdictions, including the United States and the EU, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. Our target indications may include diseases with large patient populations or may include orphan indications. However, there can be no assurances that we will be able to obtain orphan designations for our product candidates.

In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In addition, if a product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan drug

exclusivity. Orphan drug exclusivity in the United States provides that the FDA may not approve any other applications, including a full NDA, to market the same drug for the same indication for seven years, except in limited circumstances. The applicable exclusivity period is 10 years in Europe. The European exclusivity period can be reduced to six years if a drug no longer meets the criteria for orphan drug designation or if the drug is sufficiently profitable so that market exclusivity is no longer justified.

Even if we obtain orphan drug designation for a product candidate, we may not be able to obtain or maintain orphan drug exclusivity for that product candidate. We may not be the first to obtain marketing approval of any product candidate for which we have obtained orphan drug designation for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to ensure that we will be able to manufacture sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties may be approved for the same condition. Even after an orphan drug is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care or the manufacturer of the product with orphan exclusivity is unable to maintain sufficient product quantity. In response to the court decision in *Catalyst Pharms., Inc. v. Becerra*, 14 F.4th 1299 (11th Cir. 2021), in January 2023, the FDA published a notice in the Federal Register to clarify that while the agency complies with the court's order in *Catalyst*, the FDA intends to continue to apply its longstanding interpretation of the regulations to matters outside of the scope of the *Catalyst* order – that is, the agency will continue tying the scope of orphan-drug exclusivity to the uses or indications for which a drug is approved, which permits other sponsors to obtain approval of a drug for new uses or indications within the same orphan designated disease or condition that have not yet been approved. It is unclear how future litigation, including the overturning of the *Chevron* doctrine, legislation, agency decisions, and administrative actions, including changes under the current administration, will impact the scope of the orphan drug exclusivity. Orphan drug designation neither shortens the development time or regulatory review time of a drug nor gives the product candidate any advantage in the regulatory review or approval process or entitles the product candidate to priority review.

Where appropriate, we plan to secure approval from the FDA or comparable foreign regulatory authorities through the use of accelerated registration pathways. If we are unable to obtain such approval, or if we fail to meet the requirements or the timeline agreed upon with the FDA for a confirmatory trial, our regulatory approval may be delayed and we may be required to conduct additional preclinical studies or clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary marketing approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post-marketing requirements, the FDA may seek to withdraw accelerated approval.

Where possible, we plan to pursue accelerated development strategies in areas of high unmet need. We may seek an accelerated approval pathway for one or more of our product candidates. Under the accelerated approval provisions in the Federal Food, Drug, and Cosmetic Act, and the FDA's implementing regulations, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that the product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The Food and Drug Omnibus Reform Act made several changes to the FDA's authorities and its regulatory framework, including, among other changes, reforms to the accelerated approval pathway, such as requiring the FDA to specify conditions for post-approval study requirements and setting forth procedures for the FDA to withdraw a product on an expedited basis for non-compliance with post-approval requirements. If the FDA finds that the confirmatory trial is not sufficiently underway or that the sponsor has not met all the requirements or enrollment timeline for the confirmatory trial agreed upon with the FDA before submitting an application for accelerated approval, the FDA may issue a complete response letter and refuse to grant accelerated approval. If we are not able to meet the FDA's requirements for accelerated approval, then our regulatory approval may be delayed.

The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. If such post-approval studies fail to confirm the drug's clinical benefit, the FDA may withdraw its approval of the drug.

Prior to seeking such accelerated approval, we will seek feedback from the FDA and will otherwise evaluate our ability to seek and receive such accelerated approval, including alignment with the FDA on requirements for a confirmatory trial. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit an NDA for accelerated approval or any other form of expedited development, review or approval. Similarly, there can be no assurance that after subsequent FDA feedback we will continue to pursue or apply for accelerated approval or any other form of expedited development, review or approval, even if we initially decide to do so. Furthermore, if we decide to submit an application for accelerated approval or under another expedited regulatory designation (e.g., breakthrough therapy designation), there can be no assurance that such submission or application will be accepted or that any expedited development, review or approval will be granted on a timely basis, or at all. The FDA or other comparable foreign regulatory authorities could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review or approval for our product candidate would result in a longer time period to commercialization of such product candidate, could increase the cost of development of such product candidate and could harm our competitive position in the marketplace.

We may face difficulties from changes to current regulations and future legislation.

Existing regulatory policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We 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 lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability.

For example, in March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the ACA), was passed, which substantially changed the way healthcare is financed by both the government and private insurers and continues to significantly impact the U.S. pharmaceutical industry. Since its enactment, there have been legislative and judicial efforts to repeal, replace, or change some or all of the ACA. In June 2021, the United States Supreme Court held that Texas and other challengers had no legal standing to challenge the ACA, dismissing the case without specifically ruling on the constitutionality of the ACA. It is unclear how future litigation and healthcare measures promulgated by the current administration will impact the implementation of the ACA, our business, financial condition and results of operations. Complying with any new legislation or reversing changes implemented under the ACA could be time-intensive and expensive, resulting in a material adverse effect on our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, effective April 1, 2013, which will stay in effect through 2032, unless Congress takes additional action. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and accordingly, our financial operations.

Moreover, there has been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several 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 programs, and reform government program reimbursement methodologies for drug products. For example, the American Rescue Plan Act of 2021 eliminated the statutory cap on Medicaid Drug Rebate Program rebates that manufacturers pay to state Medicaid programs. Elimination of this cap may require pharmaceutical manufacturers to pay more in rebates than they receive on the sale of products, which could have a material impact on our business. In August 2022, Congress passed the IRA, which includes prescription drug provisions that have significant implications for the pharmaceutical industry and Medicare beneficiaries, including allowing the federal government to negotiate a maximum fair price for certain high-priced single-source Medicare drugs, imposing penalties and excise tax for manufacturers that fail to comply with the drug price negotiation requirements, requiring inflation rebates for all Medicare Part B and Part D drugs, with limited exceptions, if their drug prices increase faster than inflation, and redesigning Medicare Part D to reduce out-of-pocket prescription drug costs for beneficiaries, among other changes. Various industry stakeholders, including pharmaceutical companies and the Pharmaceutical Research and Manufacturers of America have initiated lawsuits against the federal government asserting that the price negotiation provisions of the IRA are unconstitutional. Further, the current administration has issued executive orders focused on decreasing prescription drug prices, including directing the Secretary of Health and Human Services to establish a mechanism through which American patients can buy drugs directly from manufacturers who sell at a most-favored-nation price (MFN) and directing the U.S. Trade Representative and Secretary of Commerce to take action to ensure foreign countries are not engaged in practices that purposefully and unfairly undercut market prices and drive price hikes in the United States. The One Big Beautiful Bill Act (OBBBA), which was signed into law in July 2025, includes provisions that will impact the U.S. healthcare system in various ways, including by cuts to Medicaid and introducing new participant work and eligibility requirements for Medicaid coverage, which are expected to significantly change the administration and applicability of Medicaid coverage. In November 2025, CMS announced a voluntary initiative called the GENEROUS Model

(GENErating cost Reductions fOr U.S. Medicaid Model) to introduce the option of most-favored-nation pricing to the Medicaid program, whereby a drug manufacturer may voluntarily offer supplemental rebates to participating state Medicaid programs for a manufacturer's covered outpatient drugs. In June 2026, the CMS issued a proposed rule that would codify policies established in guidance documents for the Medicare Drug Price Negotiation Program for initial price applicability year 2029 and beyond. CMS plans to release guidance in 2026 to implement policies related to the effectuation of the MFP for the Medicare Drug Price Negotiation Program for 2028, consistent with the Inflation Reduction Act. This guidance will specify the requirements that will be applicable to manufacturers and Part B providers for the effectuation of the maximum fair price (MFP) in 2028. MFN pricing agreements and other measures that use most-favored-nation pricing targets for prescription drugs, including the use of international pricing reference to set drug prices in the United States, or increase generic and biosimilar drug entry sooner than expected, could have a material adverse effect on our industry, ability to set adequate pricing for new drugs to recover research and development costs, and ability to attract potential investors and potential buyers in the future. We cannot predict the full impact of the executive orders focused on reducing prescription drug prices or increasing domestic drug manufacturing capacity, or other measures that may be implemented by the current administration related to drug pricing, drug supply chain and manufacturing in the United States. The impact of ongoing and future judicial challenges as well as other legislative, executive, and administrative actions and agency rules implemented by the government on us and the pharmaceutical industry as a whole is unclear. Further, uncertainties created by the IRA, including its long-term impact on drug pricing, may negatively impact investments, company valuation, royalty-based earnings, mergers, and acquisitions in the industry. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our product candidates if approved. Complying with any new legislation and regulatory changes could be time-intensive and expensive, resulting in a material adverse effect on our business, and expose us to greater liability.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. A number of states are considering or have recently enacted state drug price transparency and reporting laws that could substantially increase our compliance burdens and expose us to greater liability under such state laws once we begin commercialization after obtaining regulatory approval for any of our products. In addition, the FDA has authorized the state of Florida to develop Section 804 Importation Programs to import certain prescription drugs from Canada for a limited time to help reduce drug costs, provided that Florida's Agency for Health Care Administration meets the requirements set forth by the FDA. Other states may follow Florida. We are unable to predict the future course of federal or state healthcare legislation in the United States directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. These and any further changes in the law or regulatory framework that reduce our revenue or increase our costs could also have a material and adverse effect on our business, financial condition and results of operations.

Further, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 (Right to Try Act), was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new product candidates that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its products available to eligible patients as a result of the Right to Try Act.

We expect that the ACA, the IRA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we 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. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for biotechnology products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be. In addition, increased scrutiny by Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements. In June 2024, the U.S. Supreme Court overruled the *Chevron* doctrine, which gives deference to regulatory agencies' statutory interpretations in litigation against federal government agencies, such as the FDA, where the law is ambiguous. This landmark Supreme Court decision may invite more companies and other stakeholders to bring lawsuits against the FDA and other federal agencies to challenge longstanding decisions and policies, which could undermine the FDA's authority, lead to uncertainties in the industry, and disrupt the FDA's normal operations, any of which could delay the FDA's review of our regulatory submissions. We cannot predict the full impact of this decision, future judicial challenges brought against the FDA, or the nature or extent of government regulation that may arise from future legislation or administrative action.

Additionally, the collection, use and other processing of health data relating to individuals in the EU is governed by the General Data Protection Regulation (GDPR), which extends the geographical scope of EU data protection law to non-EU entities under certain conditions and imposes substantial obligations upon companies and new rights for individuals. Failure to comply with

the GDPR and the applicable national data protection laws of EU Member States may result in fines up to €20,000,000 or up to 4% of the total worldwide annual turnover of the preceding financial year, whichever is higher, and other administrative penalties and liabilities. The GDPR has increased our responsibility and liability in relation to personal data that we may process, and we may be required to put in place additional mechanisms in an effort to comply with the GDPR or other laws and regulations relating to privacy, data protection and cybersecurity. This may be onerous and if our efforts to comply with GDPR or other applicable laws and regulations are not successful, it could adversely affect our business. Further, the European Court of Justice in 2020 invalidated the EU-U.S. Privacy Shield and imposed additional requirements for companies making use of standard contractual clauses issued by the European Commission (SCCs), including requirements to make use of updated SCCs. The UK also has issued updated standard contractual clauses that are required to be implemented. Additionally, the U.S. Department of Justice issued in January 2025 a final rule, effective April 8, 2025, which places limitations, and in some cases prohibitions, on certain transfers of sensitive personal data to business partners located in China or with other specified links to China and other designated countries. These and other developments with respect to cross-border data transfer may impose additional obligations with respect to cross-border data transfer and may require us to modify our policies and practices and engage in additional contractual negotiations, each of which could increase our costs and obligations and impose limitations upon our ability to efficiently transfer personal data across borders.

Further, the UK has implemented legislation that substantially implements and complements the GDPR, with penalties for noncompliance of up to the greater of £17.5 million or four percent of worldwide revenues. The UK enacted the UK Data (Use and Access) Act 2025 (DUAA) on June 19, 2025, which made targeted amendments to the UK's data protection regime that cause it to deviate further from the GDPR. This has introduced additional compliance complexity to the UK's data protection regime. We may be required to incur significant costs and expenses in an effort to comply with distinct privacy and data protection requirements in the EU and UK. More generally, we may incur liabilities, expenses, costs, and other operational losses under the GDPR and the privacy and data protection laws of applicable EU Member States and the UK in connection with any measures we take to comply with them.

Finally, state and foreign laws may apply generally to the privacy and security of information we maintain, and may differ from each other in significant ways, thus complicating compliance efforts. For example, the California Consumer Privacy Act of 2018 (CCPA), which took effect on January 1, 2020, gives California residents expanded rights to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. In addition, the CCPA (a) allows enforcement by the California Attorney General or the California Privacy Protection Agency, with fines set at $2,500 per violation (i.e., per person) or $7,500 per intentional violation and (b) authorizes private lawsuits to recover statutory damages for certain data breaches. While it exempts some data regulated by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and certain clinical trials data, the CCPA may increase our compliance costs and potential liability with respect to other personal information we collect about California residents. Additionally, the California Privacy Rights Act (CPRA) became operative in most respects on January 1, 2023. The CPRA significantly modified the CCPA, which may require us to modify our practices and policies and may further increase our compliance costs and potential liability. Numerous other states' legislatures are considering or have enacted similar laws that will require ongoing compliance efforts and investment, and which may increase our potential liability and adversely affect our business. For example, Colorado, Connecticut, Utah and Virginia have enacted legislation similar to the CCPA and CPRA that took effect in 2023; Florida, Montana, Oregon and Texas have enacted similar legislation that became effective in 2024; Tennessee, Iowa, Delaware, Maryland, Minnesota, Nebraska, New Hampshire and New Jersey have enacted similar legislation that became effective in 2025; Indiana, Rhode Island and Kentucky have enacted similar legislation that have become effective in 2026; Oklahoma and Alabama have enacted similar legislation that will become effective in 2027; and Vermont has enacted similar legislation that will become effective in 2028. Further, other states have enacted laws that cover certain aspects of the collection, use, disclosure, and/or other processing of health information, such as Washington's My Health, My Data Act, which, among other things, provides for a private right of action.

The interpretation and application of laws and regulations relating to privacy, data protection, data security, and other matters in the United States, the EEA, and elsewhere are often uncertain, contradictory, and in flux. Any failure or perceived failure to comply with federal, state, or foreign laws or regulations, or contractual or other legal obligations, may result in claims, warnings, communications, requests, or investigations from individuals, supervisory authorities, or other legal or regulatory authorities, and regulatory investigations or other proceedings. It is possible that these laws, regulations, and other actual or asserted obligations may be interpreted and applied in a manner that is inconsistent with our practices. If so, this could result in claims, demands, and litigation or other proceedings initiated by regulatory authorities or others, and fines, penalties, damages, or other liabilities, as well as government-imposed orders requiring that we change our practices, which could adversely affect our business. Our efforts to comply with emerging and changing legal and regulatory requirements relating to privacy, data protection, data security and other matters may cause us to incur costs or require us to change our business practices, which could harm our business, financial condition, and results of operations and prospects.

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

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. 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 slow the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, in recent years, the U.S. government shut down several times and certain regulatory agencies, such as the FDA and the SEC, had to furlough critical employees and stop critical activities. Separately, in response to the COVID-19 public health emergency, the FDA temporarily postponed inspections of foreign manufacturing facilities and routine surveillance inspections of domestic manufacturing facilities. If a prolonged government shutdown or other disruption occurs, or if global health or other concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities in a timely manner, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Our relationships with healthcare professionals, clinical investigators, CROs and third party payors in connection with our current and future business activities may be subject to federal and state healthcare fraud and abuse laws, false claims laws, transparency laws, government price reporting, and health information privacy and security laws, which could expose us to significant losses, including, among other things, criminal sanctions, civil penalties, contractual damages, exclusion from governmental healthcare programs, reputational harm, administrative burdens and diminished profits and future earnings.

Healthcare providers and third-party payors play a primary role in the recommendation and prescription of any product candidates for which we obtain marketing approval. Our current and future arrangements with healthcare professionals, clinical investigators, CROs, third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, as well as market, sell and distribute our products for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations may include the following:

- the federal Anti-Kickback Statute (AKS) prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under a federal healthcare program such as Medicare and Medicaid;
- the federal false claims laws, including the civil False Claims Act (FCA), which can be enforced by private citizens through civil whistleblower or qui tam actions, and civil monetary penalties laws, prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;
- the federal HIPAA, prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (HITECH) and their implementing regulations, also imposes obligations, including mandatory contractual terms, on covered entities, which are health plans, healthcare clearinghouses, and certain health care providers, as those terms are defined by HIPAA, and their respective business associates, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;
- the federal Physician Payments Sunshine Act requires applicable manufacturers of covered drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to annually report to CMS information regarding payments and other transfers of value to covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare providers (such as physician assistants and nurse practitioners), and teaching hospitals, as well as information regarding 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, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance regulations 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, marketing expenditures, or drug pricing; state and local laws that require the registration of pharmaceutical sales and medical representatives; state laws that govern the privacy and security of health information in some circumstances (such as Washington's My Health, My Data Act, which, among other things, provides for a private right of action), many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare and data privacy laws and regulations will involve on-going substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant 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, 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 is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Our employees, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers 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, independent contractors, consultants, commercial collaborators, principal investigators, CROs, suppliers and vendors may engage in misconduct or other improper activities. Misconduct by these parties could include failures to comply with FDA regulations, provide accurate information to the FDA, comply with federal and state health care fraud and abuse laws and regulations, accurately report financial information or data or disclose unauthorized activities to us. In particular, research, sales, marketing and business arrangements in the health care industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Misconduct by these parties could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. We have adopted a code of conduct, but it is not always possible to identify and deter misconduct by these 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 comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant 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.

If we fail to comply with other U.S. healthcare laws and compliance requirements, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.

In the United States, our current and future activities with investigators, healthcare professionals, consultants, third-party payors, patient organizations and customers are subject to regulation by various federal, state and local authorities in addition to the FDA, which may include but are not limited to, CMS, other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice (DOJ) and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, our business practices, including our clinical research, sales, marketing and scientific/educational grant programs may be required to comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the patient data privacy and security provisions of HIPAA transparency requirements, and similar state laws, each as amended, as applicable.

The federal AKS prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any good, item, facility or service reimbursable, in whole or part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been interpreted broadly to

include anything of value. The federal AKS has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the AKS. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor.

Additionally, the intent standard under the federal AKS was amended by the ACA, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the federal AKS or specific intent to violate it in order to have committed a violation. Rather, if "one purpose" of the remuneration is to induce referrals, the federal AKS is implicated. In addition, the ACA codified case law that a claim that includes items or services resulting from a violation of the federal AKS constitutes a false or fraudulent claim for purposes of the federal civil FCA (discussed below).

The civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal healthcare program that the person knows or should know is for a medical or other item or service that was not provided as claimed or is false or fraudulent.

The federal civil FCA prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, a false claim for payment to, or approval by, the federal government, knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government, or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to the federal government. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. Pharmaceutical and other healthcare companies are being investigated or, in the past, have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies' marketing of the product for unapproved, and thus non-reimbursable, uses.

HIPAA imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the AKS, the ACA amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Analogous U.S. state laws and regulations, including state anti-kickback and false claims laws, may apply to claims involving healthcare items or services reimbursed by any third-party payor.

HIPAA, as amended by HITECH, and their implementing regulations, imposes requirements on certain types of individuals and entities relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates that are independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

Additionally, the federal Physician Payments Sunshine Act within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to covered recipients, including physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician healthcare providers (such as physician assistants and nurse practitioners) and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, such covered recipients, and to report annually certain ownership and investment interests held by physicians and their immediate family members.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some

states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain.

State and local laws also require pharmaceutical and biotechnology companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the U.S. federal government, establish marketing compliance programs, restrict payments that may be made to healthcare providers, professionals and entities and other potential referral sources, file periodic reports with the state relating to pricing and marketing, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register field representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws. Ensuring that our internal operations and future business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private "qui tam" actions brought by individual whistleblowers in the name of the government, exclusion, debarment or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business.

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

Although we maintain workers' compensation insurance to cover us for costs and expenses, we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us in connection with our storage or disposal of hazardous and flammable materials, including chemicals and biological materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or commercialization efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Our business activities may be subject to the U.S. Foreign Corrupt Practices Act (FCPA) and similar anti-bribery and anti-corruption laws of other countries in which we operate, as well as U.S. and certain foreign export controls, trade sanctions, and import laws and regulations. Compliance with these legal requirements could limit our ability to compete in foreign markets and subject us to liability if we violate them.

Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate. The FCPA generally prohibits companies and their employees and third-party intermediaries from offering, promising, giving or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals are owned and operated by the government, and doctors and other hospital employees would be considered foreign officials under the FCPA. Recently, the SEC and DOJ have increased their FCPA enforcement activities with respect to biotechnology and pharmaceutical companies. There is no certainty that all of our employees, agents or contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, disgorgement, and other sanctions and remedial measures, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one

or more countries and could materially damage our reputation, our brand, our international activities, our ability to attract and retain employees and our business, prospects, operating results and financial condition.

In addition, our products may be subject to U.S. and foreign export controls, trade sanctions and import laws and regulations. Governmental regulation of the import or export of our products, or our failure to obtain any required import or export authorization for our products, when applicable, could harm our international sales and adversely affect our revenue. Compliance with applicable regulatory requirements regarding the export of our products may create delays in the introduction of our products in international markets or, in some cases, prevent the export of our products to some countries altogether. Furthermore, U.S. export control laws and economic sanctions prohibit the shipment of certain products and services to countries, governments, and persons targeted by U.S. 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. Moreover, any new export or import restrictions, new legislation or shifting approaches in the enforcement or scope of existing regulations, or in the countries, persons, or products targeted by such regulations, could result in decreased use of our products by, or in our decreased ability to export our products to, existing or potential customers with international operations. Any decreased use of our products or limitation on our ability to export or sell our products would likely adversely affect our business.

Enhanced trade tariffs, import restrictions, export restrictions, Chinese regulations or other trade barriers may materially harm our business.

We are continuing to expand our international operations as part of our strategy. There is currently significant uncertainty about the future relationship between the United States and various other countries, most significantly China, with respect to trade policies, treaties, government regulations and tariffs. There is a possibility that the United States could continue to impose greater restrictions on international trade and significant increases in tariffs on goods imported into the United States. Over the last decade, and especially under the current administration, the U.S. government has enacted various new and increased tariffs. For example, in September 2018, the U.S. Trade Representative (USTR) enacted multiple tranches of tariffs on the import of various Chinese products. Since that time USTR has modified these tariff rates and imposed tariffs on additional goods. In addition, since February 4, 2025, the U.S. government has imposed additional global, country-specific, and commodity-specific tariffs on the import of goods of China and most other U.S. trading partners, with various exemptions, pursuant to executive orders issued under various trade authorities, including the International Emergency Economic Powers Act (IEEPA), Sections 122 and 301 of the Trade Act of 1974, Section 232 of the Trade Expansion Act of 1962, and Section 338 of the Tariff Act of 1930. Additional tariffs may in the future be implemented by the U.S. government, the implementation, scope, and duration of which remain uncertain and which may change significantly as a result of trade negotiations between the United States and other countries. Tariffs on imports of Active Pharmaceutical Ingredients (APIs) and starting materials used in our product candidates as well as product candidates themselves, or retaliatory trade measures taken by China or other countries, which could potentially include restricted access to APIs or starting materials used in our product candidates, could result in us needing to make changes to our product candidates, or materially harm our business, financial condition and results of operations. Further, the continued threats of tariffs, trade restrictions, and trade barriers could have a generally disruptive impact on the global economy and, therefore, negatively impact our company.

Risks related to employee matters, managing our growth and other risks related to our business

Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.

To succeed, we must recruit, retain, manage and motivate qualified clinical, scientific, technical and management personnel, and we face significant competition for experienced personnel. We are highly dependent on the principal members of our management and scientific and medical staff. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our operating results. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. We could in the future have difficulty attracting and retaining experienced personnel and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Many of the other biotechnology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide higher compensation, more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If we are unable to continue to attract and retain high-quality personnel, the rate and success at which we can develop and commercialize our product candidates will be limited and the potential for successfully growing our business will be harmed.

Additionally, we rely on our scientific founders and other scientific and clinical advisors and consultants to assist us in formulating our research, development and clinical strategies. These advisors and consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. In addition, these advisors and consultants typically will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. Furthermore, our advisors may have arrangements with other companies to assist those companies in developing products or technologies that may compete with ours. In particular, if we are

unable to maintain consulting relationships with our scientific founders or if they provide services to our competitors, our development and commercialization efforts will be impaired and our business will be significantly harmed.

Our strategic pipeline prioritization and the associated workforce reduction announced in August 2025 may not result in anticipated cost savings and could disrupt our business.

On August 12, 2025, we announced a strategic pipeline prioritization to focus operational and financial resources on the continued advancement of our two lead clinical programs, rinzimetostat and enozertinib. This initiative has resulted in a substantial decrease in preclinical research, primarily from the elimination of our discovery research group. This resulted in an approximately 20% workforce reduction. We may not realize, in full or in part, the anticipated benefits, savings and improvements in our operating structure from our new strategic efforts due to unforeseen difficulties, delays or unexpected costs. If we are unable to realize the expected operational efficiencies and cost savings from the strategic pipeline prioritization, our results of operation and financial condition would be adversely affected. We also cannot guarantee that we will not have to undertake additional workforce reductions or related activities in the future. Such cost reduction efforts may in the future adversely affect our ability to attract and retain employees, and may adversely affect our culture and impact our ability to effectively pursue our business strategy. Furthermore, our strategic pipeline prioritization may be disruptive to our operations. For example, our workforce reduction could yield unanticipated consequences, such as attrition beyond planned staff reductions, increased difficulties in our day-to-day operations and reduced employee morale. If employees who were not affected by the reduction in force seek alternate employment, this could result in us seeking contract support which may result in unplanned additional expense or harm our productivity. Our workforce reduction could also harm our ability to attract and retain qualified management, scientific, and clinical personnel who are critical to our business. Any failure to attract or retain qualified personnel could prevent us from successfully developing our product candidates in the future.

If we are unable to establish sales or marketing capabilities or enter into agreements with third parties to sell or market our product candidates, we may not be able to successfully sell or market our product candidates that obtain regulatory approval.

We currently do not have and have never had a marketing or sales team. In order to commercialize any product candidates, if approved, we must build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services for each of the territories in which we may have approval to sell or market our product candidates. We may not be successful in accomplishing these required tasks.

Establishing an internal sales or marketing team with technical expertise and supporting distribution capabilities to commercialize our product candidates will be expensive and time-consuming and will require significant attention of our executive officers to manage. Any failure or delay in the development of our internal sales, marketing and distribution capabilities could adversely impact the commercialization of any of our product candidates that we obtain approval to market, if we do not have arrangements in place with third parties to provide such services on our behalf. Alternatively, if we choose to collaborate, either globally or on a territory-by-territory basis, with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems, we will be required to negotiate and enter into arrangements with such third parties relating to the proposed collaboration and such arrangements may prove to be less profitable than commercializing the product on our own. If we are unable to enter into such arrangements when needed, on acceptable terms, or at all, we may not be able to successfully commercialize any of our product candidates that receive regulatory approval, or any such commercialization may experience delays or limitations. If we are unable to successfully commercialize our approved product candidates, either on our own or through collaborations with one or more third parties, our future product revenue will suffer, and we may incur significant additional losses.

In order to successfully implement our plans and strategies, we will need to grow the size of our organization, and we may experience difficulties in managing this growth.

As of September 30, 2026, we had 119 full-time employees, including 90 employees engaged in research and development. In order to successfully implement our development and commercialization plans and strategies, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical, FDA, EMA and other comparable foreign regulatory agencies' review process for our product candidates, while complying with any contractual obligations to contractors and other third parties we may have; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to successfully develop and, if approved, commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities.

We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors and consultants to provide certain services, including key aspects of clinical development and manufacturing. We cannot assure you that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. Moreover, there is the potential that our independent contractors could be deemed to be misclassified under applicable worker classification laws, which could subject us to penalties or other liabilities. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by third party service providers is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain marketing approval of our product candidates or otherwise advance our business. We cannot assure you that we will be able to manage our existing third-party service providers or find other competent outside contractors and consultants on economically reasonable terms, or at all.

If we are not able to effectively expand our organization by hiring new employees and/or engaging additional third-party service providers, we may not be able to successfully implement the tasks necessary to further develop and commercialize our product candidates and, accordingly, may not achieve our research, development and commercialization goals.

Our internal computer systems, or those of any of our CROs, manufacturers, other contractors or consultants or potential future collaborators, may fail or suffer security or data privacy breaches or incidents or other unauthorized or improper access to, use of, or destruction of our proprietary or confidential data, employee data, or personal data, which could result in additional costs, loss of revenue, significant liabilities, harm to our brand and material disruption of our operations.

Despite the implementation of security measures in an effort to protect systems that store our information, given their size and complexity and the increasing amounts of information maintained and otherwise processed on our information technology systems, and those of our third-party CROs, other contractors (including sites performing our clinical trials) and consultants, these systems are potentially vulnerable to breakdown or other damage, disruption, or interruption from service interruptions, system malfunction, natural disasters, terrorism, war and telecommunication and electrical failures, as well as security breaches and incidents from inadvertent or intentional actions by our employees, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, phishing and other means of social engineering, and other means to affect service reliability and threaten the confidentiality, integrity and availability of information), which may compromise our system infrastructure or that of our third-party CROs, other contractors (including sites performing our clinical trials) and consultants or lead to the loss, destruction, alteration, disclosure, or dissemination of, or damage or unauthorized access to, our data or data that is processed or maintained on our behalf, or other assets. For example, we have received phishing attacks, and companies have experienced an increase in phishing and social engineering attacks from third parties in recent years, and the increase in remote working further increases security threats. Additionally, for example, our third-party CROs or other contractors and consultants have suffered, and in the future may suffer, instances of unauthorized access to their systems. To date, we have not identified any such instance that we have assessed as material to our business or operations. International military conflicts and geopolitical tensions may increase cybersecurity threats that we and our CROs and other contractors and consultants face. Moreover, advancements in technology, such as AI and machine learning, are changing and may continue to change the way companies are subjected to attempts to gain unauthorized access and disrupt systems, thereby increasing the risks of security threats and attacks and the potential impacts of security breaches and incidents. For example, certain AI technologies may greatly enhance the identification and exploitation of security vulnerabilities. Any disruption or security breach or incident resulting in any loss, destruction, unavailability, or unauthorized alteration, disclosure, dissemination, or processing of, or damage or unauthorized access to, our applications, any data processed or maintained on our behalf, or other assets, or any belief or reporting that any of these has occurred, could cause us to incur liability, financial harm and reputational damage and delays in the development and commercialization of our product candidates. We cannot assure you that our data protection efforts and our investment in information technology, or the efforts or investments of CROs, consultants or other third parties, have prevented or will prevent significant breakdowns, disruptions, or breaches in systems or have prevented or will prevent security breaches or incidents leading to loss, destruction, unavailability, alteration or dissemination of, or damage or unauthorized access to, our data or other data processed or maintained on our behalf or other assets that could have a material adverse effect upon our reputation, business, operations or financial condition. Any such event causing interruptions in our operations could result in a material disruption of our programs and delays in development of our product candidates. In addition, the loss, corruption, or unavailability of clinical trial data for our product candidates could result in delays in our marketing approval efforts and significantly increase our costs to recover or reproduce the data. Furthermore, significant disruptions of information technology systems or security breaches or incidents suffered by us or any of our third-party CROs, other contractors, or consultants, could result in the loss, misappropriation, and/or unauthorized access, use, or disclosure, dissemination, or other processing of, or the prevention of access to, data (including trade secrets or other confidential information, intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. Any such event or any other security breach or incident leading to loss, corruption, or unavailability of, damage to, unauthorized access to, or use, alteration, disclosure, dissemination, or other processing of, personal information, including personal information regarding our clinical trial subjects or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal

information, which could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

Notifications and follow-up actions related to a security breach or incident could impact our reputation and cause us to incur significant costs, including legal expenses and remediation costs. We expect to incur significant costs in our efforts to detect and prevent security incidents, and we may face increased costs and requirements to expend substantial resources in the event of an actual or perceived security breach or incident. We also rely on third parties to manufacture our product candidates, and similar events relating to their systems could also have a material adverse effect on our business. Any damage, disruption, or interruption of systems, or security breach or incident resulting in any disruption of our operations or loss, destruction, unavailability, or alteration of, or damage or unauthorized access to, our data or other information that is processed or maintained on our behalf, or inappropriate disclosure or dissemination of any such information, could expose us to litigation and governmental investigations, delays in development and commercialization of our product candidates, and significant fines or penalties for any noncompliance with certain state, federal and/or international privacy and security laws.

Our insurance policies may not be adequate to compensate us for the potential losses arising from any such disruption in or, failure or security breach or incident of our systems or third-party systems where information important to our business operations or commercial development is stored or otherwise processed. In addition, such insurance may not be available to us in the future on economically reasonable terms, or at all. Further, our insurance may not cover all claims made against us and could have high deductibles in any event, and defending a suit, regardless of its merit, could be costly and divert management attention.

Rapid developments in AI technologies, and in the laws and regulations governing them, could increase our costs and expose us to operational, compliance, privacy and security risks, including through our vendors and malicious third parties, any of which could adversely affect our business.

AI is a rapidly evolving field, and we cannot predict how AI technologies and their adoption will develop or how those developments will affect our business. AI, including generative AI, may have errors or inadequacies that are not easily detectable. If the data used to train AI or the content AI applications assist in producing are deficient, inaccurate, or biased, our business may be adversely affected. Our use of, or reliance on, AI technologies may also result in the generation or dissemination of inaccurate, misleading, or otherwise harmful content, and may expose us to claims or liability for potential discrimination, defamation, or intellectual property infringement or misappropriation, and to compliance risks under applicable sanctions and export control laws, among others.

In addition, the legal and regulatory framework governing AI remains evolving and uncertain, and it is unclear how existing or future laws may apply to content produced by AI systems. While various jurisdictions have proposed or enacted AI-specific legislation, such as the EU Artificial Intelligence Act (the EU AI Act), the final implementation, interpretation, enforcement of these laws and the impact of these laws on our business are in flux. For example, obligations under the EU AI Act, which establishes broad obligations for the development and use of AI-based technologies in the European Union (EU) based on their potential risks and level of impact, have gone into effect and will continue to be implemented in phases. Other jurisdictions have similarly amended or delayed enforcement deadlines for their AI laws, and the scope and content of those laws remain subject to revision, while the U.S. federal government has taken steps to preempt or challenge certain state-level AI regulations, including through executive action and legislative recommendations urging Congress to establish a uniform federal framework, though the legal and legislative landscapes remain unsettled. Such laws and regulations may significantly increase our compliance costs, may impose significant obligations on providers and deployers of AI systems, and could affect our ability to protect our proprietary rights.

As we expand our use of AI, including generative AI, in our operations, or to the extent we integrate AI into our products, we may be subject to new or enhanced governmental or regulatory scrutiny, litigation, or other legal liability, ethical concerns, or other complications that could adversely affect our business or reputation, and we may be required to apply significant resources to design, develop, test and maintain such technologies to help ensure that any such AI is implemented in accordance with applicable law and regulation and in a socially responsible manner and to minimize any real or perceived unintended harmful impacts. We also may need to expend further resources to adjust our business practices, as these laws and regulations evolve, especially where requirements across jurisdictions are inconsistent. Such an increase in operating expenses, as well as any actual or perceived failure to comply with such laws and regulations, could materially and adversely affect our business, financial condition, results of operations, and prospects.

Our vendors, including our CROs, manufacturers and other contractors, may in turn incorporate AI tools (including generative AI) into their own offerings and operations. The providers of these AI tools may not meet existing or rapidly evolving regulatory or industry standards, including with respect to privacy and data security, and we may have limited ability to control or verify how such tools process our data. Furthermore, the integration of third-party AI models with our operations relies on certain safeguards implemented by the third-party developers of the underlying AI models, including those related to security and the accuracy, bias, and other variables of the data, and these safeguards may be insufficient. The use of AI applications used by other companies has resulted in, and may in the future result in, cybersecurity incidents that implicate the data analyzed within such applications and may lead to the inadvertent release of confidential information. Further, bad actors around the world could use increasingly sophisticated methods, including the use of generative AI, to engage in illegal activities involving the theft and misuse of

personal information, financial and other confidential information and intellectual property. Any of these effects could damage our reputation, result in the loss of valuable property and information, cause us to breach applicable laws and regulations, and adversely impact our business.

Our operations are vulnerable to interruption by natural disasters, extended power loss, telecommunications failure, terrorist activity, pandemics and other events beyond our control, which could harm our business.

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

Our Chief Business Officer was sued by the Securities and Exchange Commission for insider trading on a matter unrelated to ORIC.

On August 17, 2021, the SEC filed a civil enforcement action against our Chief Business Officer for insider trading in violation of the securities laws. The lawsuit involved transactions that occurred in 2016 while our Chief Business Officer was employed by a different company. On April 5, 2024, a jury found our Chief Business Officer liable for insider trading. Pursuant to the final judgment entered by the Court on October 24, 2024, our Chief Business Officer is subject to a monetary penalty and is permanently enjoined from violating Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder but is not in any way prohibited or enjoined from serving as an officer or director of a public company. Our Chief Business Officer has appealed the decision to the Ninth Circuit Court of Appeals.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes to offset future taxable income may be limited.

Our net operating loss (NOL) carryforwards may be unavailable to offset future taxable income because of restrictions under U.S. federal or state tax law. Our U.S. federal NOLs generated in tax years beginning prior to January 1, 2018, are only permitted to be carried forward for 20 taxable years under applicable U.S. federal tax law, and therefore could expire unused. Our U.S. federal NOLs generated in tax years beginning after December 31, 2017, may be carried forward indefinitely, but the deductibility of such NOLs generally is limited to 80% of our current year taxable income for tax years beginning after December 31, 2020. As of December 31, 2025, we had available U.S. federal NOL carryforwards of $424.3 million, of which $382.7 million do not expire. We also had available California NOL carryforwards of approximately $573.9 million as of December 31, 2025, which begin to expire in 2034 and are subject to limitation on use, including that such NOLs may not be available to offset California income prior to 2027. In addition, as of December 31, 2025, we had U.S. federal and California research and development credit carryforwards totaling $21.7 million and $9.4 million, respectively. The U.S. federal credits begin to expire in 2034, while the state credits do not expire.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (Code), if a corporation undergoes an "ownership change" (generally defined as a cumulative change in the corporation's ownership by "5-percent shareholders" that exceeds 50 percentage points over a rolling three-year period), the corporation's ability to use its pre-change NOLs and certain other pre-change tax attributes to offset its post-change taxable income may be limited. Limitations on the use of state NOLs also may apply under state tax laws. We may have experienced such ownership changes in the past, and we may experience ownership changes in the future as a result of shifts in our stock ownership, some of which are outside our control. We are currently in the process of conducting a Section 382 study to determine annual limitations, if any, that could result from such changes in the ownership. Our ability to utilize our NOLs and certain other tax attributes could be limited by an "ownership change" as described above and consequently, we may not be able to utilize a material portion of our NOLs and certain other tax attributes before they expire, which could have a material adverse effect on our cash flows and results of operations.

Changes in tax laws could have a material adverse effect on our business, cash flow, results of operations or financial conditions.

We are subject to tax laws, regulations, and policies of several taxing jurisdictions. Changes in tax laws, as well as other factors, could cause us to experience fluctuations in our tax obligations and effective tax rates and otherwise adversely affect our tax positions and/or our tax liabilities. For example, legislation commonly known as the One Big Beautiful Bill Act (OBBBA) was signed into law in July 2025, which enacts significant changes to U.S. tax and related laws, including but not limited to current deduction of domestic research expenses, increasing the limit of the deduction of interest expense to thirty percent of EBITDA and one hundred percent bonus depreciation on eligible property acquired after January 19, 2025. There were no material changes to the Company's tax expense or effective income tax rate due to these rules given the Company's valuation allowance position. Further, many countries, and organizations such as the Organisation for Economic Cooperation and Development (OECD) have proposed implementing changes to existing tax laws, including a 15% global minimum tax (Pillar Two). Many EU member states and other countries have enacted or are considering enacting such legislation. The United States has withdrawn support for Pillar Two, and the OECD and participating jurisdictions have recently agreed to a side-by-side arrangement that would exempt U.S. parent groups from certain

provisions of Pillar Two for fiscal years beginning on or after January 1, 2026. Any of these developments or changes in U.S. federal or state, or international tax laws or tax rulings could adversely affect our effective tax rate and our operating results. There can be no assurance that our effective tax rates, tax payments, or tax credits and incentives will not be adversely affected by these or other developments or changes in law.

A variety of risks associated with contracting with foreign third parties or marketing our product candidates internationally could materially adversely affect our business.

We may contract with foreign third parties or seek regulatory approval of our product candidates outside of the United States and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements and reimbursement regimes in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls, export controls (including related to data), and other regulatory requirements;
- the imposition of retaliatory trade measures by China or other countries in response to new or escalated tariffs, export controls, or other trade measures by the United States;
- economic weakness, including inflation, financial market volatility and uncertainty or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the FCPA or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations.

In particular, there is currently significant uncertainty about the future relationship between the United States and various other countries, such as China, with respect to trade policies, treaties, tariffs, taxes, and other limitations on cross-border operations, collaboration, and investment. The U.S. government has and continues to make significant additional changes in U.S. trade policy and may continue to take future actions that could negatively impact U.S. trade.

For example, the National Defense Authorization Act of 2026, which includes Section 851, imposes a “[p]rohibition on contracting with certain biotechnology providers” (the BIOSECURE Act), which restricts federal government contracts, grants, and loans from being issued to companies that use biotechnology equipment or services from any designated “biotechnology company of concern,” as part of such companies’ performance of those agreements with the U.S. government. Once fully implemented through regulations to be published by approximately mid-2028, the BIOSECURE Act may ultimately limit certain U.S. biotechnology companies (such as ours) from using equipment or services produced or provided by Chinese biotechnology companies that meet the designation criteria of the new law, or certain affiliated entities. In addition, even if we do not seek any covered federal government contracts, grants, or loans, commercial partners, government agencies, or other third parties may view our business less favorably if we engage with entities that ultimately become biotechnology companies of concern. For example, we currently contract with Chinese companies for certain research and development services, which may be designated a biotechnology company of concern, and this association could affect the perception of our business among third parties.

As another example, the U.S. Department of Justice's Data Security Program places limitations on U.S. companies’ ability to enter into (and in some cases prohibits) certain contracts involving transfers of sensitive personal data to business partners located in China, or with other specified links to China and other designated countries. The rule further requires U.S. persons to obtain from certain foreign counterparties contractual commitments to refrain from engaging in subsequent transfers of sensitive personal data to

entities located in China or with other specified links to China and other designated countries. This new rule will impact our ability to contract not just with Chinese companies but also with foreign entities in general, potentially requiring us to extract promises related to compliance with this new rule.

Additionally, we or our customers may be affected by developments related to tariffs; see our risk factor above "*Enhanced trade tariffs, import restrictions, export restrictions, Chinese regulations or other trade barriers may materially harm our business*." If we are unable to obtain or use services from existing service providers, are restricted from sharing relevant data with such service providers, or to do so at reasonable cost, or with others, or become unable to export or sell our products to any of our customers or service providers, our business, liquidity, financial condition, and/or results of operations would be materially and adversely affected.

We are currently operating in a period of economic uncertainty and capital markets disruption, which has been significantly impacted by geopolitical instability, including the ongoing international military conflicts.

U.S. and global markets are experiencing volatility and disruption following the escalation of certain geopolitical tensions, including international military conflicts, and the related political and economic responses. Changes in countries' economic, trade and financial policies could trigger retaliatory actions by other affected countries, resulting in a "trade war," "cyberwar," escalation of conventional military conflicts, and other adverse events that could impact our business. For example, the military conflicts like those in Ukraine and the Middle East, and any resulting effects that may follow, could result in increased costs for, or unavailability of, certain materials used in the third-party manufacturing of our product candidates and potential future product candidates. These increased costs could have a negative effect on our financial condition, and any supply interruptions could hinder our product development and make it harder for us to find favorable pricing and reliable sources for the materials needed to manufacture our product candidates and potential future product candidates. It is impossible to predict the extent to which our operations will be impacted in the short and long term, or the ways in which our business may be impacted. The extent and duration of international conflicts, geopolitical tensions, and resulting market disruptions are impossible to predict but could be substantial.

Inflation and market volatility may adversely affect us by increasing our costs.

Recently, inflation and market volatility have increased and caused economic uncertainty throughout the U.S. and global economy. Inflation and market volatility can adversely affect us by increasing the costs of clinical trials and research, the development of our product candidates, administration and other costs of doing business. In fact, we have experienced, and continue to experience, increases in the prices of labor and other costs of doing business. In an inflationary, volatile and economically uncertain environment, cost increases may outpace our expectations, causing us to use our cash and other liquid assets faster than forecasted. If this continues to occur or happens more frequently or at a larger scale, we may need to raise additional capital to fund our operations sooner than expected and we may not be able to secure financing on acceptable terms.

Risks related to our intellectual property

Our success depends on our ability to protect our intellectual property and our proprietary technologies.

Our commercial success depends in part on our ability to obtain and maintain patent protection and trade secret protection for our product candidates, proprietary technologies and their uses as well as our ability to operate without infringing upon the proprietary rights of others. We generally seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates, proprietary technologies and their uses that are important to our business. We also seek to protect our proprietary position by acquiring or in-licensing relevant issued patents or pending patent applications from third parties.

Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless, and until, patents issue from such applications, and then only to the extent the issued claims cover the technology. There can be no assurance that our patent applications or the patent applications of our licensors will result in additional patents being issued or that issued patents will afford sufficient protection against competitors with similar technology, nor can there be any assurance that the patents issued will not be infringed, designed around or invalidated by third parties.

Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. The degree of future protection for our and our licensors' proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. These uncertainties and/or limitations in our ability to properly protect the intellectual property rights relating to our product candidates could have a material adverse effect on our financial condition and results of operations.

Although as of September 30, 2026, we owned fourteen and licensed ten issued patents in the United States pertaining to our product candidates, we cannot be certain that the claims in our other U.S. pending patent applications, corresponding international patent applications and patent applications in certain foreign territories, or those of our licensors, will be considered patentable by the United States Patent and Trademark Office (USPTO), courts in the United States or by the patent offices and courts in foreign countries, nor can we be certain that the claims in our issued or licensed patents will not be found invalid or unenforceable if challenged.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our potential future collaborators will be successful in protecting our product candidates by obtaining and defending patents. These risks and uncertainties include the following:

- the USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with or eliminate our ability to make, use and sell our potential product candidates;
- there may be significant pressure on the U.S. government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates.

The patent prosecution process is also expensive and time-consuming, and we and our licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner or in all jurisdictions where protection may be commercially advantageous. Additionally, recent reforms and changes at government agencies of the United States and those of non-U.S. jurisdictions could increase the delays, uncertainties and costs surrounding the prosecution of our owned and licensed patent applications, and the maintenance, enforcement, or defense of our owned and licensed issued patents. For example, the ability of the USPTO and other applicable patent authorities to properly administer their functions is highly dependent on the levels of funding available to the agency and their ability to retain personnel and fill key leadership appointments, among various factors. Termination of employees or delays in replacing or hiring for positions could significantly impact the ability of the USPTO and other applicable patent authorities to fulfill their functions and could greatly impact our ability to timely and adequately prosecute or maintain our owned and licensed patent applications, and our ability to timely and adequately maintain, enforce, or defend our owned and licensed issued patents. It is also possible that we or our licensors will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection.

In addition, although we enter into non-disclosure and confidentiality agreements with parties who have access to patentable aspects of our research and development output, such as our employees, outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection.

Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical product candidates would be adversely affected.

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. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications and those of our licensors may not result in patents being issued which protect our product candidates or which effectively prevent others from commercializing competitive product candidates.

Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own or in-license currently or in the future 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 that we own or in-license may be challenged or circumvented by third parties or may be narrowed or invalidated as a result of challenges by third parties. Consequently, we do not know whether our product candidates will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents or the patents of our licensors 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.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents or the patents of our licensors may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, derivation, revocation, reexamination, post-grant review (PGR) and *inter partes* review (IPR), or other similar proceedings challenging our owned or in-licensed patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights or those of our licensors, allow third parties to commercialize our product candidates and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third-party patent rights. Moreover, our patents or the patents of our licensors may become subject to post-grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our patents and patent applications and those of our licensors. Such challenges may result in loss of patent rights, loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our product candidates. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. In addition, if the breadth or strength of protection provided by our patents and patent applications or the patents and patent applications of our licensors is threatened, regardless of the outcome, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

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

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

- others may be able to develop products that are similar to our product candidates but that are not covered by the claims of the patents that we own or license;
- we or our licensors or collaborators might not have been the first to make the inventions covered by the issued patents or patent application that we own or license;
- we or our licensors or collaborators might not have been the first to file patent applications covering certain of our inventions;
- others, including ANDA applicants, may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that the pending patent applications we own or license will not lead to issued patents;
- issued patents that we own or license may be held invalid or unenforceable, as a result of legal challenges by our competitors, including ANDA applicants;
- our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we may not develop additional proprietary technologies that are patentable;
- the patents of others may have an adverse effect on our business; and
- we may choose not to file a patent in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent covering such intellectual property.

Should any of these events occur, it could significantly harm our business, results of operations and prospects.

In the United States, drug products may obtain FDA marketing approval pursuant to an NDA (described above) for innovator products, or an ANDA for generic products. Relevant to ANDAs, the Hatch-Waxman Act amended the FDCA to establish a statutory procedure for submission and FDA review and approval of ANDAs for generic versions of branded drugs previously approved by the FDA (such previously approved drugs are also referred to as reference listed drugs). Because the safety and efficacy of reference listed drugs have already been established by the brand company (sometimes referred to as the innovator), the FDA typically does not require new human clinical trials to establish safety and efficacy of generic products. Rather, a generic manufacturer is typically required to conduct bioequivalence studies of its test product against the reference listed drug. The bioequivalence studies for orally administered, systemically available drug products assess the rate and extent to which the active pharmaceutical ingredient is absorbed into the bloodstream from the drug product and becomes available at the site of action. Bioequivalence is established when there is an absence of a significant difference in the rate and extent for absorption of the generic product and the reference listed drug. In addition to the bioequivalence data, an ANDA must contain patent certifications and chemistry, manufacturing, labeling, and stability data.

Any applicant who files an ANDA seeking approval of a generic equivalent version of a drug listed in the Orange Book must make one of the following certifications to the FDA concerning patents: (1) the patent information concerning the reference listed drug product has not been submitted to the FDA; (2) any such patent that was filed has expired; (3) the date on which such patent will expire; or (4) such patent is invalid, unenforceable or will not be infringed upon by the manufacture, use or sale of the drug product for which the application is submitted. There might also be no relevant patent certification. If the ANDA applicant does not challenge the listed patents or certify that the listed patents will not be infringed by the new product, the ANDA application will not be approved by FDA until all the patents listed in the Orange Book claiming the referenced product or its use have expired.

The last patent certification described above is known as a paragraph IV certification. A notice of the paragraph IV certification must be provided to each owner of the patent that is the subject of the certification and to the holder of the approved NDA to which the ANDA refers. The applicant may also elect to submit a "section viii" statement certifying that its proposed label does not contain (or "carves out") any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. An application with a section viii statement or carve out may be approved if the removal of language from the label necessitated by the carve out does not make the generic drug less safe or effective. This section viii statement does not require notice to the patent holder or NDA owner.

If the reference NDA holder or patent owners assert a patent challenge directed to one of the Orange Book listed patents within 45 days of the receipt of the paragraph IV certification notice, the FDA is prohibited from approving the application until the earlier of 30 months from the receipt of the paragraph IV certification, expiration of the patent, settlement of the lawsuit or a decision in the infringement case that is favorable to the applicant. The ANDA application also will not be approved until any applicable non-patent exclusivity has expired. Thus approval of an ANDA can be prevented until all the listed patents claiming the referenced product or use thereof have expired, until any non-patent exclusivity, such as exclusivity for obtaining approval of a new chemical entity, has expired, and, in the case of a Paragraph IV certification and subsequent patent infringement suit, until the earlier of 30 months, settlement of the lawsuit or a decision in the infringement case that is favorable to the ANDA applicant.

The FDA may issue tentative approval of an ANDA application if the application meets all conditions for approval, but the applicant cannot receive effective approval because the listed patents, the 30-month stay or another period of regulatory exclusivity, as applicable, has not expired. If tentative approval is granted, then once such listed patents, 30-month stay or other regulatory exclusivity have expired or, in the case of patents that are subject to a patent infringement suit, been found to be invalid or not infringed, the applicant may seek final approval by submitting an amendment that, among other things, includes a safety update and any other changes, if any, in the conditions under which the product was tentatively approved. Prior to granting final approval, the FDA must review and approve any changes reflected in the amendment and may consider any other new information that has come to its attention.

Our commercial success depends significantly on our ability to operate without infringing the patents and other proprietary rights of third parties. Claims by third parties that we infringe their proprietary rights may result in liability for damages or prevent or delay our developmental and commercialization efforts.

Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. However, our research, development and commercialization activities may be subject to claims that we infringe or otherwise violate patents or other intellectual property rights owned or controlled by third parties. Other entities may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidates and products that may be approved in the future, or impair our competitive position. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biopharmaceutical industry, including patent infringement lawsuits, oppositions, reexaminations, IPR proceedings and PGR proceedings before the USPTO and/or corresponding foreign patent offices. Numerous third-party U.S. and foreign issued patents and pending patent applications exist in the fields in which we are developing product candidates. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. Because patent applications are maintained as confidential for a certain period of time, until the relevant application is published, we may be unaware of third-party patents that may be infringed by commercialization of any of our product candidates, and we cannot be certain that we or our licensors were the first to file a patent application related to a product candidate or technology. Moreover, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, identification of third-party patent rights that may be relevant to our technology is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. There is also no assurance that there is not prior art of which we are aware, but which we do not believe is relevant to our business, which may, nonetheless, ultimately be found to limit our ability to make, use, sell, offer for sale or import our products that may be approved in the future, or impair our competitive position. In addition, third parties may obtain patents in the future and claim

that use of our technologies infringes upon these patents. Any claims of patent infringement asserted by third parties would be time consuming and could:

- result in costly litigation that may cause negative publicity;
- divert the time and attention of our technical personnel and management;
- cause development delays;
- prevent us from commercializing any of our product candidates until the asserted patent expires or is held finally invalid, not infringed, or unenforceable in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- subject us to significant liability to third parties; or
- require us to enter into royalty or licensing agreements, which may not be available on commercially reasonable terms, or at all, or which might be non-exclusive, which could result in our competitors gaining access to the same technology.

Although no third party has asserted a material claim of patent infringement against us as of the date of this periodic report, others may hold proprietary rights that could prevent our product candidates from being marketed.

It is possible that a third party may assert a claim of patent infringement directed at any of our product candidates. Any patent-related legal action against us claiming damages and seeking to enjoin commercial activities relating to our products, treatment indications, or processes could subject us to significant liability for damages, including treble damages if we were determined to willfully infringe, and require us to obtain a license to manufacture or market our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions or that any license required under any of these patents would be made available on commercially reasonable terms, if at all. Moreover, even if we or our future strategic partners were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. In addition, we cannot be certain that we could redesign our product candidates, treatment indications, or processes to avoid infringement, if necessary. Accordingly, an adverse determination in a judicial or administrative proceeding, or the failure to obtain necessary licenses, could prevent us from developing and commercializing our product candidates, which could harm our business, financial condition and operating results. In addition, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology.

Parties making claims against us may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or administrative proceedings, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, results of operations, financial condition 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. Additionally, we may be subject to claims of patent infringement during those proceedings, and delays caused by the federal agencies may increase the time period that we are subject to such claims. For example, administrative changes, including reduced personnel and budgets experienced by the Patent and Trial Appeal Board, could further delay our ability to timely challenge any such patents. 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 our product candidates.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

Because our development programs may require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party proprietary rights. 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 for our product candidates. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain or maintain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations, and prospects.

We may be involved in lawsuits to protect or enforce our patents or our licensors' patents, which could be expensive, time consuming and unsuccessful. Further, our issued patents or our licensors' patents could be found invalid, unenforceable or not infringed if challenged in court.

Competitors may infringe our intellectual property rights. To prevent infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in a patent infringement proceeding, a court may decide that a patent we own or in-license is not valid, is unenforceable and/or is not infringed. If we or any of our potential future collaborators were to initiate legal proceedings against a third party to enforce a patent directed at one of our product candidates, the defendant could counterclaim that our patent or the patent of our licensors is invalid and/or unenforceable in whole or in part. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, lack of sufficient written description, non-enablement, or obviousness-type double patenting. For example, the U.S. Supreme Court recently 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 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. Grounds for an unenforceability assertion could include an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution.

Third parties may also raise similar invalidity claims before the USPTO or patent offices abroad, even outside the context of litigation. Such mechanisms include re-examination, PGR, IPR, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). The outcome following legal assertions of invalidity and/or 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, our licensors, and the patent examiners are unaware during prosecution. There is also no assurance that there is not prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim in our patents and patent applications or the patents and patent applications of our licensors, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. 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 on our technology or platform, or any product candidates that we may develop. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects.

As of June 1, 2023, European patent applications have the option, upon grant of a patent, of becoming a Unitary Patent, which will be subject to the jurisdiction of the Unitary Patent Court (UPC). The option of a Unitary Patent will be a significant change in European patent practice, and our European patent applications, if issued, could be challenged in the UPC. As the UPC is a new court system, there is limited precedent for the court, increasing the uncertainty of any litigation in the UPC. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries that are subject to its jurisdiction. The UPC may, as a single court system, invalidate or centrally revoke our future European patents that are subject to its jurisdiction, and such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates due to increased competition and, resultantly, on our financial condition, prospects and results of operations. 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, where applicable, opt our future European patents out of the UPC, and as such each of our future European patents for which we opted out would need to be challenged in each individual country. Moreover, our future European patents could remain under the jurisdiction of the UPC if we do not meet all of the opt-out formalities and requirements under the UPC. If we decide to opt out our future European patents from the UPC, doing so may preclude us from realizing the benefits of the UPC, such as the ability to obtain a pan-European injunction against our competitors. The UPC will also provide our competitors with a new forum to potentially obtain pan-European injunctions, and the granting of such pan-European injunctions against us could have a material adverse impact on our business and our ability to commercialize our technology and product candidates and, resultantly, on our financial condition, prospects and results of operations.

In addition, if the breadth or strength of protection provided by our patents and patent applications or the patents and patent applications of our licensors is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

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

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation or other legal proceedings relating to our intellectual property rights, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation or other proceedings.

In addition, the issuance of a patent does not give us the right to practice the patented invention. Third parties may have blocking patents that could prevent us from marketing our own patented product and practicing our own patented technology.

Intellectual property litigation may lead to unfavorable publicity that harms our reputation and causes the market price of our common shares to decline.

During the course of any intellectual property litigation, there could be public announcements of the initiation of the litigation as well as results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our existing products, programs or intellectual property could be diminished. Accordingly, the market price of shares of our common stock may decline. Such announcements could also harm our reputation or the market for our future products, which could have a material adverse effect on our business.

Derivation proceedings may be necessary to determine priority of inventions, and an unfavorable outcome may require us to cease using the related technology or to attempt to license rights from the prevailing party.

Derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of derivation proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with such proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties or enter into development or manufacturing partnerships that would help us bring our product candidates to market.

Recent patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications or those of our licensors and the enforcement or defense of our issued patents or those of our licensors.

On September 16, 2011, the Leahy-Smith America Invents Act (the Leahy-Smith Act), was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a “first inventor to file” system in which, assuming that other requirements of patentability are met, the first inventor to file a patent application will be entitled to the patent regardless of whether a third party was first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013 but before us could therefore be awarded a patent covering an invention of ours even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we may not be certain that we or our licensors are the first to either (1) file any patent application related to our product candidates or (2) invent any of the inventions claimed in the patents or patent applications.

The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and also may affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including PGR, IPR, and derivation proceedings. An adverse determination in any such submission or proceeding could reduce the scope or enforceability of, or invalidate, our patent rights, which could adversely affect our competitive position.

Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States 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 that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications or those of our licensors and the enforcement or defense of our issued patents or those of our licensors, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects.

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 our product candidates.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the pharmaceutical industry involve a high degree of technological and legal complexity. Therefore, obtaining and enforcing pharmaceutical patents is costly, time consuming and inherently uncertain. Changes in either the patent laws or in the interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property and may increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. We cannot predict the breadth of claims that may be allowed or enforced in our patents, those of our licensors or in third-party patents. In addition, Congress or other foreign legislative bodies may pass patent reform legislation that is unfavorable to us.

For example, the U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the U.S. federal courts, the USPTO, or similar authorities in foreign jurisdictions, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and those of our licensors and the patents we might obtain or license in the future.

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

We may also be subject to claims that former employees, other affiliates, or other third parties have an ownership interest in our patents or those of our licensors or other intellectual property. For example, a current or former employee, other affiliate, or other third party may allege that certain invention assignment agreements or invention assignments are invalid, unenforceable, or otherwise incomplete. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as our ability to enforce or defend our patents or those of our licensors. 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 distraction to management and other employees.

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

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Additionally, the United States Court of Appeals for the Federal Circuit issued a decision involving the interaction of patent term adjustment (PTA), terminal disclaimers, and obviousness-type double patenting that creates uncertainty regarding the patent terms of certain U.S. patents that share the same priority claim where one patent expires later than another patent due to accrued PTA. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain patent term extension for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of FDA marketing approval of our product candidates, one or more of our U.S. patents or those of our licensors may be eligible for limited patent term restoration under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Amendments). The Hatch-Waxman Amendments permit a patent restoration term of up to five years as compensation for patent term lost during product development and the FDA regulatory review process. A maximum of one patent may be extended per FDA-approved product as compensation for the patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval and only those claims covering such approved drug product, a method for using it or a method for manufacturing it may be extended. Patent term extension may also be available in certain foreign countries upon regulatory approval

of our product candidates. However, 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. Additionally, administrative changes at the USPTO or other applicable patent authorities, such as reduced hiring and/or funding, may result in delays in issuance of a patent or in accrual of patent term extension, thereby reducing the amount of patent term extension that could otherwise be received. Administrative changes (*e.g.*, at the FDA or USPTO) may also lead to delays in review and analysis of regulatory submissions or requests for patent term extension, which could result in a patent term extension not being timely granted (*e.g.*, before the expiration of the patent) and there may be no patent eligible for extension. Moreover, the applicable time period or the scope of patent protection afforded could be less than we project or request. If we are unable to obtain patent term extension or restoration or the term of any such extension is less than we project or request, our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced, possibly materially. Further, if this occurs, our competitors may take advantage of our investment in development and trials by referencing our clinical and preclinical data and launch their product earlier than might otherwise be the case.

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

Although as of September 30, 2026, we owned fourteen and licensed ten issued patents in the United States pertaining to our product candidates and pending patent applications in the United States and other countries, filing, prosecuting and defending patents in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our product candidates, and our patents, the patents of our licensors, 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 many foreign countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents or our licensors' patents or marketing of competing products in violation of our proprietary rights. Proceedings to enforce our patent rights and those of our licensors in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents or the patents of our licensors at risk of being invalidated or interpreted narrowly and our patent applications or the patent applications of our licensors at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop, license, or obtain.

Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. 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.

Geo-political actions in the United States and in foreign countries 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 or those of any current or future licensors. For example, the United States and foreign government actions related to Russia's invasion of Ukraine may limit or prevent filing, prosecution and maintenance of patent applications in Russia. Government actions may also prevent maintenance of issued patents in Russia. These actions could result in abandonment or lapse of our patents or patent applications, resulting in partial or complete loss of patent rights in Russia. If such an event were to occur, it could have a material adverse effect on our business. In addition, a decree was adopted by the Russian government in March 2022, allowing Russian companies and individuals to exploit inventions owned by patentees that have citizenship or nationality in, are registered in, or have a predominately primary place of business or profit-making activities in the United States and other countries that Russia has deemed unfriendly without consent or compensation. Consequently, we would not be able to prevent third parties from practicing our inventions in Russia or from selling or importing products made using our inventions in and into Russia. Accordingly, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected.

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

Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on patents and/or patent applications will be due to the USPTO and various foreign patent offices at various points over the lifetime of our patents and/or patent applications and those of our licensors. We have systems in place to remind us to pay these fees, and we rely on our outside patent annuity service to pay these fees when due. Additionally, the USPTO and various foreign patent offices require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply and, in many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with rules applicable to the particular jurisdiction. However, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If such an event were to occur, it could have a material adverse effect on our business.

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.

We intend to use registered or unregistered trademarks or trade names to brand and market ourselves and our products. As of September 30, 2026, we had two trademarks registered with the USPTO. Trademark applications we may file in the future may not result in any trademark registrations being issued, and our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on 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 our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

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

In addition, we rely on the protection of our trade secrets, including unpatented know-how, technology and other proprietary information to maintain our competitive position. Although we have taken steps to protect our trade secrets and unpatented know-how, including entering into confidentiality agreements with third parties, and confidential information and inventions agreements with employees, consultants and advisors, we cannot provide any assurances that all such agreements have been duly executed, and any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets.

Additionally, if any of our employees, consultants, advisors, or other parties with access to our confidential information use any third-party AI-powered systems or tools in connection with our business or the services they provide to us, it may lead to the inadvertent disclosure of our confidential information, including inadvertent disclosure of our confidential information into third-party training sets, some of which may be publicly available, and which may impact our ability to realize the benefit of, or adequately maintain, protect and enforce our intellectual property or confidential information, which could harm our competitive position and business.

Moreover, third parties may still obtain our trade secrets or other confidential information or may come upon this or similar information independently, and we would have no right to prevent them from using that information to compete with us. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced, and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

We may be subject to claims that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets.

We have entered into and may enter in the future into non-disclosure and confidentiality agreements to protect the proprietary positions of third parties, such as outside scientific collaborators, CROs, third-party manufacturers, consultants, advisors, potential partners, lessees of shared multi-company property and other third parties. We may become subject to litigation where a third party asserts that we or our employees inadvertently or otherwise breached the agreements and used or disclosed trade secrets or other information proprietary to the third parties. A third party has inquired about a potential breach of a non-disclosure and confidentiality

agreement in view of our developments in the CD73 inhibitor program. The inquiry may progress to a claim that we or our employees inadvertently or otherwise breached the agreement and used trade secrets or other information proprietary to the third party. Defense of such matters, regardless of their merit, could involve substantial litigation expense and be a substantial diversion of employee resources from our business. We cannot predict whether we would prevail in any such actions. Moreover, intellectual property litigation, regardless of its outcome, may cause negative publicity and could prohibit us from marketing or otherwise commercializing our product candidates and technology. Failure to defend against any such claim could subject us to significant liability for monetary damages or prevent or delay our developmental and commercialization efforts, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Parties making claims against us may be able to sustain the costs of complex intellectual property litigation more effectively than we can because they have substantially greater resources. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise additional funds or otherwise have a material adverse effect on our business, operating results, financial condition and prospects.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is common in the pharmaceutical industry, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidates. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other pharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. 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, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

Our rights to develop and commercialize our technology and product candidates may be subject, in part, to the terms and conditions of licenses granted to us by others.

We have entered into license agreements with third parties and we may enter into additional license agreements in the future with others to advance our research or allow commercialization of product candidates. These and other licenses may not provide 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 technology and products in the future.

In addition, subject to the terms of any such license agreements, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technology that we license from third parties. In such an event, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are the subject of such licensed rights could be adversely affected.

Our licensors may have relied on third party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If other affiliates or third parties have ownership rights to our in-licensed patents, they may be able to hinder our ability to enforce or defend such patents, or they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

It is possible that we may be unable to obtain additional licenses at a reasonable cost or on reasonable terms, if at all. Even if we are able to obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to redesign our technology, product candidates, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third party patents do not exist which might be enforced against our current technology, manufacturing methods, product candidates, or future methods or products resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

If we 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 licensors, we could lose license rights that are important to our business.

Our existing license agreements, and we expect that our future agreements will, impose various development, diligence, commercialization, and other obligations on us. Certain of our license agreements also require us to meet development timelines, or to exercise commercially reasonable efforts to develop and commercialize licensed products, in order to maintain the license.

Moreover, disputes may arise between us and our 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 on 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 diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- our right to transfer or assign the license;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

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

In spite of our best efforts, our licensors might conclude that we have materially breached our obligations under such license agreements and might therefore terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products identical to ours and we may be required to cease our development and commercialization of certain of our product candidates. For example, if Mirati terminates the Mirati License Agreement, we may be required to cease our development and commercialization of licensed products directed to PRC2 and would be obligated to assign to Mirati, or grant an exclusive license to Mirati with respect to, certain of our patents, know-how and regulatory filings. Likewise, if Voronoi terminates the Voronoi License Agreement, we may be required to cease our development and commercialization of licensed products directed to epidermal growth factor receptor (EGFR, or ErbB1) and human epidermal growth factor receptor 2 (ErbB2) with exon 20 insertion mutations and we would be obligated to grant a nonexclusive license to Voronoi under certain of our patents and know-how, and to assign to Voronoi certain of our regulatory filings. Any of the foregoing could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

The patent protection and patent prosecution for some of our product candidates may be dependent on third parties.

While we normally seek to obtain the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of the patent applications and patents relating to our product candidates, there may be times when the preparation, filing, prosecution, maintenance, enforcement and defense activities for patents and patent applications relating to our product candidates are controlled by our licensors or collaboration partners. If any of our licensors or collaboration partners fail to prepare, file, prosecute, maintain, enforce, and defend such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our licensors and their counsel that took place prior to the date upon which we assumed control over such activities.

Intellectual property discovered through government funded programs may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

As of September 30, 2026, we co-own one pending U.S. patent application and one European patent application, claiming inventions that were generated, in part, through the use of U.S. government funding. In the future, we may acquire or license other intellectual property rights that have been generated through the use of U.S. government funding or grants. Pursuant to the Bayh-Dole Act of 1980, the U.S. government has certain rights in inventions developed with government funding. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). If the U.S. government exercised its march-in rights in our future intellectual property rights that are generated through the use of U.S. government funding or grants, we could be forced to license or sublicense intellectual property developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U.S. government for the exercise of such rights. The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property.

The use of new and evolving technologies, such as AI, in our operations may present risks and challenges that can impact our business, including by posing security and other risks to our confidential information, proprietary information and personal information, any of which may result in reputational harm and liability, or otherwise adversely affect our business.

We may integrate AI, including generative AI, machine learning, and automated decision-making technologies into our operations. The use of AI technology, including generative AI, can give rise to intellectual property risks, including uncertainty regarding ownership of AI-generated inventions, compromises to proprietary IP, data provenance disputes, and infringement or misappropriation claims, as well as inaccuracy, bias, and data privacy and cybersecurity issues. The legal landscape for AI-generated inventions remains uncertain, and development of the law in the U.S. and abroad could impact our ability to enforce proprietary rights or protect against infringing uses. Depending on actions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents. For example, on February 13, 2024, the USPTO issued AI Inventorship guidance entitled "Inventorship Guidance for AI-assisted Inventions" which indicated that the three-part test articulated in *Pannu v. Iolab Corp.* 155 F.3d 1344 (Fed. Cir. 1998) was relevant to the inventorship analysis of AI-assisted inventions. However, the USPTO rescinded the February 13, 2024 guidance and issued a new guidance document entitled "Revised Inventorship Guidance for AI-Assisted Inventions" in November 2025, which treats AI systems as tools, applies the same inventorship standard regardless of AI assistance, and provides that the *Pannu* factors only apply when determining whether multiple natural persons qualify as joint inventors. Although this guidance reduces certain uncertainty, it is not binding on courts, and its application to specific AI-assisted inventions is fact-dependent, and the standards applied in other jurisdictions may differ and may change.

Our employees may use AI, including generative AI, in certain circumstances to perform portions of their work. There can be no assurance that employees will not inadvertently or improperly input proprietary, confidential, or sensitive information, including trade secrets, into AI systems in a manner that results in unauthorized disclosure or loss of confidentiality. Many AI tools are provided by third-party vendors, and we may have limited ability to control or verify how information submitted by employees is processed, stored, retained, or used by such providers, including whether such information may be incorporated into model training or otherwise accessed or disclosed. Any failure to adequately prevent the disclosure or misuse of our proprietary or confidential information, whether due to employee error, inadequate controls, evolving AI system functionality, or third-party practices, could result in the loss of trade secret protection and the disclosure of confidential information related to our inventions and product candidates, which could preclude us from obtaining patents covering disclosed inventions and product candidates, all of which could adversely affect our business.

Risks related to our dependence on third parties

We depend on third-party suppliers, and the loss of these third-party suppliers or their inability to supply us could harm our business.

We depend on third-party suppliers, including from certain manufacturers located in China that provide us with active pharmaceutical ingredients (API) required for the production of our product candidates, and we expect to continue to depend on third-party suppliers located in various jurisdictions around the world. Our dependence on these third-party suppliers and the challenges faced in obtaining adequate supplies involve several risks, including supply chain issues caused by the effects of worldwide economic conditions, including disruptions due to public health concerns, national security concerns, export or import restrictions, tariffs, or other geopolitical events, limited control over pricing, the availability of such materials, the quality of such materials, and delivery schedules. To the extent our business relies on suppliers, customers, or vendors in countries where the U.S. government has imposed any of these or other trade restrictions, our business may experience a material adverse effect. We may be unable to fully mitigate the effects of these disruptions or conditions. Any supply interruption could materially harm our ability to manufacture our product candidates, or to manufacture our product candidates on commercially reasonable terms, until a new source of supply, if any, can be identified and qualified. In such an event, we may be unable to find a sufficient alternative supply channel in a reasonable time or on commercially reasonable terms. Any performance failure on the part of the suppliers could delay the development and potential commercialization of our product candidates, including limiting supplies necessary for clinical trials and regulatory approvals, which would have a material adverse effect on our business.

In particular, there is currently significant uncertainty about the future relationship between the U.S. and various other countries, most significantly China, with respect to trade policies, including sanctions, treaties, tariffs, taxes, regulatory requirements, and other limitations on cross-border operations. The U.S. government has made and continues to make significant additional changes in U.S. trade policy and may continue to take future actions that could negatively impact our business. For more information, please see our risk factor above "*Enhanced trade tariffs, import restrictions, export restrictions, Chinese regulations or other trade barriers may materially harm our business.*" We cannot predict what actions may ultimately be taken with respect to trade relations between the U.S. and China or other countries, what interactions, including products or services, may be subject to such actions, or what actions may be taken by the other countries in retaliation. We may also be subject to indirect supply chain risks caused by recent and new changes in these policies, including an increased risk of recession, inflation, or a general macroeconomic slowdown. If our interactions with third-party suppliers, including the manufacturers we work with in China that supply API required for the production of our product candidates, are affected by any such governmental actions, our business, liquidity, financial condition, or results of operations could be materially and adversely affected.

We rely on third parties to conduct our clinical trials and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such trials, research and studies.

We do not have the ability to independently conduct our clinical trials. We currently rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to conduct our current and planned clinical trials of our product candidates. Third parties have a significant role in the conduct of our clinical trials and the subsequent collection and analysis of data. These third parties are not our employees, and except for remedies available to us under our agreements with such third parties, we have limited ability to control the amount or timing of resources that any such third party will devote to our clinical trials. The third parties we rely on for these services may also have relationships with other entities, some of which may be our competitors. Some of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements with a third party, it would delay our drug development activities.

Our reliance on these third parties for such drug development activities will reduce our control over these activities but will not relieve us of our regulatory responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with GCP standards, regulations for conducting, recording and reporting the results of clinical trials to assure that data and reported results are reliable and accurate and that the rights, integrity and confidentiality of trial participants are protected. The EMA also requires us to comply with similar standards. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials substantially comply with GCP regulations. In addition, our clinical trials must be conducted with product produced under current cGMPs regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the marketing approval process.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates.

We contract with third parties for the production of our product candidates for preclinical studies and, in the case of rinzimetostat and enozertinib, our ongoing clinical trials, and expect to continue to do so for additional clinical trials and ultimately for commercialization. This reliance on third parties increases the risk that we will not have sufficient quality and quantities of our product candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development or commercialization efforts.

We do not currently have the infrastructure or internal capability to manufacture supplies of our product candidates for use in development and commercialization. We rely, and expect to continue to rely, on third-party manufacturers for the production of our product candidates for preclinical studies and clinical trials under the guidance of members of our organization. For each of our product candidates, we rely on a single third-party manufacturer and we currently have no alternative manufacturer in place. We do not have long-term supply agreements, and we purchase our required drug product on a purchase order basis, which means that aside from any binding purchase orders we have from time to time, our supplier could cease supplying to us or change the terms on which it is willing to continue supplying to us at any time. If we were to experience an unexpected loss of supply of any product candidates for any reason, whether as a result of manufacturing, supply or storage issues or otherwise, we could experience delays, disruptions, suspensions or terminations of, or be required to restart or repeat, any pending or ongoing studies or clinical trials.

We expect to continue to rely on third-party manufacturers for the commercial supply of any of our product candidates for which we obtain marketing approval. We may be unable to maintain or establish required agreements with third-party manufacturers or to do so on acceptable terms. Even if we are able to establish agreements with third-party manufacturers, reliance on third-party manufacturers entails additional risks, including:

- the failure of the third party to manufacture our product candidates according to our schedule and specifications, or at all, including if our third-party contractors give greater priority to the supply of other products over our product candidates or otherwise do not satisfactorily perform according to the terms of the agreements between us and them;
- the termination or nonrenewal of arrangements or agreements by our third-party contractors at a time that is costly or inconvenient for us;
- the breach by the third-party contractors of our agreements with them;
- the failure of third-party contractors to comply with applicable regulatory requirements, including cGMPs;
- the failure of the third party to manufacture our product candidates according to our specifications;
- the mislabeling of clinical supplies, potentially resulting in the wrong dose amounts being supplied or active drug or placebo not being properly identified;
- clinical supplies not being delivered to clinical sites on time, leading to clinical trial interruptions, or of drug supplies not being distributed to commercial vendors in a timely manner, resulting in lost sales; and
- the misappropriation of our proprietary information, including our trade secrets and know-how.

We do not have complete control over all aspects of the manufacturing process of our contract manufacturing partners and are dependent on these contract manufacturing partners for compliance with cGMPs regulations for manufacturing both API and finished drug products. To date, we have obtained API and drug product for our product candidates from single-source third party contract manufacturers. We are in the process of developing our supply chain for each of our product candidates and intend to put in place framework agreements under which third-party contract manufacturers will generally provide us with necessary quantities of API and drug product on a project-by-project basis based on our development needs. As we advance our product candidates through development, we will consider our lack of redundant supply for the API and drug product for each of our product candidates to protect against any potential supply disruptions. However, we may be unsuccessful in putting in place such framework agreements or protecting against potential supply disruptions.

Third-party manufacturers may not be able to comply with cGMPs regulations or similar regulatory requirements outside of the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or others, they will not be able to secure and/or maintain marketing approval for their manufacturing facilities. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA, EMA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we will need to find alternative manufacturing facilities, and those new facilities would need to be inspected and approved by FDA, EMA or comparable regulatory authority prior to commencing manufacturing, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, 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 drugs, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates or drugs and harm our business and results of operations.

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

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

From time to time, we evaluate various acquisition opportunities and strategic partnerships, including licensing or acquiring complementary products, intellectual property rights, technologies or businesses. For instance, in August 2020, we entered into the Mirati License Agreement pursuant to which we licensed from Mirati exclusive worldwide development and commercialization rights to its allosteric PRC2 inhibitor program and, in October 2020, we entered into the Voronoi License Agreement pursuant to which we licensed from Voronoi exclusive development and commercialization rights to its EGFR exon 20 insertion mutation program worldwide (other than in the People's Republic of China, Hong Kong, Macau and Taiwan). Any such acquisition or strategic partnership may entail numerous risks, including:

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

In addition, if we undertake acquisitions or pursue partnerships in the future, we may issue dilutive securities, assume or incur debt obligations, incur large one-time expenses and acquire intangible assets that could result in significant future amortization expense. For instance, in connection with the Mirati License Agreement, we issued to Mirati 588,235 shares of our common stock and, in connection with the Voronoi License Agreement, we issued Voronoi 283,259 shares of our common stock, each of which resulted in dilution to our existing stockholders.

If we decide to establish additional collaborations, but are not able to establish those collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans.

Our drug development programs and the potential commercialization of our product candidates will require substantial additional cash to fund expenses. We may seek to selectively form collaborations to expand our capabilities, potentially accelerate research and development activities and provide for commercialization activities by third parties. For example, we completed a Phase 1b trial of ORIC-533 as a single-agent, in patients with relapsed/refractory multiple myeloma, and intend to evaluate strategic partnerships to develop ORIC-533 in combination with other immune-based antimyeloma therapies. Any of these relationships may

require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing stockholders, or disrupt our management and business.

We would face significant competition in seeking additional appropriate collaborators and the negotiation process is time-consuming and complex. Whether we reach a definitive agreement for a collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, EMA or comparable foreign regulatory authorities, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing drugs, the existence of uncertainty with respect to our ownership of intellectual property and industry and market conditions generally. The potential collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such collaboration could be more attractive than the one with us for our product candidate. Further, we may not be successful in our efforts to establish a collaboration or other alternative arrangements for product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view them as having the requisite potential to demonstrate safety and efficacy.

In addition, 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. Even when we are successful in entering into a collaboration, the terms and conditions of that collaboration may restrict us from entering into future agreements on certain terms with potential collaborators.

If and when we seek to enter into additional collaborations, 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 a product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to 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.

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

If we enter into any collaboration arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities and efforts to successfully perform the functions assigned to them in these arrangements. Collaborations involving our product candidates would pose numerous risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to, and the manner in which they perform their obligations under, these collaborations and may not perform their obligations as expected;
- collaborators may deemphasize or not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus, including as a result of a business combination or sale or disposition of a business unit or development function, or available funding or external factors such as an acquisition that diverts resources or creates competing priorities;
- collaborators may rely on third parties to conduct development, manufacturing, and/or commercialization activities, and except for remedies available to us under our collaboration agreements, we have limited ability to control the conduct of such activities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- a collaborator with marketing and distribution rights to multiple products may not commit sufficient resources to the marketing and distribution of our product relative to other products;
- we may grant exclusive rights to our collaborators that would prevent us from collaborating with others;

- collaborators may not properly obtain, maintain, defend or enforce our intellectual property rights or may use our proprietary information and intellectual property in such a way as to invite litigation or other intellectual property related proceedings that could jeopardize or invalidate our proprietary information and intellectual property or expose us to potential litigation or other intellectual property related proceedings;
- disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates;
- collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all;
- collaborators may not provide us with timely and accurate information regarding development progress and activities under the collaboration or may limit our ability to share such information, which could adversely impact our ability to report progress to our investors and otherwise plan our own development of our product candidates;
- collaborators may own or co-own intellectual property covering our products that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings.

Risks related to the securities markets and ownership of our common stock

We do not know whether an active, liquid and orderly trading market will continue for our common stock or what the market price of our common stock will be and as a result it may be difficult for you to sell your shares of our common stock.

Prior to our initial public offering in April 2020, there was no public market for shares of our common stock and we can provide no assurance that we will be able to sustain an active trading market for our shares. 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. The lack of an active market may also reduce the fair market value of your shares. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies, technologies or other assets by using our shares of common stock as consideration.

The price of our stock is volatile.

The trading price of our common stock is highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. The stock market in general, and pharmaceutical and biotechnology companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies.

Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this periodic report, these factors include:

- the timing and results of preclinical studies and clinical trials of our product candidates, those conducted by third parties or those of our competitors;
- the success of competitive products or announcements by potential competitors of their product development efforts;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated changes in our growth rate relative to our competitors;
- regulatory or legal developments in the United States and other countries;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations or capital commitments;

- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- market conditions in the pharmaceutical and biotechnology sector;
- changes in the structure of healthcare payment systems;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders or our other stockholders;
- expiration of market stand-off or lock-up agreements;
- the impact of any natural disasters or public health emergencies, such as the COVID-19 pandemic; and
- general economic, political, industry and market conditions, including international military conflicts and instability in the financial markets and banking industry.

The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and adverse impact on the market price of our common stock.

If securities or industry analysts do not publish research or reports, or if they publish adverse or misleading research or reports, regarding us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that securities or industry analysts publish about us, our business or our market. We currently have research coverage from a limited number of securities or industry analysts. If any of the analysts who cover us issue adverse or misleading research or reports regarding us, our business model, our intellectual property, our stock performance or our market, or if our operating results fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or our guidance.

Our quarterly and annual operating results may fluctuate significantly in the future, which makes it difficult for us to predict our future operating results. From time to time, we may enter into license or collaboration agreements or strategic partnerships with other companies that include development funding and significant upfront and milestone payments and/or royalties, which may become an important source of our revenue. These upfront and milestone payments may vary significantly from period to period and any such variance could cause a significant fluctuation in our operating results from one period to the next.

In addition, we measure compensation cost for stock-based awards made to employees at the grant date of the award, based on the fair value of the award as determined by our board of directors, and recognize the cost as an expense over the employee's requisite service period. As the variables that we use as a basis for valuing these awards change over time, including, our underlying stock price and stock price volatility, the magnitude of the expense that we must recognize may vary significantly.

Furthermore, our operating results may fluctuate due to a variety of other factors, many of which are outside of our control and may be difficult to predict, including the following:

- the timing and cost of, and level of investment in, research and development activities relating to our current product candidates and any future product candidates and research-stage programs, which will change from time to time;
- our ability to enroll patients in clinical trials and the timing of enrollment;
- the cost of manufacturing our current product candidates and any future product candidates, which may vary depending on FDA, EMA or other comparable foreign regulatory authority guidelines and requirements, the quantity of production and the terms of our agreements with manufacturers;
- expenditures that we will or may incur to acquire or develop additional product candidates and technologies or other assets;
- the timing and outcomes of clinical trials for any of our product candidates, or competing product candidates;
- the need to conduct unanticipated clinical trials or trials that are larger or more complex than anticipated;

- competition from existing and potential future products that compete with any of our product candidates, and changes in the competitive landscape of our industry, including consolidation among our competitors or partners;
- any delays in regulatory review or approval of any of our product candidates;
- the level of demand for any of our product candidates, if approved, which may fluctuate significantly and be difficult to predict;
- the risk/benefit profile, cost and reimbursement policies with respect to our product candidates, if approved, and existing and potential future products that compete with any of our product candidates;
- our ability to commercialize any of our product candidates, if approved, inside and outside of the United States, either independently or working with third parties;
- our ability to establish and maintain collaborations, licensing or other arrangements;
- our ability to adequately support future growth;
- potential unforeseen business disruptions that increase our costs or expenses;
- future accounting pronouncements or changes in our accounting policies; and
- the changing and volatile global economic and political environment.

The cumulative effect 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. Investors should not rely on our past results as an indication of our future performance. 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 revenue or operating results 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 principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

As of September 30, 2026, our executive officers, directors, holders of 5% or more of our common stock and their respective affiliates beneficially owned a significant percentage of our outstanding common stock. These stockholders, acting together, may be able to impact matters requiring stockholder approval. For example, they may be able to impact elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

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 could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

Certain holders of shares of our common stock have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Registration of these shares under the Securities Act would result in the shares becoming freely tradeable in the public market, subject to the restrictions of Rule 144 in the case of our affiliates. For example, on June 11, 2025, we filed a Form S-3 registration statement, which the SEC declared effective on June 20, 2025, registering 14,130,313 shares of our common stock and 5,100,532 shares of our common stock underlying pre-funded warrants sold in a private placement on May 29, 2025. On January 26, 2024, we filed a Form S-3 registration statement, which the SEC declared effective on February 2, 2024, registering 12,500,000 shares of our common stock sold in a private placement on January 23, 2024. In addition, on December 15, 2023, we filed a Form S-3 registration statement, which the SEC declared effective on December 28, 2023, registering 9,285,710 shares of our common stock and 2,857,142 shares of our common stock underlying pre-funded warrants sold in a private placement on June 27, 2023. Any sales of securities by these stockholders could have a material adverse effect on the market price for our common stock.

We incur increased costs as a result of operating as a public company, and our management devotes substantial time to related compliance initiatives. Additionally, if we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company, and these expenses may increase even more now that we are no longer an "emerging growth company" or a "smaller reporting company" as of December 31, 2025. We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Protection Act, as well as rules adopted, and to be adopted, by the SEC and Nasdaq. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly, which will increase our operating expenses. For example, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage, particularly in light of recent cost increases related to coverage. We cannot accurately predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers.

In addition, as a public company we are required to incur additional costs and obligations in order to comply with SEC rules that implement Section 404 of the Sarbanes-Oxley Act. Under these rules, we are required to make a formal assessment of the effectiveness of our internal control over financial reporting, and once we cease to be a non-accelerated filer, we may be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaging in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively, and implement a continuous reporting and improvement process for internal control over financial reporting.

The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation to meet the detailed standards under the rules. During the course of its testing, our management may identify material weaknesses or deficiencies which may not be remedied in time to meet the deadline imposed by the Sarbanes-Oxley Act. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities.

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

We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the facts that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

We may be subject to securities litigation, which is expensive and could divert management attention.

The market price of our common stock is volatile and, in the past, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. This risk is especially relevant for us because biotechnology companies have experienced significant stock price volatility in recent years and we may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could seriously harm our business.

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

We have never declared or paid any cash dividends 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. Any return to stockholders will therefore be limited to any appreciation in the value of their stock.

Provisions in our amended and restated certificate of incorporation and amended and restated bylaws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock.

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could depress the market price of our common stock by acting to discourage, delay or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things:

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- provide that directors may only be removed "for cause" and only with the approval of two-thirds of our stockholders;
- authorize the issuance of "blank check" preferred stock that our board could use to implement a stockholder rights plan (also known as a "poison pill");
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting;
- authorize our board of directors to amend the bylaws;
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings; and
- require a super-majority vote of stockholders to amend some provisions described above.

In addition, Section 203 of the General Corporation Law of the State of Delaware (DGCL), prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Any provision of our amended and restated certificate of incorporation, amended and restated bylaws or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which may limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated bylaws provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another State court in Delaware or the federal district court for the District of Delaware) is the exclusive forum for the following (except for any claim as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court (and the indispensable party does not consent to the personal jurisdiction of such court within 10 days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than such court or for which such court does not have subject matter jurisdiction):

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of fiduciary duty;
- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

This provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction.

Our amended and restated bylaws further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act.

These exclusive-forum provisions may 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, which may discourage lawsuits against us and our directors, officers and other employees. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings.

It is possible that a court could find these types of provisions to be inapplicable or unenforceable, and if a court were to find either exclusive-forum provision in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

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

Recent Sales of Unregistered Securities

None.

Use of Proceeds from Registered Securities

None.

Repurchase of Our Common Stock

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

None.

Item 5. Other Information.

Securities Trading Arrangements of Directors and Executive Officers

During the last fiscal quarter, certain directors and officers, as defined in Rule 16a-1(f) of the Exchange Act, adopted a "Rule 10b5-1 trading arrangement" as defined in Regulation S-K Item 408, as follows:

On September 2, 2026, Pratik Multani, M.D., our Chief Medical Officer, adopted a "Rule 10b5-1 trading arrangement" providing for the sale from time to time of an aggregate of up to 250,100 shares of our common stock. The trading arrangement is intended to satisfy the affirmative defense in Rule 10b5-1(c) of the Exchange Act. The duration of the trading arrangement is from December 4, 2026, until September 30, 2027, or earlier if all transactions under the trading arrangement are completed.

On September 2, 2026, Jacob Chacko, M.D., our President and Chief Executive Officer, adopted a "Rule 10b5-1 trading arrangement" providing for the sale from time to time of an aggregate of up to 130,100 shares of our common stock. The trading arrangement is intended to satisfy the affirmative defense in Rule 10b5-1(c) of the Exchange Act. The duration of the trading arrangement is from December 3, 2026, until September 7, 2027, or earlier if all transactions under the trading arrangement are completed.

Except as described above, no officers or directors, as defined in Rule 16a-1(f) of the Exchange Act, adopted and/or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," each as defined in Regulation S-K Item 408, during the last fiscal quarter.

Item 6. Exhibits.

Exhibit Number	Exhibit Description	Incorporated by Reference			
		Form	File No.	Exhibit	Filing Date
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.				Filed herewith
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.				Filed herewith
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.				Furnished herewith
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.				Furnished herewith
101.INS	INLINE XBRL Instance Document				Furnished herewith
101.SCH	INLINE XBRL Taxonomy Extension Schema with Embedded Linkbase Document				Furnished herewith
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)				Furnished herewith

* The certifications attached as Exhibits 32.1 and 32.2 that accompany this quarterly report on Form 10-Q are not deemed filed with the Securities and Exchange Commission and are not to be incorporated by reference into any filing of ORIC Pharmaceuticals, Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, whether made before or after the date of this Form 10-Q, irrespective of any general incorporation language contained in such filing.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ORIC Pharmaceuticals, Inc.

Date: November 16, 2026

By: /s/ Jacob M. Chacko

Jacob M. Chacko, M.D.

President and Chief Executive Officer

Date: November 16, 2026

By: /s/ Dominic Piscitelli

Dominic Piscitelli

Chief Financial Officer

Exhibit 31.1

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

I, Jacob M. Chacko, certify that:

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

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

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

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

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

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

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

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

5. The registrant's other certifying officer 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 16, 2026

By: /s/ Jacob M. Chacko
Jacob M. Chacko, M.D.
President and Chief Executive Officer

Exhibit 31.2

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

I, Dominic Piscitelli, certify that:

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

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

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

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

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

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

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

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

5. The registrant's other certifying officer 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 16, 2026

By: /s/ Dominic Piscitelli
Dominic Piscitelli
Chief Financial Officer

Exhibit 32.1

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

In connection with the Quarterly Report of ORIC Pharmaceuticals, 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:

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

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

Date: November 16, 2026

By: /s/ Jacob M. Chacko

Jacob M. Chacko, M.D.
President and Chief Executive Officer

Exhibit 32.2

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

In connection with the Quarterly Report of ORIC Pharmaceuticals, 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:

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

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

Date: November 16, 2026

By: /s/ Dominic Piscitelli

Dominic Piscitelli
Chief Financial Officer