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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2026

☐ **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 001-40366

WEREWOLF THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**82-3523180**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
303 Wyman Street, Suite 300 Waltham, Massachusetts	**02451**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 952-0555

(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	HOWL	The Nasdaq Capital Market

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company.

See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

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

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

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

As of November 9, 2026, there were 48,599,066 shares of common stock, $0.0001 par value per share, outstanding.

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References to Werewolf

Throughout this Quarterly Report on Form 10-Q, or Quarterly Report, the "Company," "Werewolf," "Werewolf Therapeutics," "we," "us," "our," and similar references, except where the context requires otherwise, refer to Werewolf Therapeutics, Inc. and its consolidated subsidiaries, and "board of directors" refers to the board of directors of Werewolf Therapeutics, Inc.

Cautionary Note Regarding Forward-Looking Statements and Industry Data

This Quarterly Report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act, that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly Report, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth, are forward-looking statements.

The words "aim," "anticipate," "believe," "contemplate," "continue," "could," "design," "designed to," "engineered," "estimate," "expect," "goal," "intend," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "promise," "project," "should," "target," "will," "would," or the negative of these words or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among other things, statements about:

- the timing and completion of the Merger (as defined below) with Ambros (as defined below) and the Concurrent PIPE Financing (as defined below), including the satisfaction or waiver of the conditions to closing, and the anticipated benefits of the Merger;
- our ability to complete the transfer of the EMD Transferred Assets (as defined below) technology to EMD (as defined below) and to receive any payment in connection therewith;
- the initiation, timing, progress and results of our research and development programs, preclinical studies and clinical trials, including the anticipated timing of data announcements;
- our estimates regarding expenses, capital requirements, need for additional financing and the period over which we believe our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements;
- if the Merger is not completed, our ability to identify and consummate another strategic transaction, and the possibility that our board of directors may decide to pursue a dissolution and liquidation of our company;
- our ability to continue as a going concern;
- our plans to develop and, if approved, subsequently commercialize product candidates;
- the timing of and our ability to submit applications and obtain and maintain regulatory approvals for product candidates;
- our estimates regarding the potential market opportunities for our product candidates;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our intellectual property position and our expectations regarding our ability to obtain and maintain intellectual property protection;
- our ability to identify additional products, product candidates or technologies with significant commercial potential that are consistent with our commercial objectives;
- the impact of government laws and regulations;
- the impact of general economic conditions, including inflation and the imposition of new or revised global trade tariffs;
- our competitive position and expectations regarding developments and projections relating to our competitors and any competing therapies that are or become available; and
- developments and expectations regarding developments and projections relating to our competitors and our industry.

There are a number of important risks and uncertainties that could cause our actual results to differ materially from those indicated by forward-looking statements. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this Quarterly Report, particularly in Part II, Item

1A. “Risk Factors”, that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments that we may make or enter into.

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

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, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete. 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 on these statements.

Trademarks and Trade names

We own or have rights to trademarks, service marks and trade names that we use in connection with the operation of our business, including our corporate name, logos and website names. The service marks and trademarks that we own include the marks PREDATOR®, INDUKINE™, and INDUCER™. Other trademarks, service marks and trade names appearing in this Quarterly Report are the property of their respective owners. Solely for convenience, some of the trademarks, service marks and trade names referred to in this Quarterly Report are listed without the ® and ™ symbols, but we will assert, to the fullest extent under applicable law, our rights to our trademarks, service marks and trade names.

Risk Factor Summary

Our business is subject to numerous risks that, if realized, could materially and adversely affect our business, financial condition, results of operations and future growth prospects. These risks are discussed more fully in Part II, Item 1A. “Risk Factors” in this Quarterly Report. These risks include, but are not limited to, the following:

- Failure to complete, or delays in completing, the Merger could materially and adversely affect our and Ambros’ results of operations, business, financial results and stock prices, and if the Merger is not completed, the price of our common stock may decline significantly.
- If the conditions to the Merger are not satisfied or waived, the Merger may not occur.
- Our stockholders may not realize a benefit from the Merger commensurate with the ownership dilution they will experience, including from the securities issued in the Concurrent PIPE Financing, and our stockholders will have a reduced ownership and voting interest in, and will exercise less influence over the management of, the combined company
- Certain provisions of the Merger Agreement (as defined below), including a termination fee that may become payable in specified circumstances, may discourage third parties from submitting competing proposals, including proposals that may be superior to the Contemplated Transactions (as defined below).
- The exchange ratio set forth in the Merger Agreement will not be adjusted based on the market price of our common stock, so the merger consideration at the Merger Closing (as defined below) may have a greater or lesser value than at the time the Merger Agreement was signed.
- Lawsuits may be filed against us, Ambros or the members of our respective boards of directors arising out of the Merger, which may delay or prevent the Merger.
- We believe there is substantial doubt about our ability to continue as a going concern for at least twelve months from the date that these condensed consolidated financial statements are issued in this Quarterly Report. We are currently evaluating strategies to raise additional capital, however, there can be no assurances that we will be successful in mitigating the conditions that raise substantial doubt about our ability to continue as a going concern in the near term, if at all.
- Our ability to continue operations is dependent on consummating the Merger on a timely basis. If the Merger is not completed, we will need additional funding and may be required to significantly reduce or discontinue our operations, pursue another strategic transaction or pursue a dissolution and liquidation.

- We have a limited operating history, have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future. We have no products approved for commercial sale and have not generated any revenue from product sales, and we may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.
- We will need to obtain substantial additional funding to finance our operations and any development and commercialization activities we may pursue with respect to product candidates. If we are unable to raise this capital when needed, we may be forced to delay, reduce or eliminate any research and development programs we may pursue or other operations.
- Any product candidates we may develop will require successful completion of preclinical and clinical development before we can seek regulatory approval, and preclinical studies and clinical trials are expensive, time-consuming and difficult to design and implement, and involve uncertain outcomes.
- We may encounter substantial delays in the commencement or completion, or termination or suspension, of any clinical trials we may conduct, which could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.
- Product candidates we may develop may cause undesirable or unexpectedly severe side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.
- We have in the past, and may in the future, develop product candidates in combination with third-party products, and we will have limited or no control over the safety, supply, regulatory status or regulatory approval of such products.
- We have never commercialized a product candidate, and even if a product candidate we develop receives marketing approval, it may fail to achieve market acceptance or to obtain adequate coverage and reimbursement from third-party payors.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- We expect to rely on third parties to conduct any preclinical studies and clinical trials and to manufacture preclinical, clinical and commercial supplies of any product candidates we develop, and if these third parties do not perform successfully, we may not be able to obtain regulatory approval of or commercialize any product candidates.
- If we are unable to obtain and maintain patent protection for any product candidates or proprietary technologies we develop, or if our efforts to protect our intellectual property are not adequate, our competitors could develop and commercialize similar product candidates and technology and we may not be able to compete effectively.
- Our proprietary position in part depends upon patents that are manufacturing, formulation or method-of-use patents, which may not prevent a competitor or other third party from using the same product candidate for another use.
- Third-party claims of intellectual property infringement may prevent or delay our product discovery and development efforts, and if we breach our license agreements, it could have a material adverse effect on our commercialization efforts.
- The regulatory approval process is expensive, time-consuming and uncertain, and failure to obtain marketing approval in the United States or in foreign jurisdictions would prevent us from commercializing any product candidates.
- Any product candidate for which we obtain marketing approval will be subject to ongoing regulation and could be subject to restrictions or withdrawal from the market, and we may be subject to substantial penalties if we fail to comply with regulatory requirements.
- We may be subject to healthcare, privacy and data security, export control, anti-corruption and other laws and regulations, which could expose us to criminal sanctions, civil penalties, reputational harm and other adverse consequences.
- Current and future legislation may increase the difficulty and cost of obtaining reimbursement for, and may limit the prices of, any product candidates that receive marketing approval.
- Our future success depends on our ability to retain key employees, consultants and advisors and to attract, retain and motivate qualified personnel.
- Our business could be negatively affected by cyberattacks or deficiencies in our cybersecurity, and our computer systems and data, or those of third parties with whom we work, may fail or suffer security breaches.

- We have received notices from Nasdaq that we are not in compliance with the minimum bid price requirement for continued listing, and our common stock may be delisted if we do not regain compliance.
- The price of our common stock could be subject to volatility related or unrelated to our operations.
- In the past, we have identified material weaknesses in our internal control over financial reporting, and if we are unable to implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports, and the market price of our common stock may be materially adversely affected.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

Werewolf Therapeutics, Inc.
Condensed Consolidated Balance Sheets (unaudited)
(amounts in thousands, except share and per share amounts)

	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 41,870	$ 57,050
Prepaid expenses and other current assets	883	1,536
Total current assets	42,753	58,586
Property and equipment, net	—	4,688
Restricted cash and cash equivalents	—	901
Operating lease right of use asset	—	5,216
Other assets	—	5
Total assets	$ 42,753	$ 69,396
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,426	$ 754
Accrued expenses and other current liabilities	4,718	5,407
Deferred income	28,850	—
Operating lease liability, current	—	1,751
Note payable, net of discount and issuance costs	—	28,236
Total current liabilities	35,994	36,148
Operating lease liability, net of current portion	—	7,684
Derivative liability	—	759
Total liabilities	35,994	44,591
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value, 5,000,000 shares authorized as of September 30, 2026 and December 31, 2025; no shares issued or outstanding as of September 30, 2026 and December 31, 2025	—	—
Common stock, $0.0001 par value, 200,000,000 shares authorized as of September 30, 2026 and December 31, 2025; 48,599,066 and 48,596,817 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	5	5
Additional paid-in capital	501,903	500,210
Accumulated deficit	(495,149)	(475,410)
Total stockholders' equity	6,759	24,805
Total liabilities and stockholders' equity	$ 42,753	$ 69,396

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

Werewolf Therapeutics, Inc.
Condensed Consolidated Statements of Operations (unaudited)
(amounts in thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Revenue:				
Collaboration revenue	$ —	$ —	$ 21,000	$ —
Operating expenses:				
Research and development	2,175	11,634	16,518	37,897
General and administrative	7,879	4,092	20,649	13,362
Total operating expenses	10,054	15,726	37,167	51,259
Operating loss	(10,054)	(15,726)	(16,167)	(51,259)
Other income (expense):				
Interest income	183	697	893	2,544
Interest expense	—	(1,341)	(1,843)	(3,905)
Loss on extinguishment of note payable	—	—	(3,354)	—
Other (expense) income, net	(6)	—	732	179
Total other income (expense)	177	(644)	(3,572)	(1,182)
Net loss	$ (9,877)	$ (16,370)	$ (19,739)	$ (52,441)
Net loss per common share, basic and diluted	$ (0.20)	$ (0.36)	$ (0.41)	$ (1.16)
Weighted-average common shares outstanding, basic and diluted	48,599,066	45,804,042	48,597,814	45,207,894

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

Werewolf Therapeutics, Inc.
Condensed Consolidated Statements of Stockholders' Equity (unaudited)
(amounts in thousands, except share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2025	48,596,817	$ 5	$ 500,210	$ (475,410)	$ 24,805
Stock-based compensation expense	—	—	929	—	929
Net loss	—	—	—	(13,532)	(13,532)
Balance at March 31, 2026	48,596,817	5	501,139	(488,942)	12,202
Issuance of common stock, net	2,249	—	1	—	1
Stock-based compensation expense	—	—	419	—	419
Net income	—	—	—	3,670	3,670
Balance at June 30, 2026	48,599,066	5	501,559	(485,272)	16,292
Stock-based compensation expense	—	—	344	—	344
Net loss	—	—	—	(9,877)	(9,877)
Balance at September 30, 2026	48,599,066	$ 5	$ 501,903	$ (495,149)	$ 6,759

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2024	44,827,159	$ 5	$ 487,973	$ (414,588)	$ 73,390
Stock-based compensation expense	—	—	2,006	—	2,006
Net loss	—	—	—	(18,089)	(18,089)
Balance at March 31, 2025	44,827,159	5	489,979	(432,677)	57,307
Issuance of common stock from at the market offering, net of issuance costs of $255	421,766	—	305	—	305
Issuance of common stock, net	86,340	—	41	—	41
Stock-based compensation expense	—	—	1,793	—	1,793
Net loss	—	—	—	(17,982)	(17,982)
Balance at June 30, 2025	45,335,265	5	492,118	(450,659)	41,464
Issuance of common stock from at the market offering, net of issuance costs of $179	1,938,420	—	3,287	—	3,287
Stock-based compensation expense	—	—	1,233	—	1,233
Net loss	—	—	—	(16,370)	(16,370)
Balance at September 30, 2025	47,273,685	$ 5	$ 496,638	$ (467,029)	$ 29,614

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

Werewolf Therapeutics, Inc.
Condensed Consolidated Statements of Cash Flows (unaudited)
(amounts in thousands)

	Nine Months Ended September 30,	
	2026	**2025**
Operating activities:		
Net loss	$ (19,739)	$ (52,441)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	1,692	5,032
Depreciation expense	4,113	1,234
Loss on sale and disposal of property and equipment, net	159	—
Non-cash interest expense	771	1,561
Non-cash lease expense	307	579
Loss on extinguishment of note payable	3,354	—
Change in fair value of derivative liability	(707)	(215)
Gain on modification of lease liability	(1,142)	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	658	(117)
Accounts payable, accrued expenses and other liabilities	983	(3,553)
Operating lease liability	(3,384)	(1,348)
Net cash used in operating activities	(12,935)	(49,268)
Investing activities:		
Proceeds from sale of intellectual property	28,850	—
Proceeds from sale of property and equipment	416	—
Net cash provided by investing activities	29,266	—
Financing activities:		
Repayment of note payable and extinguishment costs	(32,413)	—
Proceeds from at the market offering of common stock, net of issuance costs	—	3,621
Proceeds from issuances under Employee Stock Purchase Plan	1	41
Net cash (used in) provided by financing activities	(32,412)	3,662
Net decrease in cash, cash equivalents and restricted cash and cash equivalents	(16,081)	(45,606)
Cash, cash equivalents and restricted cash and cash equivalents—beginning of period	57,951	112,215
Cash, cash equivalents and restricted cash and cash equivalents—end of period	$ 41,870	$ 66,609
Reconciliation of cash, cash equivalents and restricted cash and cash equivalents to the condensed consolidated balance sheets		
Cash and cash equivalents	$ 41,870	$ 65,711
Restricted cash and cash equivalents	—	898
Total cash, cash equivalents and restricted cash and cash equivalents	$ 41,870	$ 66,609
Supplemental disclosure of cash flow information:		
Cash paid for interest	$ 1,338	$ 2,352
Supplemental disclosure of non-cash investing and financing activities:		
Adjustment to right of use asset in exchange for reduction in lease liability	$ 4,909	$ —
Issuance costs in accounts payable and accrued expenses	$ —	$ 113

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

Werewolf Therapeutics, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)

1. Nature of Business

Werewolf Therapeutics, Inc. was incorporated in the state of Delaware in October 2017. As used throughout these unaudited, condensed consolidated financial statements, the terms "Werewolf," the "Company," "we," "us," and "our" refer to the business of Werewolf Therapeutics, Inc., and its wholly owned subsidiaries. We are an innovative biopharmaceutical company pioneering the development of therapeutics engineered to stimulate the body's immune system for the treatment of cancer and other immune-mediated conditions. Our headquarters are located in Waltham, Massachusetts.

Since inception, we have devoted substantially all of our efforts and financial resources to organizing and staffing the company; business planning; raising capital; developing and optimizing our platform technology; identifying potential product candidates; enhancing our intellectual property portfolio; undertaking research, preclinical studies, and clinical trials; and enabling manufacturing for our development programs. We are subject to risks and uncertainties common to early-stage companies in the biotechnology industry including, but not limited to, technical risks associated with the successful research, development and manufacturing of product candidates, development by competitors of new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations and the ability to secure additional capital to fund operations. Current and future programs will require significant research and development efforts, including extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel and infrastructure. Even if our product development efforts are successful, it is uncertain when, if ever, we will realize significant revenue from product sales.

2. Merger

Merger Agreement

On August 21, 2026, we entered into an Agreement and Plan of Merger (the "Merger Agreement") by and among Ambros Therapeutics, Inc. ("Ambros"), Werewolf, and Wave Atlantis Merger Sub, Inc., a direct, wholly owned subsidiary of Werewolf ("Merger Sub").

Pursuant to the Merger Agreement, and upon the terms and subject to the satisfaction of the conditions described therein, Merger Sub will be merged with and into Ambros, with Ambros surviving as a wholly owned subsidiary of Werewolf (the "Merger" and, together with the other transactions contemplated by the Merger Agreement, the "Contemplated Transactions"). The Merger is intended to qualify as a tax-free reorganization for U.S. federal income tax purposes.

Subject to the terms and conditions of the Merger Agreement, (i) immediately prior to the effective time of the Merger (the "Effective Time"), the then-outstanding shares of Ambros preferred stock, par value $0.00001 per share, will be converted into shares of Ambros common stock, par value $0.00001 per share ("Ambros Common Stock") and (ii) at the Effective Time, each then-outstanding share of Ambros Common Stock (excluding shares held by stockholders who have exercised and perfected appraisal rights for such shares) will be converted into the right to receive a number of shares of Werewolf common stock, par value $0.0001 per share ("Werewolf Common Stock"), calculated in accordance with the exchange ratio as set forth in the Merger Agreement and subject to any election pursuant to the terms of the Merger Agreement to receive pre-funded warrants to acquire Werewolf Common Stock with an exercise price of $0.001 per share ("Merger Pre-Funded Warrants") in lieu of any shares of Werewolf Common Stock in excess of the Beneficial Ownership Limitation (as defined in the Merger Agreement). In addition, at the Effective Time, each then-outstanding option to purchase shares of Ambros Common Stock will be assumed by Werewolf and converted into an option to acquire Werewolf Common Stock, with the number of underlying shares and exercise price adjusted in accordance with the exchange ratio as set forth in the Merger Agreement.

At the closing of the Merger (the "Merger Closing" and such date, the "Merger Closing Date"), on a pro forma basis and based upon the number of shares of Werewolf Common Stock and Merger Pre-Funded Warrants and pre-funded warrants to purchase shares of Werewolf Common Stock with an exercise price of $0.001 per share expected to be issued in connection with the Concurrent PIPE Financing (as defined below) ("PIPE Pre-Funded Warrants" and, together with the Merger Pre-Funded Warrants, the "Pre-Funded Warrants"), pre-merger equity holders of Werewolf, other than those participating in the private placement, are expected to own approximately 6.4% of the combined company, pre-merger Ambros stockholders are expected to own approximately 72.0% of the combined company and Investors (as defined below) participating in the private placement are expected to own approximately 21.6% of the combined company, in each case, calculated on a fully diluted basis, using the treasury stock method, and subject to certain assumptions, including (i) an implied valuation for Werewolf of $47.5 million, (ii) a valuation for Ambros of $500.0 million, and (iii) the relative capitalization of Werewolf and Ambros. The percentage of the combined company that each party's equity holders will own following the Merger Closing is subject to certain adjustments as described in the Merger Agreement.

In connection with the Merger, Werewolf, in cooperation with Ambros, filed with the Securities and Exchange Commission (the "SEC") a registration statement on Form S-4 on September 22, 2026 (as amended, the "Form S-4"). The Form S-4 contains a proxy statement to be used by Werewolf to solicit approval of the applicable stockholder matters at a special meeting of Werewolf stockholders. The Form S-4 was declared effective on November 12, 2026 and the special meeting of Werewolf stockholders is scheduled for December 17, 2026. The Merger Closing is subject to certain closing conditions.

Either party may be required to pay a termination fee in the event of termination of the Merger Agreement. Specifically, a termination fee of $20.0 million may become payable by Ambros to Werewolf, or a termination fee of $1.9 million may become payable by Werewolf to Ambros if certain circumstances result in the termination of the Merger Agreement.

Pre-Funded Warrants

Each PIPE Pre-Funded Warrant and each Merger Pre-Funded Warrant has an exercise price of $0.001 per share of Werewolf Common Stock. The Pre-Funded Warrants will be exercisable at any time and from time to time on or after the Effective Time until exercised in full. A holder (together with its affiliates and other attribution parties) may not exercise any portion of a Pre-Funded Warrant to the extent that, immediately after giving effect to such exercise, the holder would own more than a specified percentage of the outstanding common stock of the combined company (9.99% in the case of the Merger Pre-Funded Warrants and 4.99% or 9.99%, at the choice of the holder, in the case of the PIPE Pre-Funded Warrants), which percentage may be increased at the holder's option (not to exceed 19.99%), subject to the terms of the Pre-Funded Warrants.

Werewolf Contingent Value Rights Agreement

In connection with the Merger and immediately prior to the Effective Time, Werewolf is expected to enter into a Contingent Value Rights Agreement (the "CVR Agreement"), with a nationally recognized rights agent agreed to between Werewolf and Ambros ("Rights Agent") pursuant to which Werewolf will distribute to each holder of Werewolf Common Stock of record as of the close of business on the last business day prior to the Effective Time one non-transferable contingent value right (each, a "CVR") for each outstanding share of Werewolf Common Stock held by such stockholder as of such date. Each CVR represents the right to receive contingent cash payments (any such cash payments, "CVR Payment Amounts") in respect of certain of Werewolf's legacy assets, consisting of WTX-124 and WTX-330 (together, the "Legacy Assets"), pursuant to the terms and conditions of the CVR Agreement.

The CVR Payment Amounts, if any, will become payable to the Rights Agent for subsequent distribution to the CVR holders in accordance with the terms of the CVR Agreement. In the event that no such proceeds are received during the CVR Term (as defined in the CVR Agreement), holders of the CVRs will not receive any payment pursuant to the CVR Agreement. There can be no assurance that the CVR holders will receive any payments with respect to the CVR Agreement.

Concurrent PIPE Financing

Concurrently with entering into the Merger Agreement, Werewolf entered into a securities purchase agreement (the "Securities Purchase Agreement") with certain qualified institutional buyers or accredited investors (the "Investors"). Pursuant to the Securities Purchase Agreement, and subject to the terms and conditions therein, Werewolf agreed to sell, and the Investors agreed to purchase, immediately prior to the Merger Closing, shares of Werewolf Common Stock (the "Shares") and, in the case of certain Investors, in lieu of shares of Werewolf Common Stock, PIPE Pre-Funded Warrants (together with the Shares, the "Securities") for an aggregate purchase price of $150.0 million (the "Concurrent PIPE Financing"). The closing of the Concurrent PIPE Financing is anticipated to occur immediately prior to the Merger Closing, subject to the satisfaction of customary closing conditions. Werewolf has also agreed to enter into a registration rights agreement with the Investors at the closing of the Concurrent PIPE Financing.

3. Strategic Review and Liquidity

In February 2026, we adopted a restructuring plan to extend our capital resources (the "2026 Restructuring") in connection with initiating a process to explore a full range of strategic alternatives to advance our promising platform and drug development pipeline to maximize stockholder value. We have engaged Piper Sandler & Co. ("Piper Sandler") to serve as exclusive financial advisor to assist in the strategic review process. Measures contemplated during the strategic review process include the Merger and the Contemplated Transactions described in Note 2, and the asset purchase agreements described in Note 5 and Note 15. If the Merger is not completed, we will need to consider alternative options, which may include, among other options, a sale of our company, a business combination or merger, a sale of our assets, licensing or collaboration arrangements, or other strategic transactions. There can be no assurance that the strategic review process will result in any agreement or transaction that will enhance stockholder value, or any agreement or transaction at all.

As part of the 2026 Restructuring, our board of directors approved a reduction in force in February 2026, representing 64% of our workforce to better align our resources with our pursuit of strategic alternatives. In May 2026, an additional reduction in force occurred, representing 36% of our workforce at that time. See Note 13 for further discussion of the impact of the 2026 Restructuring.

We had cash and cash equivalents of $41.9 million at September 30, 2026. The outcome of the Merger and the Contemplated Transactions will inform future development plans and the costs associated with those efforts. We expect to incur substantial operating losses and negative cash flows from operations for the foreseeable future as we continue to execute on our strategic review process. Our ability to maintain ongoing operations is dependent on our ability to consummate the Merger on a timely basis, as to which we can make no assurance. These conditions raise substantial doubt about our ability to continue as a going concern for at least twelve months from the date these condensed consolidated financial statements are issued in this Quarterly Report. There can be no assurance that the Merger or the Contemplated Transactions will be completed, or that, in the event they are not completed, our strategic review process will result in any other agreement or transaction that will mitigate the conditions which raise substantial doubt about our ability to continue as a going concern, or at all.

Our condensed consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and settlement of liabilities and commitments in the ordinary course of business. Our condensed consolidated financial statements do not include any adjustments that might result from the outcome of the conditions described above.

4. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying condensed consolidated financial statements as of September 30, 2026 and December 31, 2025, and for the three and nine months ended September 30, 2026 and 2025, have been prepared in accordance with the rules and regulations of the SEC and generally accepted accounting principles in the United States of America ("GAAP") as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB") for condensed consolidated financial information. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. In the opinion of management, these condensed consolidated financial statements reflect all normal recurring adjustments which are necessary for a fair presentation of our financial position and results of our operations, as of and for the periods presented. These condensed consolidated financial statements should be read in conjunction with the consolidated financial statements and notes thereto contained in our Annual Report on Form 10-K for the year ended December 31, 2025 filed with the SEC on March 27, 2026 (the "2025 Annual Report").

The information presented in the condensed consolidated financial statements and related notes as of September 30, 2026, and for the three and nine months ended September 30, 2026 and 2025, is unaudited. The December 31, 2025 condensed consolidated balance sheet included herein was derived from the audited financial statements as of that date, but does not include all disclosures, including notes, required by GAAP for complete financial statements.

Interim results for the three and nine months ended September 30, 2026 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2026, or any future period.

The accompanying condensed consolidated financial statements include the accounts of Werewolf Therapeutics, Inc. and its wholly owned subsidiaries, Werewolf Therapeutics Mass Securities, Inc. and Merger Sub. All intercompany transactions and balances have been eliminated in consolidation.

Summary of Significant Accounting Policies

The significant accounting policies and estimates used in the preparation of the condensed consolidated financial statements are described in our audited financial statements as of and for the year ended December 31, 2025, and the notes thereto, which are included in our 2025 Annual Report. Other than as set forth below, there have been no material changes in our significant accounting policies during the nine months ended September 30, 2026.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the financial statements and accompanying notes. Significant estimates and assumptions reflected in these condensed consolidated financial statements include, but are not limited to, those related to accrued expenses and assumptions used in the valuation of stock-based compensation expense and the fair value of the derivative liability. Actual results could differ from those estimates.

Recent Accounting Pronouncements

In November 2024, the FASB issued ASU No. 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-04)* ("ASU No. 2024-03"), which requires the disclosure of additional information about specific expense categories in the notes to the consolidated financial statements at interim and annual reporting periods. The provisions of ASU No. 2024-03 are effective for annual reporting periods beginning after December 31, 2026, with early adoption permitted. We are currently evaluating the impact that this standard will have on our consolidated financial statements.

Other accounting standards that have been issued or proposed by the FASB or other standards-setting bodies that do not require adoption until a future date are not expected to have a material impact on our consolidated financial statements upon adoption.

Subsequent Events

We have evaluated subsequent events and transactions that occurred after the balance sheet date up to the date that the financial statements were issued. Other than as described in these condensed consolidated financial statements, we did not identify any subsequent events that require adjustment or disclosure in the condensed consolidated financial statements.

5. Collaboration Revenue

In April 2022, we entered into an exclusive global collaboration and license agreement (the "Collaboration Agreement") with Jazz Pharmaceuticals Ireland Limited ("Jazz") pursuant to which we granted Jazz certain licenses to develop and commercialize products containing our Interferon alpha ("IFNα") INDUKINE™ molecule, JZP898 (the "898 Program"), as well as products containing certain isolated recombinant polypeptides comprising IFNα that meet specified criteria (each such product, a "Licensed Product"). Under the Collaboration Agreement, we were responsible for certain preclinical development activities with respect to JZP898 and other development activities specified in mutually agreed upon development plans. Jazz had generally reimbursed us for the cost of such activities. Jazz is responsible for all other development and commercialization activities conducted to exploit the Licensed Products, including submission of an investigational new drug application ("IND") to the U.S. Food and Drug Administration (the "FDA"). In June 2024, we executed a transfer agreement (the "Transfer Agreement") to assign our rights in a development agreement with a contract manufacturer of JZP898 to Jazz. The execution of this Transfer Agreement was the last material performance obligation required of us under the Collaboration Agreement. We were eligible to receive up to $515.0 million in development and regulatory milestones, and up to $740.0 million in sales-based milestones for all Licensed Products upon meeting certain conditions.

On May 6, 2026 (the "Jazz Closing"), we entered into an asset purchase agreement (the "Jazz Purchase Agreement") with Jazz. Subject to the terms and conditions of the Jazz Purchase Agreement, we sold to Jazz the 898 Program for the development, manufacturing, commercialization, use and other exploitation of the Licensed Product. Pursuant to the Jazz Purchase Agreement and related ancillary agreements, in consideration for all material assets, properties, rights and interests used or held for use in the conduct of the 898 Program, Jazz paid us upfront consideration of $21.0 million, and has agreed to pay an additional $2.0 million upon the consent to the partial assignment of a certain license agreement, as and to the extent such agreement relates to the conduct of the 898 Program. Jazz also assumed certain liabilities of ours relating to the 898 Program arising after the Jazz Closing.

The Jazz Purchase Agreement contains customary representations, warranties and covenants of each of us and Jazz. The Jazz Purchase Agreement further provides that, subject to certain limitations, we and Jazz will each indemnify the other for certain losses arising from such breaches of representations, warranties and covenants and liabilities allocated to such party pursuant to the terms of the Jazz Purchase Agreement.

In addition, the Jazz Purchase Agreement contains a non-competition covenant pursuant to which we agreed not to exploit any IFNα or variant thereof, or any product containing any IFNα or variant thereof, for a period of eighteen (18) months after the Jazz Closing, subject to customary exceptions for change of control transactions.

Effective as of the Jazz Closing, the Collaboration Agreement was terminated, and as a result, we are no longer eligible to receive payment for meeting the conditions of the development and regulatory milestones or sales-based milestones for any Licensed Products.

Concurrently with the Jazz Purchase Agreement, we also entered into a license agreement (the "New License Agreement") with Jazz to license to them certain patents and "know-how" (the "Licensed Patents" and "Licensed Know-How," respectively). The Licensed Patents and the Licensed Know-How are necessary in the development of the 898 Program, however are not exclusive to the 898 Program.

Accounting Analysis under ASC 606

Identification of the Contract(s)

We have previously concluded that the Collaboration Agreement represents a contract with a customer within the scope of ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606").

We have assessed the Jazz Purchase Agreement and the New License Agreement, and have concluded that they represent a single combined arrangement due to the fact that they were negotiated as a package with a single commercial objective. We have further concluded that the Jazz Purchase Agreement and the New License Agreement represent a modification to the Collaboration Agreement within the scope of ASC 606.

Identification of Promises and Performance Obligations

Previously, we have concluded that the license granted to Jazz under the Collaboration Agreement, and the corresponding "know-how" are not capable of being distinct from the other promises within the contract, and as such, determined that the license and the "know-how" combined with the other research and development services and supply represent a single combined performance obligation. Under the Jazz Purchase Agreement and the New License Agreement, Jazz continues to have rights to the same patents and "know-how" that were granted under the Collaboration Agreement. However, under the Jazz Purchase Agreement, we transferred ownership of certain patents and "know-how" to Jazz. At the time of the Jazz Closing, our performance obligation to Jazz had been fulfilled.

Determination of Transaction Price

We have assessed the Jazz Purchase Agreement and the New License Agreement, and have concluded that they represent a modification that results in an increase in the overall transaction price of the contract with Jazz. We've determined that the upfront consideration included in the Jazz Purchase Agreement of $21.0 million should be added to the overall transaction price.

The Jazz Purchase Agreement also includes a $2.0 million contingent payment that is payable to us upon the successful partial assignment of a certain license agreement. We've determined that this contingent payment represents variable consideration that should not be included in the transaction price. We used the most likely amount method to estimate variable consideration and estimated that the most likely amount of the contingent payment was zero at the Jazz Closing as the success of completing the partial assignment of the license agreement is highly susceptible to factors outside of our control.

The Collaboration Agreement included various development and regulatory and sales-based milestones. The payments associated with these milestones represented variable consideration that were excluded from the overall transaction price at the inception of the Collaboration Agreement. As of the Jazz Closing, we are no longer entitled to receipt of payment for any of the unpaid milestones included in the Collaboration Agreement. Accordingly, the unpaid milestone payments are no longer considered for inclusion in the overall transaction price as of the Jazz Closing.

We re-evaluate the transaction price at the end of each reporting period and as uncertain events are resolved or other changes in circumstances occur, and adjust the transaction price as necessary. During the period from the Jazz Closing through September 30, 2026, we did not recognize any adjustment to the transaction price associated with the contingent payment.

Revenue Recognition

As noted above, we have no remaining performance obligation to Jazz as of the Jazz Closing. Accordingly, we have recognized revenue of $21.0 million during the nine months ended September 30, 2026 related to the increase in the overall transaction price described above. As of September 30, 2026, all consideration included in the overall transaction price has been recognized as revenue.

6. Financial Instruments and Fair Value Measurements

Our assets that are required to be measured at fair value on a recurring basis consist of money market funds classified as cash and cash equivalents on our condensed consolidated balance sheets as of September 30, 2026 and December 31, 2025.

Our liabilities that are required to be measured at fair value on a recurring basis consist of a derivative liability pursuant to a loan and security agreement (the "K2HV Loan Agreement") with K2 HealthVentures LLC ("K2HV") (see Note 8, *Term Loan*) on our condensed consolidated balance sheet as of December 31, 2025. We do not have any liabilities that are required to be measured at fair value on a recurring basis as of September 30, 2026.

The carrying amounts reflected in the condensed consolidated balance sheets for cash, prepaid expenses and other current assets, accounts payable and accrued expenses approximate their fair values, due to their short-term nature.

Assets measured at fair value on a recurring basis as of September 30, 2026 were as follows:

	Level 1	Level 2	Level 3	Total
		(in thousands)		
Assets:				
Money market funds	$ 41,372	$ —	$ —	$ 41,372
Total assets	$ 41,372	$ —	$ —	$ 41,372

Assets and liabilities measured at fair value on a recurring basis as of December 31, 2025 were as follows:

	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:				
Money market funds	$ 56,548	$ —	$ —	$ 56,548
Total assets	$ 56,548	$ —	$ —	$ 56,548
Liabilities:				
Derivative liability	$ —	$ —	$ 759	$ 759
Total liabilities	$ —	$ —	$ 759	$ 759

There were no changes in valuation techniques used during the three or nine months ended September 30, 2026.

Derivative Liability

In May 2024, we entered into the K2HV Loan Agreement, as further described in Note 8, which provided up to $60.0 million principal in term loans. Pursuant to the terms of the K2HV Loan Agreement, the lenders thereto could elect, prior to the full repayment of the term loans, to convert up to $5.0 million of the outstanding principal of the term loans into shares of our common stock at a conversion price of the lesser of $6.3182 per share (the "Fixed Price Conversion") and the lowest effective price per share of our first equity financing following the closing of the K2HV Loan Agreement (the "Variable Price Conversion"), subject to customary adjustments and 9.99% and 19.99% beneficial ownership limitations. The Fixed Price Conversion and Variable Price Conversion within the K2HV Loan Agreement were required to be bifurcated as a single compound embedded derivative carried at fair value, with subsequent changes in fair value recognized in the condensed consolidated statements of operations.

In May 2026, we repaid all amounts owed under K2HV Loan Agreement, as described in Note 8. Upon repayment of the outstanding principal of the term loan, the lenders' ability to exercise the conversion option expired.

The following table reconciles the change in fair value of the derivative liability based on Level 3 inputs:

	Nine Months Ended September 30,	
	2026	2025
	(in thousands)	
Balance at beginning of period	$ 759	$ 2,829
Change in fair value	(707)	(215)
Extinguishment of note payable	(52)	—
Balance at end of period	$ —	$ 2,614

The change in fair value of the derivative liability is included in other (expense) income, net in the accompanying condensed consolidated statements of operations. We recognized a nominal gain related to change in fair value of the derivative liability during the three months ended September 30, 2025. We recognized gains of $0.7 million and $0.2 million related to change in fair value of the derivative liability during the nine months ended September 30, 2026 and 2025, respectively. The fair value of the derivative liability immediately prior to repayment of the amounts owed under K2HV Loan Agreement was written off and is included in the loss on extinguishment of note payable in the accompanying condensed consolidated statement of operations in the amount of $0.1 million for the nine months ended September 30, 2026.

The fair value of the derivative liability in the term loan was estimated using the Monte Carlo and the Black-Scholes models, each weighted based on the probable outcomes of various scenarios. A summary of the weighted-average significant unobservable inputs (Level 3 inputs) used in measuring the derivative liability in the term loan as of December 31, 2025 is as follows:

Stock price	$0.63
Volatility	105.0%
Risk-free rate (continuous)	3.5%
Expected term (in years)	0.25
Dividend yield (continuous)	—%

7. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities were comprised as follows:

	September 30, 2026	December 31, 2025
	(in thousands)	
Professional fees	$ 4,019	$ 1,388
Contract research	315	2,376
Employee compensation and benefits	205	302
Manufacturing	85	928
Restructuring costs	20	—
Accrued interest	—	266
Other	74	147
Total accrued expenses and other current liabilities	$ 4,718	$ 5,407

8. Term Loan

In May 2024, we, as borrower, entered into the K2HV Loan Agreement with K2HV (together with any other lender from time to time, the "Lenders"); K2HV, as administrative agent for the Lenders (in such capacity, together with its successors, the "Administrative Agent"); and Ankura Trust Company, LLC, as collateral trustee for the Lenders (the "Collateral Trustee"). The K2HV Loan Agreement provided up to $60.0 million principal in term loans. We received $30.0 million in gross loan proceeds at closing; $25.0 million from the first tranche commitment and $5.0 million from the second tranche commitment. A third tranche commitment of up to $10.0 million was available to be drawn at our option through June 30, 2025, subject to the achievement, as determined by the Administrative Agent in its discretion, of certain time-based, clinical and regulatory milestones and receipt of not less than $60.0 million in net cash proceeds from certain financing activities, with at least $50.0 million from a single offering of common stock. Our ability to draw upon the third tranche commitment expired on June 30, 2025 without being drawn upon. A fourth tranche commitment of up to $20.0 million was available to be drawn at our option through May 1, 2026, subject to Lenders' review of our clinical, financial and operating plan and subject to the Lender's consent in its sole and absolute discretion. Our ability to draw upon the fourth tranche commitment expired on May 1, 2026 without being drawn upon.

The term loan was scheduled to mature on May 1, 2028, and we were obligated to make interest only payments for the first 24 months followed by equal interest and principal payments each month thereafter through the maturity date. The term loan bore a variable interest rate equal to the greater of (i) 10.3%, and (ii) the sum of (A) the prime rate last quoted in The Wall Street Journal (or a comparable replacement rate if The Wall Street Journal ceases to quote such rate) and (B) 1.8%. We could prepay, at our option, all, but not less than all, of the outstanding principal balance and all accrued and unpaid interest with respect to the principal balance being prepaid of the term loans, subject to a prepayment premium to which the Lenders were entitled and certain notice requirements. We were obligated to pay a final fee equal to 6.95% of the aggregate amount of the term loans funded (the "Final Fee") to occur upon the earliest of (i) the maturity date, (ii) the acceleration of the term loans, and (iii) the prepayment of the term loans. The Final Fee was being accreted to interest expense using the effective interest method over the life of the debt.

The Lenders had the option, prior to the full repayment of the term loans, to convert up to $5.0 million of outstanding principal of the term loans into shares of our common stock, pursuant to the Fixed Price Conversion or the Variable Price Conversion, subject to customary adjustments and 9.99% and 19.99% beneficial ownership limitations. There would have been no prepayment penalty for any principal amount converted into common stock. We determined that the Fixed Price Conversion and the Variable Price Conversion within the K2HV Loan Agreement were required to be bifurcated as an embedded derivative under ASC Topic 815, *Derivatives and Hedging* ("ASC 815"), at fair value, and recorded as a discount on the debt on the date of issuance, with subsequent changes in fair value recognized in the accompanying condensed consolidated statements of operations. See Note 6 for further discussion on this derivative instrument.

As security for our obligations under the K2HV Loan Agreement, we granted the Lenders a first-priority security interest on substantially all of our assets (other than intellectual property), subject to certain exceptions. The K2HV Loan Agreement contained customary representations and warranties, events of default and affirmative and negative covenants, including covenants that limited or restricted our ability to, among other things, dispose of assets, make changes to our business, management, ownership or business locations, merge or consolidate, incur additional indebtedness, incur additional liens, pay dividends or other distributions or repurchase equity, make investments, and enter into certain transactions with affiliates, in each case subject to certain exceptions. Upon the occurrence of an event of default, a default interest rate of an additional 5.0% per annum may have been applied to the outstanding loan balances, and the Lenders may have declared all outstanding

obligations immediately due and payable and exercised all of their rights and remedies as set forth in the K2HV Loan Agreement and under applicable law.

Subject to certain conditions, we granted the Lenders the right, prior to repayment of the term loans, to invest up to $5.0 million in the aggregate in future offerings of capital stock, at market terms, subject to certain exceptions and conditions.

We incurred debt issuance costs of $0.7 million in connection with the term loans, composed of the facility fee of $0.4 million and other expenses paid to the Lenders of $0.2 million and external legal fees of $0.1 million. These debt issuance costs, together with the fair value of the embedded derivative of $4.5 million at inception of the K2HV Loan Agreement, resulted in a debt discount of $5.1 million, which was being amortized to interest expense over the term of the K2HV Loan Agreement using the effective interest method.

On May 6, 2026, we entered into a letter agreement providing for the repayment by us of all amounts owed under the K2HV Loan Agreement. On May 6, 2026, upon payment by us of $31.4 million, all of our indebtedness and obligations to the Collateral Trustee and the Lenders under the K2HV Loan Agreement and any other related loan and collateral security documents were deemed paid and discharged in full. During the nine months ended September 30, 2026, we recognized a loss on the extinguishment of debt in the amount of $3.4 million, primarily due to the write off of unamortized debt issuance costs and the unaccreted balance of the Final Fee.

The outstanding note payable consisted of the following as of December 31, 2025 (in thousands):

Note payable	$ 30,000
Unamortized debt discount and issuance costs	(1,764)
Net carrying amount of note payable	$ 28,236

The following table provides the components of interest expense related to the K2HV Loan Agreement:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	(in thousands)			
Interest expense based on coupon interest rate (10.3%) of outstanding term loans	$ —	$ 790	$ 1,072	$ 2,344
Amortization of debt discount and accretion of Final Fee (8.94%)	—	551	771	1,561
Total interest expense on effective rate (19.24%)	$ —	$ 1,341	$ 1,843	$ 3,905

We had presented the full amount of the term loan payable, net of discount and issuance costs, as a current liability as of December 31, 2025 based on our assessment that repayment of the loan was probable in the subsequent twelve months following December 31, 2025.

9. Common and Preferred Stock

Common Stock

We are authorized to issue 200,000,000 shares of common stock. Common stockholders are entitled to dividends if and when declared by our board of directors. As of September 30, 2026, no dividends on common stock had been declared by us.

On May 10, 2022, we entered into a Sales Agreement (the "Sales Agreement") with Leerink Partners LLC ("Leerink Partners"), pursuant to which we are entitled to offer and sell shares of our common stock (the "ATM Offering"). The Sales Agreement provides that Leerink Partners will be entitled to a sales commission equal to 3.0% of the gross sales price per share of all shares sold under the ATM Offering. We were initially entitled to offer and sell shares of our common stock having an aggregate offering price of up to $50.0 million in the ATM Offering, which was subsequently increased in February 2024 to $75.0 million. On May 8, 2025, we filed a new Registration Statement on Form S-3 and filed a new prospectus covering the ATM Offering (the "Prospectus"), for the offer and sale of shares of our common stock with an aggregate offering price of up to $12.5 million in the ATM Offering as a result of being subject to General Instruction I.B.6 of Form S-3 (the "Baby Shelf Limitation"). As of September 30, 2026, we remain subject to the Baby Shelf Limitation. During the nine months ended September 30, 2026, we did not sell any shares of our common stock under the ATM Offering. During the nine months ended September 30, 2025, we sold 2,360,186 shares of our common stock at an average price of $1.71 per share for net proceeds of $3.6 million after deducting sales commissions and offering expenses.

We have reserved shares of common stock for issuance as follows:

	As of September 30, 2026	As of December 31, 2025
Shares reserved for exercises of outstanding stock options	8,040,475	9,954,872
Shares reserved for issuance under the 2021 Employee Stock Purchase Plan	1,044,648	560,929
Shares reserved for issuance under the 2021 Stock Incentive Plan	6,236,010	2,039,026
Shares reserved for issuance as part of the K2HV Loan Agreement conversion feature	—	791,364
Total shares reserved for future issuance	15,321,133	13,346,191

Preferred Stock

We are authorized to issue 5,000,000 shares of undesignated preferred stock in one or more series. As of September 30, 2026, no shares of preferred stock were issued or outstanding.

10. Stock-based Compensation

2017 Stock Incentive Plan

In December 2017, we adopted the 2017 Stock Incentive Plan (the "2017 Plan"), as amended and restated, pursuant to which we have outstanding stock options. No future awards may be granted under the 2017 Plan.

2021 Stock Incentive Plan

In April 2021, our board of directors adopted and our stockholders approved the 2021 Stock Incentive Plan (the "2021 Plan"), which became effective immediately prior to the effectiveness of our initial public offering (the "IPO"). As a result of the adoption of the 2021 Plan, no further awards will be made under the 2017 Plan.

The 2021 Plan provides for the grant of incentive stock options ("ISOs"), non-qualified stock options, restricted stock awards ("RSAs"), restricted stock units ("RSUs"), stock appreciation rights and other stock-based awards. Our employees, officers, directors, consultants and advisors are eligible to receive awards under the 2021 Plan. The terms of awards, including vesting requirements, are determined by our board of directors, subject to the provisions of the 2021 Plan.

We initially registered 3,352,725 shares of common stock under the 2021 Plan, pursuant to a Registration Statement on Form S-8 filed with the SEC on April 30, 2021, which was comprised of (i) 2,843,116 shares of common stock reserved for issuance under the 2021 Plan, (ii) 31,884 shares of common stock originally reserved for issuance under the 2017 Plan that became available for issuance under the 2021 Plan upon the completion of the IPO, and (iii) 477,725 shares of unvested restricted stock subject to repurchase by us that may become issuable under the 2021 Plan following such repurchase. The 2021 Plan also provides that an additional number of shares will be added annually to the shares authorized for issuance under the 2021 Plan on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2022 and continuing until, and including, the fiscal year ending December 31, 2031. The number of shares added each year will be equal to the lesser of (i) 5% of the number of shares of outstanding common stock on such date and (ii) such amount as determined by our board of directors. As of September 30, 2026, a cumulative total of 9,582,699 additional shares have been added to the total shares authorized for issuance under the 2021 Plan in accordance with these terms.

2021 Employee Stock Purchase Plan

The 2021 Employee Stock Purchase Plan ("2021 ESPP") permits eligible employees to purchase shares of our common stock at a discount and consists of consecutive six-month offering periods, each containing a single six-month purchase period. On the first day of each offering period, each employee who is enrolled in the 2021 ESPP will automatically receive an option to purchase up to a whole number of shares of our common stock. The purchase price of each of the shares purchased, in a given purchase period, will be equal to 85% of the lesser of the closing price of a share of our common stock on (i) the first day of the offering period, or (ii) the last day of the offering period. During the nine months ended September 30, 2026 and 2025, 2,249 and 39,853 shares of our common stock, respectively, were purchased by participants of the 2021 ESPP.

Inducement Stock Option Awards

We have granted inducement equity awards in the form of non-qualified stock options to purchase shares of our common stock to newly hired employees pursuant to the Nasdaq Capital Market ("Nasdaq") Listing Rule 5635(c)(4) ("Inducement Awards"). During nine months ended September 30, 2025 we granted 201,720 Inducement Awards. No Inducement Awards were granted during the nine months ended September 30, 2026. The valuation assumptions and activity associated with Inducement Awards are included in the stock option activity described below.

Stock-Based Compensation Expense

Total stock-based compensation expense recognized in our condensed consolidated statements of operations was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	(in thousands)			
Research and development	$ 68	$ 585	$ 654	$ 2,613
General and administrative	276	648	1,038	2,419
Total stock-based compensation	$ 344	$ 1,233	$ 1,692	$ 5,032

As part of the severance benefits offered to former employees impacted by the 2026 Restructuring described in Note 3 (the "Former Employees"), the forfeiture conditions of outstanding stock options belonging to the Former Employees were modified such that the Former Employees will retain their rights to exercise their stock options through the original expiration dates of each respective stock option to the extent that such stock options had become vested at the time that the Former Employees' employment with us was terminated. Absent these modifications, the impacted stock options would have been forfeited by the Former Employees after a period of three months following the termination of their employment with us, if not exercised sooner. The expiration date for all stock options impacted by these modifications will occur on the tenth anniversary of the grant date of each respective stock option. For the three months ended September 30, 2026 the stock-based compensation expense above includes nominal expense related to these modifications. For the nine months ended September 30, 2026 the stock-based compensation expense above includes $0.7 million of expense recognized related to these modifications.

Stock Option Activity

No stock options were granted during the three or nine months ended September 30, 2026. The fair value of stock options granted during the three and nine months ended September 30, 2025 was calculated on the date of grant using the following weighted-average assumptions:

	Three Months Ended September 30, 2025	Nine Months Ended September 30, 2025
Risk-free interest rate	3.9 %	4.4 %
Expected term (in years)	5.5	5.9
Expected annual dividend yield	— %	— %
Expected volatility	96.9 %	95.4 %

Using the Black-Scholes option pricing model, the weighted-average grant date fair value of stock options granted during the three and nine months ended September 30, 2025 was $0.81 and $1.16 per share, respectively.

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

	Options Outstanding			
	Number of Options	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in millions)
Outstanding at December 31, 2025	9,954,872	$ 4.71		
Granted	—	$ —		
Exercised	—	$ —		
Cancelled	(1,914,397)	$ 2.44		
Outstanding at September 30, 2026	8,040,475	$ 5.25	6.25	$ —
Exercisable at September 30, 2026	7,020,179	$ 5.69	6.00	$ —

No stock options were exercised during the three and nine months ended September 30, 2026 and 2025.

As of September 30, 2026, we had unrecognized stock-based compensation expense related to unvested stock options of $1.5 million, which we expect to recognize over a weighted-average period of approximately 1.4 years.

11. Net Loss Attributable to Common Stockholders per Share

For purposes of the diluted net loss attributable to common stockholders per share calculation, outstanding stock options, common stock to be issued under the 2021 ESPP, and the conversion option derivative under the K2HV Loan Agreement are considered to be potentially dilutive securities; however, the following amounts were excluded from the weighted-average common stock outstanding in the calculation of diluted net loss attributable to common stockholders per share because their effect would have been anti-dilutive:

	September 30,	
	2026	2025
Outstanding stock options	8,040,475	10,191,313
Common stock to be issued under the 2021 ESPP	—	54,143
Common stock to be issued upon exercise of the K2HV Loan Agreement conversion feature	—	791,364
Total	8,040,475	11,036,820

12. Segment Information

We have one reportable segment which focuses on the discovery and development of cancer therapeutics. The segment derives its revenue from the Jazz Purchase Agreement (see Note 5, *Collaboration Revenue*).

Our chief operating decision maker ("CODM") manages our operations on an integrated basis for the purpose of allocating resources. When evaluating our financial performance, our CODM regularly reviews total expenses and expenses by function and makes decisions using this information based on the performance of the enterprise as a whole. Our CODM primarily evaluates the performance of the enterprise based on results that have a direct impact on our available cash and cash equivalents and accordingly places less significance on non-cash expenses such as stock-based compensation and depreciation expenses in determining how to allocate resources.

Segment assets regularly reviewed by our CODM include measures of liquidity, primarily available cash and cash equivalents, and are consistent with the presentation of cash and cash equivalents reported in our condensed consolidated balance sheets.

The following is a summary of our segment and consolidated net loss, including significant segment expenses:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	(in thousands)			
Collaboration revenue	$ —	$ —	$ 21,000	$ —
Less:				
General and administrative support	7,248	3,350	18,498	10,659
Clinical development	866	5,802	7,556	15,841
Research and discovery	160	3,692	3,343	10,548
Manufacturing	173	1,247	1,965	7,945
Other segment expenses[(a)]	1,607	1,635	5,805	6,266
Interest income	183	697	893	2,544
Interest expense	—	(1,341)	(1,843)	(3,905)
Loss on extinguishment of note payable	—	—	(3,354)	—
Other (expense) income, net	(6)	—	732	179
Segment and consolidated net loss	$ (9,877)	$ (16,370)	$ (19,739)	$ (52,441)

(a) Other segment expenses includes non-cash expenses for stock-based compensation and depreciation expenses.

13. Restructuring

In February 2026, we initiated a strategic review process and the 2026 Restructuring. The 2026 Restructuring is expected to be completed by the end of 2026.

We estimate that we will incur approximately $7.2 million in costs associated with the 2026 Restructuring, consisting of severance payments, retention bonuses, employee benefits and related taxes, stock-based compensation, and contract

termination costs. Our estimate of costs we expect to incur and the expected timing of when the 2026 Restructuring will be completed are subject to a number of assumptions, and actual results may differ. We may also incur additional costs not currently contemplated that may occur as a result of, or that are associated with the 2026 Restructuring.

The following table summarizes the restructuring costs incurred and the total estimated costs expected to be incurred in connection with the 2026 Restructuring:

	Three Months Ended September 30, 2026	Nine Months Ended September 30, 2026	Cumulative Costs to Date	Total Estimated Costs
		(in thousands)		
Employee severance, benefits and related taxes	$ 65	$ 2,705	$ 2,705	$ 2,768
Employee retention bonuses, benefits and related taxes	713	2,792	2,792	3,468
Stock-based compensation	31	696	696	696
Contract termination costs	—	300	300	300
Total restructuring costs	$ 809	$ 6,493	$ 6,493	$ 7,232

Total restructuring costs recognized in our condensed consolidated statements of operations were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
		(in thousands)		
Research and development	$ 267	$ —	$ 3,744	$ —
General and administrative	542	—	2,749	—
Total restructuring costs	$ 809	$ —	$ 6,493	$ —

Accrued restructuring costs, which are included in accrued expenses and other current liabilities on our condensed consolidated balance sheets were as follows (in thousands):

Balance as of December 31, 2025	$ —
Restructuring costs recognized during the period	4,305
Cash payments made during the period	(3,971)
Employee retention bonuses paid in advance	724
Non-cash charges recognized during the period	(615)
Balance as of March 31, 2026	443
Restructuring costs recognized during the period	1,379
Cash payments made during the period	(1,229)
Amortization of employee retention bonuses paid in the prior period	(509)
Non-cash charges recognized during the period	(50)
Balance as of June 30, 2026	34
Restructuring costs recognized during the period	809
Cash payments made during the period	(887)
Employee retention bonuses paid in advance	274
Amortization of employee retention bonuses paid in the prior period	(179)
Non-cash charges recognized during the period	(31)
Balance as of September 30, 2026	$ 20

14. Lease Termination

On May 7, 2026 (the "Modification Date"), we entered into an Agreement for Termination of Lease and Voluntary Surrender of Premises (the "Lease Termination") with ARE-770/784/790 Memorial Drive, LLC (the "Landlord"), pursuant to which we and

the Landlord agreed to terminate that certain lease, dated June 1, 2021, as amended, by and between us and the Landlord (the "Lease"), effective October 31, 2026 (the "Lease Termination Date"). Either party could elect to accelerate the Lease Termination Date by providing 30 days' prior written notice to the other party, provided that such notice was given no earlier than July 1, 2026 (the "Termination Option"). Under the Lease, we leased approximately 25,778 square feet of space, consisting of the entire building located at 200 Talcott Avenue, Watertown, Massachusetts. Pursuant to the Lease Termination, we paid the Landlord an aggregate termination fee of $2.7 million, which represented full satisfaction of all remaining payments and other financial obligations due from us to the Landlord under the Lease including, without limitation, Base Rent (as defined in the Lease) for the months of May 2026 through October 2026. We have no further rent obligations to the Landlord pursuant to the Lease after the Lease Termination Date.

We have assessed the Lease Termination and have concluded that it represents a modification to the Lease within the scope of ASC Topic 842, *Leases* ("ASC 842"). Upon the execution of the Lease Termination, we were reasonably certain that the Termination Option would be exercised, and accordingly we estimated that the lease would terminate on July 31, 2026 for purposes of measuring the modified lease liability. On the Modification Date, we measured our modified lease liability to be $2.5 million. We reduced our lease liability to the modified lease liability through an adjustment to our right-of-use asset as of the Modification Date. We have recognized a reduction to our operating expenses during the nine months ended September 30, 2026 in the amount of $1.1 million, representing the remaining reduction in our lease liability required after our right-of-use asset was reduced to zero. The reduction to our operating expenses has been allocated between research and development and general and administrative operating expenses proportionately with how the operating lease costs have been allocated over the term of the Lease.

As a result of the Lease Termination, we determined that the estimated useful lives for the majority of our property and equipment ended on July 31, 2026. We have recognized additional depreciation expense during the three and nine months ended September 30, 2026 as a result of the change in the estimated useful lives.

On July 1, 2026, the Landlord exercised the Termination Option to terminate the Lease, effective July 31, 2026.

15. EMD Asset Purchase Agreement

On August 14, 2026 (the "EMD Closing"), we entered into an asset purchase agreement (the "EMD Purchase Agreement") with EMD Serono Research & Development Institute Inc. ("EMD"), pursuant to which, and subject to the terms and conditions thereof, we sold to EMD technology comprising (i) our pre-clinical INDUCER platform, including all patents and know-how related thereto, pre-clinical compounds and related intangible assets, and (ii) our INDUKINE platform, including certain patents, certain know-how related thereto, and pre-clinical compounds, excluding the clinical development programs for WTX-124 and WTX-330 (collectively, the "EMD Transferred Assets"). We retain all rights necessary for the continued development of our WTX-124 and WTX-330 clinical programs, as described below.

The EMD Purchase Agreement contains customary representations, warranties and covenants of each of us and EMD. The EMD Purchase Agreement further provides that, subject to certain limitations, we and EMD will each indemnify the other for certain losses arising from such breaches of representations, warranties and covenants and liabilities allocated to such party pursuant to the terms of the EMD Purchase Agreement.

In addition, the EMD Purchase Agreement contains a non-competition covenant pursuant to which we agreed not to exploit certain compounds, products or programs claimed in the Transferred Intellectual Property (as defined in the EMD Purchase Agreement) that are directed to the same tumor target as any Transferred Compound (as defined in the EMD Purchase Agreement) for a period of twenty-four (24) months after the EMD Closing, subject to customary exceptions for change of control transactions.

Simultaneously with the execution of the EMD Purchase Agreement, on August 14, 2026 we entered into a license agreement (the "EMD License Agreement") with EMD pursuant to which EMD granted us an exclusive license to certain patents included in the EMD Transferred Assets that enable us to exploit and perform clinical development programs for WTX-124 and WTX-330.

Additionally, under the EMD License Agreement, EMD granted to us certain licenses to enable us to grant certain licenses to (i) Harpoon Therapeutics, Inc. ("Harpoon") under that certain Second Amended and Restated Assignment and License Agreement between us and Harpoon dated December 20, 2019 (the "Harpoon License") and (ii) Jazz under our existing license agreement with Jazz that was entered into in connection with the Jazz Purchase Agreement (see Note 5, *Collaboration Revenue*), under which we have granted a non-exclusive license to certain technology originally licensed to us under the Harpoon License.

Pursuant to the EMD Purchase Agreement, in consideration for the EMD Transferred Assets, EMD agreed to pay us upfront consideration of $28.0 million and an additional $5.0 million upon the completion of the transfer of the EMD Transferred Assets technology. Additionally, EMD agreed to reimburse us $0.9 million for a license fee previously paid by us related to a

license included in the EMD Transferred Assets. During the three months ended September 30, 2026, we received a non-refundable payment from EMD in the amount of $28.9 million related to the EMD Purchase Agreement.

We have assessed the EMD Purchase Agreement and have concluded that the transaction represents the sale of nonfinancial assets within the scope of ASC Topic 610, *Other Income* ("ASC 610"). ASC 610 indicates that the recognition of income from the sale of nonfinancial assets occurs at the point in time when control of the nonfinancial assets transfers between parties. The EMD Purchase Agreement includes an acceptance provision under which upon receipt of the EMD Transferred Assets, EMD is entitled to a 30-day period to confirm acceptance of the EMD Transferred Assets. We've concluded that control of the EMD Transferred Assets will occur upon EMD's confirmation of acceptance. Accordingly, the transaction price of $33.9 million, consisting of the $28.0 million upfront payment, the $0.9 million license fee reimbursement, and the $5.0 million payment due upon completion of the technology transfer, will be recognized as income upon acceptance, which is expected to occur during the fourth quarter of 2026. The $28.9 million in proceeds received to date under the EMD Purchase Agreement are included in deferred income on our condensed consolidated balance sheet as of September 30, 2026.

We have concluded that the EMD Transferred Assets do not meet the definition of a disposal of a component, and therefore do not qualify for held for sale or discontinued operations presentation in our condensed consolidated financial statements.

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

The following discussion and analysis is meant to provide material information relevant to an assessment of the financial condition and results of operations of our company, including an evaluation of the amounts and uncertainties of cash flows from operations and from outside resources, so as to allow investors to better view our company from management's perspective. The following discussion and analysis of our financial condition and results of operations should be read together with our condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q, or Quarterly Report, and our Annual Report on Form 10-K for the year ended December 31, 2025, or the 2025 Annual Report, that was filed with the United States Securities and Exchange Commission, or SEC, on March 27, 2026. In addition to historical information, the discussion and analysis contains forward-looking statements that involve risks, uncertainties and assumptions. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of certain factors. We discuss factors we believe could cause or contribute to these differences below and elsewhere in this Quarterly Report, including those factors set forth in the section entitled "Cautionary Note Regarding Forward-Looking Statements and Industry Data" and in the section entitled "Risk Factors" in Part II, Item 1A of this Quarterly Report. You should carefully read the section entitled "Risk Factors" in Part II, Item 1A of this Quarterly Report.

Overview

We are a biopharmaceutical company that has developed conditionally activated therapeutics engineered to stimulate the body's immune system for the treatment of cancer. Our clinical development program is focused on WTX-124 and WTX-330, systemically delivered, conditionally activated IL-2 and IL-12 INDUKINE molecules, respectively, designed for the potential treatment of multiple solid tumor indications.

We evaluated WTX-124 in a Phase 1/1b clinical trial as a monotherapy and in combination with Merck & Co., Inc.'s PD-1 therapy pembrolizumab in patients with immunotherapy-sensitive advanced or metastatic solid tumors who have progressed on, or are intolerant of, standard of care treatment, including checkpoint inhibitor therapy. In December 2025, we reported that WTX-124 initial Phase 1b expansion arm data showed a 21% objective response rate as a monotherapy in heavily pretreated patients with advanced or metastatic cutaneous melanoma and a 30% objective response rate in patients who were not primary resistant to immunotherapy, with no evidence of vascular leak syndrome or recurrence of prior immune-related adverse events. On November 7, 2026, we presented clinical data from the Phase 1/1b clinical trial of WTX-124 at the Society for Immunotherapy of Cancer's, or SITC's, 2026 Annual Meeting. Data for the Phase 1/1b clinical trial of WTX-124, as of the June 4, 2026, clinical database lock date, are summarized as follows:

- In dose escalation, WTX-124 as a monotherapy produced three objective responses in dose escalation, including one durable confirmed complete response, or CR, in a patient with primary immune checkpoint inhibitor-resistant cutaneous squamous-cell carcinoma, or CSCC, that has remained ongoing without any additional anticancer therapy for approximately three years, and two partial responses in patients with cutaneous melanoma and Gastroesophageal junction, or GEJ, adenocarcinoma per immune RECIST. Additional patients with non-small cell lung cancer, or NSCLC, mucosal melanoma and GEJ adenocarcinoma showed evidence of durable target lesion regression spanning 3-13 months.
- In dose escalation, WTX-124 in combination with pembrolizumab produced a confirmed CR and a confirmed partial response ongoing at the end of the study (i.e., 24 months), in patients with cutaneous melanoma, including a patient with secondary immune checkpoint inhibitor-resistant disease.
- In dose expansion, WTX-124 in combination with pembrolizumab produced a 37.5% response rate in NSCLC for patients who had prior chemoimmunotherapy, and WTX-124 as a monotherapy produced a 15.8% response rate in cutaneous melanoma for patients with prior immune checkpoint inhibitor and targeted therapy, as well as a 33% response rate in patients with non-primary immune checkpoint inhibitor resistant disease.

We have aligned with the U.S. Food and Drug Administration, or FDA, on a WTX-124 recommended phase 2 dose, or RP2D, of 18 mg IV Q2W for both monotherapy and combination with pembrolizumab. We believe the data support compelling opportunities for further development of WTX-124 in NSCLC, melanoma, CSCC and GEJ adenocarcinoma. Additional funding will be required to initiate any further development of WTX-124.

We evaluated WTX-330 in a first-in-human Phase 1 clinical trial for the treatment of patients with relapsed/refractory advanced or metastatic solid tumors or non-Hodgkin's lymphoma, including those with primary or secondary resistance to standard of care immunotherapies as well as patients with indications for which immunotherapy is not approved. That Phase 1 clinical trial was completed in the first quarter of 2025. Guided by data from the Phase 1 clinical trial, we initiated a Phase 1b/2 clinical trial of WTX-330 in the first quarter of 2025 in patients with selected advanced or metastatic solid tumors. In December 2025, we reported evidence of favorable tolerability and antitumor activity, with one confirmed partial response in a patient with metastatic gallbladder cancer who had failed all prior standard therapies but experienced a 45% reduction in tumor target lesions as measured by RECIST 1.1 in the clinical trial of WTX-330. On November 7, 2026, we presented clinical data from

the Phase 1b/2 clinical trial of WTX-330 at the SITC 2026 Annual Meeting. Data for the Phase 1b/2 clinical trial of WTX-330 as of the May 14, 2026, clinical database lock date are summarized as follows:

- WTX-330 showed high systemic prodrug exposure with low exposure of free (active) IL-12.
- The frequency of treatment-related adverse events was dramatically reduced at equivalent dose levels compared to what was observed with first-in-human WTX-330 material.
- WTX-330 produced evidence of intratumoral IL-12/STAT4 signaling in 7 of 9 patients contributing paired tumor biopsies.
- WTX-330 produced a confirmed partial response per RECIST 1.1 in a patient with gallbladder cancer whose best response to all prior standard-of-care therapy had been progressive disease, as well as multiple additional tumor regressions in patients with late-line refractory solid tumors.

We believe WTX-330 is poised for further development as a monotherapy, in combination with an immune checkpoint inhibitor, or in a sequenced combination with WTX-124. Additional funding will be required to further develop WTX-330.

We are currently seeking strategic partnerships for the further development of our clinical programs.

Prior to the EMD Purchase Agreement transaction described below under ‘‘Recent Developments,’’ we leveraged our proprietary PREDATOR platform to design conditionally activated molecules that stimulate both adaptive and innate immunity with the goal of addressing the limitations of conventional proinflammatory immune therapies. Our molecules, which we refer to as INDUKINE and INDUCER molecules, including WTX-124 and WTX-330, are intended to activate selectively in the TME. We also utilized our PREDATOR platform know-how and expertise to develop proprietary INDUCER T cell engager molecules, all of which were in preclinical studies. Immune cell engagers, such as T cell engagers, are typically bispecific antibodies that redirect immune cells to cancer cells via engagement with tumor associated cell surface antigens, leading to immune cell mediated killing of the cancer cells.

Recent Developments

Merger Agreement

On August 21, 2026, we entered into an Agreement and Plan of Merger, or the Merger Agreement, by and among Ambros Therapeutics, Inc., or Ambros, Werewolf, and Wave Atlantis Merger Sub, Inc., a direct, wholly owned subsidiary of Werewolf, or Merger Sub.

Pursuant to the Merger Agreement, and upon the terms and subject to the satisfaction of the conditions described therein, Merger Sub will be merged with and into Ambros, with Ambros surviving as a wholly owned subsidiary of Werewolf, or the Merger and, together with the other transactions contemplated by the Merger Agreement, the Contemplated Transactions. The Merger is intended to qualify as a tax-free reorganization for U.S. federal income tax purposes.

Subject to the terms and conditions of the Merger Agreement, (i) immediately prior to the effective time of the Merger, or the Effective Time, the then-outstanding shares of Ambros preferred stock, par value $0.00001 per share, will be converted into shares of Ambros common stock, par value $0.00001 per share, or Ambros Common Stock, and (ii) at the Effective Time, each then-outstanding share of Ambros Common Stock (excluding shares held by stockholders who have exercised and perfected appraisal rights for such shares) will be converted into the right to receive a number of shares of Werewolf common stock, par value $0.0001 per share, or Werewolf Common Stock, calculated in accordance with the exchange ratio as set forth in the Merger Agreement and subject to any election pursuant to the terms of the Merger Agreement to receive pre-funded warrants to acquire Werewolf Common Stock with an exercise price of $0.001 per share, or Merger Pre-Funded Warrants, in lieu of any shares of Werewolf Common Stock in excess of the Beneficial Ownership Limitation (as defined in the Merger Agreement). In addition, at the Effective Time, each then-outstanding option to purchase shares of Ambros Common Stock will be assumed by Werewolf and converted into an option to acquire Werewolf Common Stock, with the number of underlying shares and exercise price adjusted in accordance with the exchange ratio as set forth in the Merger Agreement.

At the closing of the Merger, or the Merger Closing and such date, the Merger Closing Date, on a pro forma basis and based upon the number of shares of Werewolf Common Stock and Merger Pre-Funded Warrants and pre-funded warrants to purchase shares of Werewolf Common Stock with an exercise price of $0.001 per share expected to be issued in connection with the Concurrent PIPE Financing (as defined below), or the PIPE Pre-Funded Warrants and, together with the Merger Pre-Funded Warrants, the Pre-Funded Warrants, pre-merger equity holders of Werewolf, other than those participating in the private placement, are expected to own approximately 6.4% of the combined company, pre-merger Ambros stockholders are expected to own approximately 72.0% of the combined company and Investors (as defined below) participating in the private placement are expected to own approximately 21.6% of the combined company, in each case, calculated on a fully diluted basis, using the treasury stock method, and subject to certain assumptions, including (i) an implied valuation for Werewolf of $47.5 million, (ii) a valuation for Ambros of $500.0 million, and (iii) the relative capitalization of Werewolf and Ambros. The percentage of the

combined company that each party's equity holders will own following the Merger Closing is subject to certain adjustments as described in the Merger Agreement.

In connection with the Merger, Werewolf, in cooperation with Ambros, filed with the Securities and Exchange Commission, or the SEC, a registration statement on Form S-4 on September 22, 2026, or, as amended, the Form S-4. The Form S-4 contains a proxy statement to be used by Werewolf to solicit approval of the applicable stockholder matters at a special meeting of Werewolf stockholders. The Form S-4 was declared effective on November 12, 2026 and the special meeting of Werewolf stockholders is scheduled for December 17, 2026. The Merger Closing is subject to certain closing conditions.

Either party may be required to pay a termination fee in the event of termination of the Merger Agreement. Specifically, a termination fee of $20.0 million may become payable by Ambros to Werewolf, or a termination fee of $1.9 million may become payable by Werewolf to Ambros if certain circumstances result in the termination of the Merger Agreement.

Pre-Funded Warrants

Each PIPE Pre-Funded Warrant and each Merger Pre-Funded Warrant has an exercise price of $0.001 per share of Werewolf Common Stock. The Pre-Funded Warrants will be exercisable at any time and from time to time on or after the Effective Time until exercised in full. A holder (together with its affiliates and other attribution parties) may not exercise any portion of a Pre-Funded Warrant to the extent that, immediately after giving effect to such exercise, the holder would own more than a specified percentage of the outstanding common stock of the combined company (9.99% in the case of the Merger Pre-Funded Warrants and 4.99% or 9.99%, at the choice of the holder, in the case of the PIPE Pre-Funded Warrants), which percentage may be increased at the holder's option (not to exceed 19.99%), subject to the terms of the Pre-Funded Warrants.

Werewolf Contingent Value Rights Agreement

In connection with the Merger and immediately prior to the Effective Time, Werewolf is expected to enter into a Contingent Value Rights Agreement ,or the CVR Agreement, with a nationally recognized rights agent agreed to between Werewolf and Ambros, or the Rights Agent, pursuant to which Werewolf will distribute to each holder of Werewolf Common Stock of record as of the close of business on the last business day prior to the Effective Time one non-transferable contingent value right (each, a CVR) for each outstanding share of Werewolf Common Stock held by such stockholder as of such date. Each CVR represents the right to receive contingent cash payments (any such cash payments, the CVR Payment Amounts) in respect of certain of Werewolf's legacy assets, consisting of WTX-124 and WTX-330 (together, the Legacy Assets), pursuant to the terms and conditions of the CVR Agreement.

The CVR Payment Amounts, if any, will become payable to the Rights Agent for subsequent distribution to the CVR holders in accordance with the terms of the CVR Agreement. In the event that no such proceeds are received during the CVR Term (as defined in the CVR Agreement), holders of the CVRs will not receive any payment pursuant to the CVR Agreement. There can be no assurance that the CVR holders will receive any payments with respect to the CVR Agreement.

Concurrent PIPE Financing

Concurrently with entering into the Merger Agreement, Werewolf entered into a securities purchase agreement, or the Securities Purchase Agreement, with certain qualified institutional buyers or accredited investors, or the Investors. Pursuant to the Securities Purchase Agreement, and subject to the terms and conditions therein, Werewolf agreed to sell, and the Investors agreed to purchase, immediately prior to the Merger Closing, shares of Werewolf Common Stock, or the Shares, and, in the case of certain Investors, in lieu of shares of Werewolf Common Stock, PIPE Pre-Funded Warrants (together with the Shares, the Securities) for an aggregate purchase price of $150.0 million, or the Concurrent PIPE Financing. The closing of the Concurrent PIPE Financing is anticipated to occur immediately prior to the Merger Closing, subject to the satisfaction of customary closing conditions. Werewolf has also agreed to enter into a registration rights agreement with the Investors at the closing of the Concurrent PIPE Financing.

EMD Asset Purchase Agreement

On August 14, 2026, or the EMD Closing, we entered into an asset purchase agreement, or the EMD Purchase Agreement, with EMD Serono Research & Development Institute Inc., or EMD, pursuant to which, and subject to the terms and conditions thereof, we sold to EMD technology comprising (i) our pre-clinical INDUCER™ platform, including all patents and know-how related thereto, pre-clinical compounds and related intangible assets, and (ii) our INDUKINE platform, including certain patents, certain know-how related thereto, and pre-clinical compounds, excluding the clinical development programs for WTX-124 and WTX-330 (collectively, the EMD Transferred Assets). We retain all rights necessary for the continued development of our WTX-124 and WTX-330 clinical programs, as described below.

The EMD Purchase Agreement contains customary representations, warranties and covenants of each of us and EMD. The EMD Purchase Agreement further provides that, subject to certain limitations, we and EMD will each indemnify the other for

certain losses arising from such breaches of representations, warranties and covenants and liabilities allocated to such party pursuant to the terms of the EMD Purchase Agreement.

In addition, the EMD Purchase Agreement contains a non-competition covenant pursuant to which we agreed not to exploit certain compounds, products or programs claimed in the Transferred Intellectual Property (as defined in the EMD Purchase Agreement) that are directed to the same tumor target as any Transferred Compound (as defined in the EMD Purchase Agreement) for a period of twenty-four (24) months after the EMD Closing, subject to customary exceptions for change of control transactions.

Simultaneously with the execution of the EMD Purchase Agreement, on August 14, 2026 we entered into a license agreement, or the EMD License Agreement, with EMD pursuant to which EMD granted us an exclusive license to certain patents included in the EMD Transferred Assets that enable us to exploit and perform clinical development programs for WTX-124 and WTX-330.

Additionally, under the EMD License Agreement, EMD granted to us certain licenses to enable us to grant certain licenses to (i) Harpoon Therapeutics, Inc., or Harpoon, under that certain Second Amended and Restated Assignment and License Agreement between us and Harpoon dated December 20, 2019, or the Harpoon License, and (ii) Jazz Pharmaceuticals Ireland Limited, or Jazz, under our existing license agreement with Jazz that was entered into in connection with the Jazz Purchase Agreement (as defined below), under which we have granted a non-exclusive license to certain technology originally licensed to us under the Harpoon License.

Pursuant to the EMD Purchase Agreement, in consideration for the EMD Transferred Assets, EMD agreed to pay us upfront consideration of $28.0 million and an additional $5.0 million upon the completion of the transfer of the EMD Transferred Assets technology. Additionally, EMD agreed to reimburse us $0.9 million for a license fee previously paid by us related to a license included in the EMD Transferred Assets. During the three months ended September 30, 2026, we received a non-refundable payment from EMD in the amount of $28.9 million related to the EMD Purchase Agreement.

Jazz Asset Purchase Agreement; Termination of Collaboration Agreement

On May 6, 2026, or the Jazz Closing, we entered into an asset purchase agreement, or the Jazz Purchase Agreement, with Jazz. In April 2022, we entered into a global collaboration and license agreement, or the Collaboration Agreement, with Jazz under which Jazz acquired exclusive global development and commercialization rights to JZP898, as well as products containing certain isolated recombinant polypeptides comprising IFNα that meet specified criteria (each such product, a Licensed Product). Subject to the terms and conditions of the Jazz Purchase Agreement, we sold to Jazz, which we refer to as the Jazz Asset Sale, our program, or the 898 Program, for the development, manufacturing, commercialization, use and other exploitation of the Licensed Product. Pursuant to the Jazz Purchase Agreement and related ancillary agreements, in consideration for all material assets, properties, rights and interests used or held for use in the conduct of the 898 Program, Jazz paid us upfront consideration of $21.0 million, and has agreed to pay an additional $2.0 million contingent upon the consent to the partial assignment of a certain license agreement, as and to the extent such agreement relates to the conduct of the 898 Program. Jazz also assumed certain liabilities of ours relating to the 898 Program arising after the Jazz Closing.

During the nine months ended September 30, 2026, we recognized revenue of $21.0 million due to the change in the overall transaction price of the Collaboration Agreement as a result of entering into the Jazz Purchase Agreement.

In the future, our ability to generate revenue from the Jazz Purchase Agreement will depend on successfully completing the conditions necessary to receive payment of the $2.0 million contingent payment. There can be no assurances of the timing of when we will receive the $2.0 million contingent payment, or at all.

Previously, we were eligible to receive up to $515.0 million in development and regulatory milestones, and up to $740.0 million in sales-based milestones for all Licensed Products upon meeting certain conditions under the Collaboration Agreement. Effective as of the Jazz Closing, the Collaboration Agreement was terminated, and as a result, we are no longer eligible to receive payment for meeting the conditions of the development and regulatory milestones or sales-based milestones for any Licensed Products.

Loan Repayment

On May 6, 2026, we entered into a letter agreement providing for the repayment by us of all amounts owed under the loan and security agreement, dated May 2, 2024, or the K2HV Loan Agreement, by and among us, the lenders from time to time party hereto, or the Lenders, K2 HealthVentures LLC, or K2HV, as administrative agent for the Lenders, and ANKURA TRUST COMPANY, LLC, as collateral trustee for secured parties, or the Collateral Trustee. On May 6, 2026, upon payment by us of $31.4 million, all of our indebtedness and obligations to the Collateral Trustee and the Lenders under the K2HV Loan Agreement and any other related loan and collateral security documents were deemed paid and discharged in full. During the nine months ended September 30, 2026, we recognized a loss on the extinguishment of debt in the amount of $3.4 million,

primarily due to the write off of unamortized debt issuance costs and the unaccreted balance of the final fee payable under the K2HV Loan Agreement.

Strategic Review

In February 2026, we adopted a restructuring plan to extend our capital resources, or the 2026 Restructuring, in connection with initiating a process to explore a full range of strategic alternatives to advance our promising platform and drug development pipeline to maximize stockholder value. We have engaged Piper Sandler & Co., or Piper Sandler, to serve as exclusive financial advisor to assist in the strategic review process. Measures contemplated during the strategic review process include the Merger and the Contemplated Transactions, the EMD Purchase Agreement, and the Jazz Asset Sale. If the Merger is not completed, we will need to consider alternative options, which may include, among other options, a sale of our company, a business combination or merger, a sale of our assets, licensing or collaboration arrangements, or other strategic transactions. There can be no assurance that the strategic review process will result in any agreement or transaction that will enhance stockholder value, or any agreement or transaction at all.

As part of the 2026 Restructuring, our board of directors approved a reduction in force in February 2026, representing 64% of our workforce, to better align our resources with our pursuit of strategic alternatives. In May 2026, an additional reduction in force occurred, representing 36% of our workforce at that time. As a result of the 2026 Restructuring, we recognized costs of $6.5 million during the nine months ended September 30, 2026 consisting of severance payments, retention bonuses, employee benefits and related taxes, stock-based compensation, and contract termination costs. We estimate that we will incur approximately $0.7 million in additional costs to complete the 2026 Restructuring, which is expected to be completed by the end of 2026. Our estimate of costs we expect to incur and the expected timing of when the 2026 Restructuring will be completed are subject to a number of assumptions, and actual results may differ. We may also incur additional costs not currently contemplated that may occur as a result of, or that are associated with the 2026 Restructuring.

Financial Operations Overview

Revenue

Historically, all our revenue has been generated from the Collaboration Agreement with Jazz. In June 2024, we satisfied the last material performance obligation required of us under the Collaboration Agreement. Accordingly, we did not recognize revenue related to the Collaboration Agreement during the nine months ended September 30, 2025.

In May 2026, we entered into the Jazz Purchase Agreement with Jazz. We recognized $21.0 million in revenue during the nine months ended September 30, 2026 related to the Jazz Purchase Agreement.

In the future, our ability to generate revenue from the Jazz Purchase Agreement will depend on successfully completing the conditions necessary to receive payment of the $2.0 million contingent payment. There can be no assurances of the timing of when we will receive the $2.0 million contingent payment, or at all.

Effective as of the Jazz Closing, the Collaboration Agreement was terminated.

Operating Expenses

Research and Development Expenses

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

- salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- expenses incurred under agreements with third parties that conduct research, preclinical and clinical activities on our behalf;
- costs of outside consultants, including their fees, stock-based compensation and related travel expenses;
- costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials; and
- facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

We expense research and development costs as incurred. Costs for external development activities are recognized based on an evaluation of the progress to completion of specific tasks using information provided to us by our vendors. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of performance of the individual arrangements, which may differ from the pattern of billings incurred, and are reflected in our condensed consolidated financial statements as prepaid or accrued research and development expenses.

We typically use our employee and infrastructure resources across our development programs. We track external development costs by product candidate or development program, but generally we do not allocate personnel costs, license payments made under our licensing arrangements or other internal costs to specific development programs or product candidates.

Our external development costs were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2026	2025	2026	2025
	(in thousands)			
WTX-124	$ 438	$ 3,718	$ 3,553	$ 13,086
WTX-330	257	1,502	2,447	4,714
WTX-1011	—	93	71	93
WTX-2022	1	—	51	—
WTX-712	5	4	11	108
WTX-921	—	31	—	71
WTX-518	3	50	3	52
Pre-development candidates	7	1,212	1,732	2,856
Total external development costs	$ 711	$ 6,610	$ 7,868	$ 20,980

Research and development activities have historically been central to our business model. We expect our research and development costs will decrease in the near future as we explore strategic alternatives available to advance our platform and drug development pipeline.

The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming. We cannot reasonably estimate or know the nature, timing and estimated costs of the efforts that will be necessary to complete development of our current or future product candidates, if any. The actual probability of success for our product candidates will depend on a variety of factors, including:

- the successful completion of the Merger and the Contemplated Transactions;
- the outcome of our strategic review process;
- the scope, rate of progress and expenses of our research activities as well as any preclinical studies and clinical trials, including our Phase 1/1b clinical trial for WTX-124 and the Phase 1b/2 clinical trial for WTX-330, as well as other research and development activities;
- establishing an appropriate safety profile;
- successful enrollment in and completion of clinical trials;
- whether our product candidates show safety and efficacy in our clinical trials;
- receipt of marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates;
- commercializing product candidates, if and when approved, whether alone or in collaboration with others; and
- continued acceptable safety profile of the products following any regulatory approval.

A change in the outcome of any of these variables with respect to the development of our current and future product candidates would significantly change the costs and timing associated with the development of those product candidates, and we may never succeed in achieving regulatory approval for any of our product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion costs of our research and development activities.

General and Administrative Expenses

General and administrative expenses consist primarily of professional services fees incurred as a result of our strategic review process, including costs related to the Merger and Contemplated Transactions, as well as salaries, benefits and other related costs, including stock-based compensation, for personnel in our executive, finance, people operations, business development, legal, information technology and administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters; professional fees for accounting, audit, tax and consulting services; insurance costs; travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs.

At this time, we cannot reasonably estimate the nature, timing, and estimated costs associated with the efforts that will be necessary to complete our strategic review process, including costs which may be necessary to complete the Merger and Contemplated Transactions.

Other Income (Expense)

Interest Income

Interest income consists of interest earned from cash and cash equivalents invested in money market funds.

Interest Expense

Interest expense represents interest incurred from the K2HV Loan Agreement and non-cash interest expense related to the amortization of debt issuance costs.

Loss on Extinguishment of Note Payable

Loss on extinguishment of note payable represents the residual financial impact of notes payable to lenders, specifically the extinguishment of the K2HV Loan Agreement in May 2026.

Other (Expense) Income, Net

Other (expense) income, net primarily consists of the unrealized gain or loss recognized on the change in fair value of the derivative liability associated with the K2HV Loan Agreement, as well as net foreign currency gains and losses related to services performed by foreign vendors.

Results of Operations

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

The following table summarizes our results of operations:

	Three Months Ended September 30,		
	2026	2025	$ Change
	(in thousands)		
Operating expenses:			
Research and development	$ 2,175	$ 11,634	$ (9,459)
General and administrative	7,879	4,092	3,787
Total operating expenses	10,054	15,726	(5,672)
Operating loss	(10,054)	(15,726)	5,672
Other income (expense):			
Interest income	183	697	(514)
Interest expense	—	(1,341)	1,341
Other expense, net	(6)	—	(6)
Total other income (expense)	177	(644)	821
Net loss	$ (9,877)	$ (16,370)	$ 6,493

Research and Development Expenses

The following table summarizes our research and development expenses:

	Three Months Ended September 30,		
	2026	2025	$ Change
	(in thousands)		
Facility costs	$ 909	$ 770	$ 139
Clinical trial costs	650	4,522	(3,872)
Personnel	533	3,318	(2,785)
Manufacturing	61	675	(614)
Lab consumables	13	808	(795)
Contract research organization	—	1,413	(1,413)
Other	9	128	(119)
Total research and development expenses	$ 2,175	$ 11,634	$ (9,459)

Research and development expenses for the three months ended September 30, 2026 were $2.2 million compared to $11.6 million for the three months ended September 30, 2025. The decrease of $9.5 million was primarily due to:

- $3.9 million of decreased clinical trial costs, driven by lower patient and site monitoring costs as we approach the completion of the Phase 1/1b clinical trial of WTX-124 and the Phase 1b/2 clinical trial of WTX-330, both of which were completed in the fourth quarter of 2026;
- $2.8 million of decreased personnel costs, driven primarily by cost savings recognized during the three months ended September 30, 2026 as a result of the reductions in force that were completed in February 2026 and May 2026; and
- a net decrease of $2.8 million across all other research and development activities. This decrease was due to our decision to significantly curtail our research and development spending in order to conserve our capital resources that may be necessary in our pursuit of strategic alternatives. Decreases of $2.9 million across the remaining research and development activities were partially offset by an increase in facility costs of $0.1 million due to higher depreciation expense recognized during the three months ended September 30, 2026 as a result of a change in the estimated useful lives of our property and equipment.

General and Administrative Expenses

The following table summarizes our general and administrative expenses:

	Three Months Ended September 30,		
	2026	2025	$ Change
	(in thousands)		
Professional services	$ 5,744	$ 1,078	$ 4,666
Personnel	1,291	2,038	(747)
Facility costs	363	327	36
Corporate insurance	251	266	(15)
Information technology costs	157	199	(42)
Other	73	184	(111)
Total general and administrative expenses	$ 7,879	$ 4,092	$ 3,787

General and administrative expenses were $7.9 million for the three months ended September 30, 2026 compared to $4.1 million for three months ended September 30, 2025. The increase of $3.8 million was primarily due to $4.7 million of increased professional services fees, driven by an increased reliance on external legal counsel, consultants, and advisors engaged to assist us in our strategic review process, including their significant involvement in the Merger, the Contemplated Transactions, and the EMD Purchase Agreement.

This increase was partially offset by a decrease of $0.7 million in personnel costs, driven primarily by cost savings recognized during the three months ended September 30, 2026 as a result of the reductions in force that were completed in February 2026 and May 2026.

Interest Income

Interest income was $0.2 million for the three months ended September 30, 2026 compared to $0.7 million for the three months ended September 30, 2025. This decrease in interest income was primarily the result of lower balances in money market accounts during the three months ended September 30, 2026 compared to the three months ended September 30, 2025.

Interest Expense

Interest expense was $1.3 million for the three months ended September 30, 2025. As a result of the extinguishment of the K2HV Loan Agreement in May 2026, no interest expense was incurred during the three months ended September 30, 2026.

Other expense, net

Other expense, net for the three months ended September 30, 2026 consists of net foreign currency gains and losses related to services performed by foreign vendors during the period. No such activity occurred during the three months ended September 30, 2025.

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

The following table summarizes our results of operations:

	Nine Months Ended September 30,		
	2026	2025	$ Change
	(in thousands)		
Revenue:			
Collaboration revenue	$ 21,000	$ —	$ 21,000
Operating expenses:			
Research and development	16,518	37,897	(21,379)
General and administrative	20,649	13,362	7,287
Total operating expenses	37,167	51,259	(14,092)
Operating loss	(16,167)	(51,259)	35,092
Other expense:			
Interest income	893	2,544	(1,651)
Interest expense	(1,843)	(3,905)	2,062
Loss on extinguishment of note payable	(3,354)	—	(3,354)
Other income, net	732	179	553
Total other expense	(3,572)	(1,182)	(2,390)
Net loss	$ (19,739)	$ (52,441)	$ 32,702

Revenue

During the nine months ended September 30, 2026, we recognized $21.0 million in revenue related to the Jazz Purchase Agreement. No revenue was recognized during the nine months ended September 30, 2025.

Research and Development Expenses

The following table summarizes our research and development expenses:

	Nine Months Ended September 30,		
	2026	2025	$ Change
	(in thousands)		
Personnel	$ 5,494	$ 11,399	$ (5,905)
Clinical trial costs	5,455	11,515	(6,060)
Facility costs	2,637	2,351	286
Contract research organization	1,495	3,275	(1,780)
Manufacturing	918	6,190	(5,272)
Lab consumables	291	2,795	(2,504)
Other	228	372	(144)
Total research and development expenses	$ 16,518	$ 37,897	$ (21,379)

Research and development expenses for the nine months ended September 30, 2026 were $16.5 million compared to $37.9 million for the nine months ended September 30, 2025. The decrease of $21.4 million was primarily due to:

- $5.9 million of decreased personnel costs, driven primarily by cost savings recognized during the nine months ended September 30, 2026 as a result of the reductions in force that were completed in February 2026 and May 2026;
- $6.1 million of decreased clinical trial costs, driven by lower patient and site monitoring costs as we approach the completion of the Phase 1/1b clinical trial of WTX-124 and the Phase 1b/2 clinical trial of WTX-330, both of which were completed in the fourth quarter of 2026; and
- a net decrease of $9.4 million across all other research and development activities. This decrease was due to our decision to significantly curtail our research and development spending in order to conserve our capital resources that may be necessary in our pursuit of strategic alternatives. Decreases of $9.7 million across the remaining research and development activities were partially offset by an increase in facility costs of $0.3 million due to

higher depreciation expense recognized during the nine months ended September 30, 2026 as a result of a change in the estimated useful lives of our property and equipment.

General and Administrative Expenses

The following table summarizes our general and administrative expenses:

	Nine Months Ended September 30,		
	2026	2025	$ Change
	(in thousands)		
Professional services	$ 12,214	$ 3,540	$ 8,674
Personnel	5,679	6,783	(1,104)
Facility costs	1,250	984	266
Corporate insurance	771	803	(32)
Information technology costs	483	566	(83)
Other	252	686	(434)
Total general and administrative expenses	$ 20,649	$ 13,362	$ 7,287

General and administrative expenses were $20.6 million for the nine months ended September 30, 2026 compared to $13.4 million for the nine months ended September 30, 2025. The increase of $7.3 million was primarily due to:

- $8.7 million of increased professional services fees, driven by an increased reliance on external legal counsel, consultants, and advisors engaged to assist us in our strategic review process, including their significant involvement in the Merger, the Contemplated Transactions, and the EMD Purchase Agreement; and
- $0.3 million of increased facility costs due to higher depreciation expense recognized during the nine months ended September 30, 2026 as a result of a change in the estimated useful lives of our property and equipment.

These increases were partially offset by:

- $1.1 million of decreased personnel costs, driven primarily by cost savings recognized during the nine months ended September 30, 2026 as a result of the reductions in force that were completed in February 2026 and May 2026; and
- $0.5 million of decreased costs across all other general and administrative activities as the result of cost savings initiatives implemented during the period leading up and during the nine months ended September 30, 2026.

Interest Income

Interest income was $0.9 million for the nine months ended September 30, 2026 compared to $2.5 million for the nine months ended September 30, 2025. This decrease in interest income was primarily a result of lower balances in money market accounts during the nine months ended September 30, 2026 compared to the nine months ended September 30, 2025.

Interest Expense

Interest expense was $1.8 million for the nine months ended September 30, 2026 compared to $3.9 million for the nine months ended September 30, 2025. This decrease in interest expense was due to the extinguishment of the K2HV Loan Agreement in May 2026.

Loss on Extinguishment of Note Payable

The extinguishment of the K2HV Loan Agreement in May 2026 resulted in a one-time loss of $3.4 million for the nine months ended September 30, 2026. No similar activity occurred during the nine months ended September 30, 2025.

Other Income, Net

Other income, net for the nine months ended September 30, 2026 and 2025 primarily consists of the gains recognized for the change in fair value of the derivative liability associated with the K2HV Loan Agreement during each period.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception in 2017, we have devoted substantially all of our efforts and financial resources to organizing and staffing our company; business planning; raising capital; developing and optimizing our platform technology; identifying potential product candidates; enhancing our intellectual property portfolio; undertaking research, preclinical studies, and clinical trials; and enabling manufacturing for our development programs. Our net loss was $19.7 million for the nine months ended

September 30, 2026. As of September 30, 2026, we had cash and cash equivalents of $41.9 million and an accumulated deficit of $495.1 million. As we have no products that are approved for sale, we have not generated any revenue from product sales to date, and we do not expect to generate any such revenue for the foreseeable future, if at all. Instead, we have financed our operations primarily through aggregate cash proceeds from convertible promissory notes, private placements of our convertible preferred stock, our initial public offering, payments from Jazz under the Collaboration Agreement and the Jazz Purchase Agreement, sales of common stock through our at-the-market program, the drawdown of our term loans, and proceeds from the EMD Purchase Agreement. We expect to incur substantial operating losses and negative cash flows from operations for the foreseeable future. There is substantial doubt about our ability to continue as a going concern for at least twelve months from the date these condensed consolidated financial statements are issued in this Quarterly Report, and we expect continuing operations beyond the near term will require additional liquidity.

In February 2026, we initiated the 2026 Restructuring and a process to explore a full range of strategic alternatives to advance our promising platform and drug development pipeline to maximize stockholder value. We engaged Piper Sandler to serve as exclusive financial advisor to assist in the strategic review process. Measures contemplated during the strategic review process include the Merger and the Contemplated Transactions, the EMD Purchase Agreement, and the Jazz Asset Sale. If the Merger is not completed, we will need to consider alternative options, which may include, among other options, a sale of our company, a business combination or merger, a sale of our assets, licensing or collaboration arrangements, or other strategic transactions. There can be no assurance that the strategic review process will result in any agreement or transaction that will enhance stockholder value, or any agreement or transaction at all.

As part of the 2026 Restructuring, our board of directors approved a reduction in force, representing 64% of our workforce, to better align our resources with our pursuit of strategic alternatives. In May 2026, an additional reduction in force occurred, representing 36% of our workforce at that time. As a result of the 2026 Restructuring, we have recognized restructuring costs of $6.5 million during the nine months ended September 30, 2026 consisting of severance payments, retention bonuses, employee benefits and related taxes, stock-based compensation, and contract termination costs. The 2026 Restructuring is expected to be completed by the end of 2026. We may also incur additional costs not currently contemplated that may occur as a result of, or that are associated with the 2026 Restructuring.

While our strategic review process is underway, we expect our overall costs will decrease in the near term due to the reductions in force, the completion of our clinical trials, and other cost reduction initiatives. The outcome of the Merger and the Contemplated Transactions will inform our future development plans and the costs associated with those efforts. If we decide to resume enrollment in our clinical trials or development of our preclinical product candidates, however, we expect that our research and development and general and administrative expenses would increase.

We will need additional capital to fund our operations, which we may raise through a combination of public or private equity offerings and debt financings or other sources, such as potential collaboration agreements, strategic alliances and licensing arrangements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on acceptable terms, or at all. Additionally, the extent to which we use our at-the-market program as a source of future funding will depend on a number of factors, including the prevailing market price of our common stock, general market conditions, the extent to which we are able to secure funds from other sources, and whether we are then subject to limitations on our ability to use Form S-3 to sell more than one-third of the aggregate market value of our public float in the trailing 12-month period, which limitations will remain in place until such time as our public float exceeds $75 million. Our failure to raise capital or enter into such agreements as and when needed could have a material adverse effect on our business, results of operations and financial condition.

Term Loan Facility

In May 2024, we, as borrower, entered into the K2HV Loan Agreement with K2HV (which we refer to, together with any other lender from time to time, as the Lenders); K2HV, as administrative agent for the Lenders (in such capacity, together with its successors, the Administrative Agent); and Ankura Trust Company, LLC, as collateral trustee for the Lenders, or the Collateral Trustee. The K2HV Loan Agreement provided up to $60.0 million principal in term loans. We received $30.0 million in gross loan proceeds at closing; $25.0 million from the first tranche commitment and $5.0 million from the second tranche commitment. A third tranche commitment of up to $10.0 million was available to be drawn at our option through June 30, 2025, subject to the achievement, as determined by the Administrative Agent in its discretion, of certain time-based, clinical and regulatory milestones and receipt of not less than $60.0 million in net cash proceeds from certain financing activities, with at least $50.0 million from a single offering of common stock. Our ability to draw upon the third tranche commitment expired on June 30, 2025 without being drawn upon. A fourth tranche commitment of up to $20.0 million was available to be drawn at our option through May 1, 2026, subject to the Lender's review of our clinical, financial and operating plan and subject to the

Lenders' consent in its sole and absolute discretion. Our ability to draw upon the fourth tranche commitment expired on May 1, 2026 without being drawn upon.

The term loan was scheduled to mature on May 1, 2028, and we were obligated to make interest only payments for the first 24 months followed by equal interest and principal payments each month thereafter through the maturity date. The term loan bore a variable interest rate equal to the greater of (i) 10.3%, and (ii) the sum of (A) the prime rate last quoted in The Wall Street Journal (or a comparable replacement rate if The Wall Street Journal ceases to quote such rate) and (B) 1.8%. We could prepay, at our option, all, but not less than all, of the outstanding principal balance and all accrued and unpaid interest with respect to the principal balance being prepaid of the term loans, subject to a prepayment premium to which the Lenders were entitled and certain notice requirements. We were obligated to pay a final fee equal to 6.95% of the aggregate amount of the term loans funded, or the Final Fee, to occur upon the earliest of (i) the maturity date, (ii) the acceleration of the term loans, and (iii) the prepayment of the term loans. The Final Fee was being accreted to interest expense using the effective interest method over the life of the debt.

Pursuant to the terms of the K2HV Loan Agreement, the lenders thereto had the option, prior to the full repayment of the term loans, to convert up to $5.0 million of the outstanding principal of the term loans into shares of our common stock at a conversion price of the lesser of $6.3182 per share, or the Fixed Price Conversion, and the lowest effective price per share of our first equity financing following the closing of the K2HV Loan Agreement, or the Variable Price Conversion, subject to customary adjustments and 9.99% and 19.99% beneficial ownership limitations. There would have been no prepayment penalty for any principal amount converted into common stock. We determined that the Fixed Price Conversion and the Variable Price Conversion within the K2HV Loan Agreement were required to be bifurcated as an embedded derivative under ASC Topic 815, *Derivatives and Hedging*, at fair value, and recorded as a discount on the debt on the date of issuance, with subsequent changes in fair value recognized in the accompanying condensed consolidated statements of operations.

As security for our obligations under the K2HV Loan Agreement, we granted the Lenders a first-priority security interest on substantially all of our assets (other than intellectual property), subject to certain exceptions. The K2HV Loan Agreement contained customary representations and warranties, events of default and affirmative and negative covenants, including covenants that limited or restricted our ability to, among other things, dispose of assets, make changes to our business, management, ownership or business locations, merge or consolidate, incur additional indebtedness, incur additional liens, pay dividends or other distributions or repurchase equity, make investments, and enter into certain transactions with affiliates, in each case subject to certain exceptions. Upon the occurrence of an event of default, a default interest rate of an additional 5.0% per annum may have been applied to the outstanding loan balances, and the Lenders may have declared all outstanding obligations immediately due and payable and exercised all of its rights and remedies as set forth in the K2HV Loan Agreement and under applicable law.

Subject to certain conditions, we granted the Lenders the right, prior to repayment of the term loans, to invest up to $5.0 million in the aggregate in future offerings of capital stock, at market terms, subject to certain exceptions and conditions.

We incurred debt issuance costs of $0.7 million in connection with the term loans, composed of the facility fee of $0.4 million and other expenses paid to the Lenders of $0.2 million and external legal fees of $0.1 million. These debt issuance costs, together with fair value of the embedded derivative of $4.5 million, resulted in a debt discount of $5.1 million which was being amortized to interest expense over the term of the K2HV Loan Agreement using the effective interest method.

On May 6, 2026, we entered into a letter agreement providing for the repayment by us of all amounts owed under the K2HV Loan Agreement. On May 6, 2026, upon payment by us of $31.4 million, all of our indebtedness and obligations to the Collateral Trustee and the Lenders under the K2HV Loan Agreement and any other related loan and collateral security documents were deemed paid and discharged in full. During the nine months ended September 30, 2026, we recognized a loss on the extinguishment of debt in the amount of $3.4 million, primarily due to the write off of unamortized debt issuance costs and the unaccreted balance of the Final Fee.

ATM Offering

On May 10, 2022, we entered into a sales agreement, or the Sales Agreement, with Leerink Partners LLC, or Leerink Partners, pursuant to which, from time to time, we may offer and sell shares of our common stock, which we refer to as the ATM Offering. The Sales Agreement provides that Leerink Partners is entitled to a sales commission equal to 3.0% of the gross sales price per share of all shares sold under the ATM Offering. We were initially entitled to offer and sell shares of our common stock having an aggregate offering price of up to $50.0 million in the ATM Offering, which was subsequently increased in February 2024 to $75.0 million. On May 8, 2025, we filed a new Registration Statement on Form S-3 and filed a new prospectus covering the ATM Offering, or the Prospectus, with an aggregate offering price of up to $12.5 million in the ATM Offering as a result of being subject to General Instruction I.B.6 of Form S-3, or the Baby Shelf Limitation. As of September 30, 2026, we remain subject to the Baby Shelf Limitation. During the nine months ended September 30, 2026, we did not sell any shares of our common stock under the ATM Offering.

Jazz Collaboration

As of September 30, 2026, we had received $41.0 million in payments from Jazz, excluding payments for reimbursed costs, under the terms of the Collaboration Agreement and the Jazz Purchase Agreement.

Pursuant to the Jazz Purchase Agreement, Jazz has agreed to pay us an additional $2.0 million contingent upon the consent to the partial assignment of a certain license agreement, as and to the extent such agreement relates to the conduct of the 898 Program. There can be no assurances of the timing of when we will receive the $2.0 million contingent payment, or at all.

Effective as of the Jazz Closing, the Collaboration Agreement was terminated, and as a result, we are no longer eligible to receive payment for meeting the conditions of the development and regulatory milestones or sales-based milestones we were previously eligible for under the Collaboration Agreement.

EMD Asset Purchase Agreement

As described above under the heading *"Management's Discussion and Analysis of Financial Condition and Results of Operations – Recent Developments – EMD Asset Purchase Agreement,"* on August 14, 2026, we entered into the EMD Purchase Agreement under which we sold to EMD technology comprising of the EMD Transferred Assets. As of September 30, 2026, we have received $28.9 million in non-refundable proceeds from EMD related to the EMD Purchase Agreement.

We are entitled to receive an additional payment of $5.0 million from EMD upon the completion of the transfer of the EMD Transferred Assets technology. There can be no assurances of the timing of when we will receive the additional payment of $5.0 million, or at all.

Plan of Operation and Future Funding Requirements

As of September 30, 2026, we had cash and cash equivalents of $41.9 million. Based on our current operating plan, we expect that our cash and cash equivalents will be insufficient to allow us to fund our current operating plan through at least twelve months from the date these condensed consolidated financial statements are issued in this Quarterly Report. These conditions raise substantial doubt about our ability to continue as a going concern for at least twelve months from the date these condensed consolidated financial statements are issued in this Quarterly Report. As described above, we have initiated a process to explore a full range of strategic alternatives to advance our promising platform and drug development pipeline to maximize stockholder value. This process has resulted in the Merger and the Contemplated Transactions, as described above under the heading *"Management's Discussion and Analysis of Financial Condition and Results of Operations – Recent Developments – Merger Agreement."* The outcome of the Merger and the Contemplated Transactions will inform our future funding requirements; however, because the Merger Closing is contingent upon factors that are not entirely in our control, we cannot assess the likelihood that the Merger and the Contemplated Transactions will be completed successfully, and therefore we are unable to estimate our current operating capital requirements.

The timing and amount of our operating expenditures will depend largely on:

- our ability to consummate the Merger and the Contemplated Transactions;
- the nature, timing, and extent of our strategic review process;
- the pursuit of viable strategic alternatives, if any;
- the scope, progress, timing, costs and results of researching and developing our current product candidates or any future product candidates, including with respect to our clinical trials of WTX-124 and WTX-330 and the costs associated with attracting, hiring and retaining skilled personnel and consultants as our preclinical and clinical activities increase;
- the cost of manufacturing our product candidates WTX-124, WTX-330, and any future product candidates for clinical trials and, if we are able to obtain marketing approval, for commercial sale;
- the costs of any third-party products used in our combination clinical trials that are not covered by such third parties or other sources;
- the timing of, and the cost involved in, obtaining marketing approval for WTX-124 and WTX-330 or any future product candidates, and our ability to obtain marketing approval and generate revenue from any potential commercial sales of such product candidates;
- the cost of building a sales force in anticipation of product commercialization and the cost of commercialization activities for WTX-124, WTX-330, or any future product candidates if we receive marketing approval, including marketing, sales and distribution costs;
- the potential emergence of competing therapies and other adverse market developments;

- the amount and timing of any payments we may be required to make pursuant to our license agreement with Harpoon Therapeutics, Inc., or other future license agreements or collaboration agreements;
- our ability to establish future collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- any product liability or other lawsuits related to our product candidates;
- the extent to which we in-license or acquire other products and technologies; and
- the costs of operating as a public company.

Until such time, if ever, as we can generate substantial revenue from product sales, we expect to fund our operations and capital funding needs through equity and/or debt financing. We may also consider entering into collaboration arrangements or selectively partnering for clinical development and commercialization. The sale of additional equity may result in additional dilution to our stockholders. The incurrence of debt financing would result in debt service obligations and the instruments governing such debt could provide for operating and financing covenants that would restrict our operations or our ability to incur additional indebtedness or pay dividends, among other items. If we raise additional funds through governmental funding, collaborations, strategic partnerships and alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise capital when needed or on acceptable terms, we may be forced to delay, reduce, or eliminate certain costs related to our operations and research and development programs.

Cash Flows

The following table provides information regarding our cash flows:

	Nine Months Ended September 30,	
	2026	**2025**
	(in thousands)	
Net cash (used in) provided by:		
Operating activities	$ (12,935)	$ (49,268)
Investing activities	29,266	—
Financing activities	(32,412)	3,662
Net decrease in cash, cash equivalents and restricted cash and cash equivalents	$ (16,081)	$ (45,606)

Operating Activities

Net cash used in operating activities for the nine months ended September 30, 2026 was $12.9 million compared to $49.3 million for the nine months ended September 30, 2025. The decrease of $36.3 million is the result of a $21.0 million payment from Jazz related to the Jazz Purchase Agreement in May 2026, combined with various cost reduction initiatives implemented during the nine months ended September 30, 2026. Our operating expenses, excluding non-cash expenses, have decreased $12.4 million during the nine months ended September 30, 2026 compared to the nine months ended September 30, 2025. Similarly, our cash used to pay down our current liabilities, net of prepayments, has decreased $5.3 million due to our lower operating costs. Finally, our cash paid for interest during the nine months ended September 30, 2026 was lower by $1.0 million compared to the nine months ended September 30, 2025 due to the extinguishment of the K2HV Loan Agreement in May 2026.

These increases were partially offset by higher lease payments of $2.0 million during the nine months ended September 30, 2026 compared to the nine months ended September 30, 2025 due to the termination of our lease in May 2026. Lastly, interest income recognized during the nine months ended September 30, 2026 decreased by $1.7 million compared to the nine months ended September 30, 2025.

Investing Activities

Net cash provided by investing activities for the nine months ended September 30, 2026 was $29.3 million, which primarily consists of a $28.9 million payment from EMD related to the EMD Purchase Agreement in September 2026. During the nine months ended September 30, 2026, we also received proceeds of $0.4 million from the sale of property and equipment during the period. No investing activities occurred during the nine months ended September 30, 2025.

Financing Activities

Net cash used for financing activities for the nine months ended September 30, 2026 was $32.4 million, which represents the repayment of amounts owed under the K2HV Loan Agreement during the period, plus payment of fees incurred for extinguishment of the note payable. Net cash provided by financing activities for the nine months ended September 30, 2025 was $3.7 million, and primarily consisted of net proceeds of $3.6 million from our ATM Offering.

Contractual Obligations

In the normal course of business, we enter into agreements with contract research organizations, or CROs, contract manufacturers, vendors and other third parties for preclinical studies and clinical trials, manufacturing services and other services and products for operating purposes. These contracts do not contain minimum purchase commitments and are cancellable by us upon prior written notice. Payments due upon cancellation consist only of payments for services provided or expenses incurred, including noncancelable obligations of our service providers, up to the date of cancellation.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our condensed consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States. The preparation of these condensed consolidated financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses and the disclosure of contingent assets and liabilities in our financial statements and accompanying notes. On an ongoing basis, we evaluate our estimates which include, but are not limited to those related to accrued expenses, assumptions used in the valuation of stock-based compensation expense and the fair value of the derivative liability. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances. Actual results could differ from those estimates under different assumptions and conditions.

Our critical accounting policies are described under the heading *"Management's Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies and Estimates"* in our 2025 Annual Report, which was filed with the SEC on March 27, 2026. During the three and nine months ended September 30, 2026, there were no material changes to our critical accounting policies from those previously disclosed.

Item 3. Quantitative and Qualitative Disclosures about Market Risk.

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, or the Exchange Act, and are not required to provide the information under this item.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our principal executive officer and our principal financial officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2026. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act means controls and other procedures of a company that are designed to ensure that information required to be disclosed by the company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure. Our management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and our management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of September 30, 2026, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the most recent fiscal quarter covered by this Quarterly Report that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1A. Risk Factors.

Our business is subject to numerous risks. You should carefully consider the risks described below, as well as the other information in this Quarterly Report, including our condensed consolidated financial statements and the related notes and Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations. The occurrence of any of the events or developments described below could materially and adversely affect our business, financial condition, results of operations and future growth prospects. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. This Quarterly Report also contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of a number of factors, including the risks described below.

Risks Related to the Pending Merger Transaction with Ambros

Failure to complete, or delays in completing, the Merger could materially and adversely affect our results of operations, business, financial results and/or common stock price.

On August 21, 2026, we entered into an Agreement and Plan of Merger, or the Merger Agreement, by and among Ambros Therapeutics, Inc., or Ambros, Werewolf, and Wave Atlantis Merger Sub, Inc., a direct, wholly owned subsidiary of Werewolf, or Merger Sub, pursuant to which Merger Sub will be merged with and into Ambros, with Ambros surviving as a wholly owned subsidiary of Werewolf, or the Merger, and, together with the other transactions contemplated by the Merger Agreement, the Contemplated Transactions.

Consummation of the Merger is subject to certain closing conditions, a number of which are not within our or Ambros' control. Any failure to satisfy these required conditions at the closing of the Merger, or the Merger Closing, may prevent, delay or otherwise materially adversely affect the completion of the transaction. We and Ambros cannot predict with certainty whether or when any of the required closing conditions will be satisfied or if another uncertainty may arise and cannot assure you that they will be able to successfully consummate the Merger as currently contemplated under the Merger Agreement or at all.

Our and Ambros' efforts to complete the Merger could cause substantial disruptions in, and create uncertainty surrounding, their businesses, which may materially adversely affect their results of operations and business. Uncertainty as to whether the Merger will be completed in a timely manner or at all could adversely affect our and Ambros' businesses and their relationships with employees, collaborators, vendors, manufacturers, regulators and other business partners. Changes to, or termination of, existing business relationships could adversely affect our results of operations and financial condition, as well as the market price of our common stock. The adverse effects of the pendency of the transaction could be exacerbated by any delays in completion of the transaction or termination of the Merger Agreement.

If the conditions to the Merger are not satisfied or waived, the Merger may not occur.

Before the Merger can be completed, our stockholders must approve the Werewolf Stockholder Matters, as defined in Merger Agreement, and Ambros' stockholders must adopt the Merger Agreement and approve the Merger and the related transactions. Failure to obtain these required stockholder approvals may result in a material delay in, or the abandonment of, the Merger.

Even if the Merger Agreement is adopted by, and the Contemplated Transactions are approved by, Ambros' stockholders and the Werewolf Stockholder Matters are approved by our stockholders, other specified conditions must be satisfied or, to the extent permitted by applicable law, waived to complete the Merger. We and Ambros cannot assure you that all of the conditions to the consummation of the Merger will be satisfied or waived. If the conditions are not satisfied or waived, the Merger may not occur or the effective time of the Merger, or the Effective Time, may be delayed. Any delay in completing the Merger may materially adversely affect the timing and benefits that are expected to be achieved from the Merger.

If the Merger is not completed, our stock price may decline significantly.

The market price of our common stock is subject to significant fluctuations. Market prices for securities of pharmaceutical, biotechnology and other life science companies have historically been particularly volatile. In addition, the market price of our common stock will likely be volatile based on whether stockholders and other investors believe that we can complete the Merger or otherwise raise additional capital to support its operations if the Merger is not consummated and another strategic transaction cannot be identified, negotiated and consummated in a timely manner, if at all. The volatility of the market price of our common stock has been and may be exacerbated by low trading volume. Additional factors that may cause the market price of our common stock to fluctuate include those described under the section entitled "*-Risks Related to Werewolf*" below.

Moreover, the stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may also adversely affect the trading price of our common stock. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against such companies.

Some of our and Ambros' directors and executive officers have interests in the Merger that are different from yours and that may influence them to support or approve the Merger without regard to your interests.

Directors and executive officers of Werewolf and Ambros have interests in the Merger that are different from, or in addition to, the interests of other stockholders generally. These interests with respect to our directors and executive officers may include, among others, the acceleration of vesting and other treatment of our stock options, potential change-in-control severance, bonus and continued health coverage benefits for certain executive officers under their retention arrangements, and special retention bonuses and salary increases approved for certain employees in anticipation of the Contemplated Transactions.

Further, the current members of the Ambros board of directors, or Ambros Board will continue as directors of the combined company after the Effective Time and, following the Merger Closing, non-employee directors of the combined company will be eligible to be compensated pursuant to the combined company's then-effective non-employee director compensation policy.

Our board of directors and the Ambros Board were aware of and considered those respective interests, among other matters, in reaching their respective decisions to approve and adopt the Merger Agreement and to recommend the approval of the Werewolf Stockholder Matters to our stockholders and recommend the adoption of the Merger Agreement and the approval of the Contemplated Transactions to Ambros' stockholders, respectively. These interests, among other factors, may have influenced the directors and executive officers of each company to support or approve the Merger.

Our stockholders may not realize a benefit from the Merger commensurate with the ownership dilution they will experience in connection with the Merger, including with respect to our common stock to be issued (and issuable) in connection with the Concurrent PIPE Financing.

If the combined company is unable to realize the full strategic and financial benefits currently anticipated from the Merger, our stockholders will have experienced substantial dilution of their ownership interests without receiving any commensurate benefit, or only receiving part of the commensurate benefit to the extent the combined company is able to realize only part of the strategic and financial benefits currently anticipated from the Merger.

Our stockholders will generally have a reduced ownership and voting interest in, and will exercise less influence over the management of, the combined company following the completion of the Merger as compared to their current ownership and voting interests in Werewolf.

After the completion of the Merger, our current stockholders will generally own a smaller percentage of the combined company than the percentage of Werewolf they owned prior to the Merger. Immediately after the Merger, based solely on the estimated exchange ratio, pre-merger equity holders of our capital stock, other than those participating in the Concurrent PIPE Financing, as defined in the Merger Agreement, are expected to own approximately 6.4% of the combined company; pre-merger Ambros equity holders are expected to own approximately 72.0% of the combined company; and investors in the Concurrent PIPE Financing are expected to own approximately 21.6% of the combined company, in each case, calculated on a fully diluted basis, using the treasury stock method. In addition, the Chief Executive Officer of Ambros will serve as the Chief Executive Officer of the combined company following the completion of the Merger.

Certain provisions of the Merger Agreement may discourage third parties from submitting competing proposals, including proposals that may be superior to the Contemplated Transactions.

While the Merger Agreement is in effect, each party is generally prohibited from, among other things, soliciting competing proposals or, except in certain limited circumstances set forth in the Merger Agreement, cooperating with persons making unsolicited acquisition proposals. Our board or directors or Ambros Board, as applicable, may take certain actions in response to an unsolicited competing proposal if it determines in good faith, after consultation with its outside financial advisor and outside legal counsel, that the unsolicited competing proposal constitutes, or is reasonably likely to result in, a superior competing proposal and, after consultation with its outside legal counsel, that failure to take such action would be inconsistent with the fiduciary duties of our board of directors or Ambros Board, as applicable. In addition, our current directors and executive officers have entered into support agreements concurrently with the execution of the Merger Agreement, and as an inducement to Ambros' willingness to enter into the Merger Agreement, by which they have agreed to vote all of their shares of our common stock in favor of the Werewolf Stockholder Matters, subject to certain limited exceptions. Ambros' officers, directors and certain stockholders, collectively representing the votes required to approve the Merger on behalf of Ambros' stockholders, have also entered into support agreements obligating them, among other things, to execute and deliver a written consent adopting the Merger Agreement and approving the Contemplated Transactions promptly following delivery thereof and, if applicable, to vote their shares of Ambros capital stock in favor of the adoption of the Merger Agreement and against any competing proposals, and concurrently with the execution of the Merger Agreement, certain executive officers, directors and other stockholders of Ambros entered into lock-up agreements.

The Merger Agreement further provides for the payment of termination fees, if the Merger Agreement is terminated under specified circumstances, and such termination fees may discourage third parties from submitting competing proposals that may

be superior to the Contemplated Transactions. A termination fee of $20.0 million may become payable by Ambros to Werewolf if the Merger Agreement is terminated by (a) Werewolf following certain specified events relating to a change in the recommendation of the Ambros Board or certain other actions by Ambros relating to an acquisition proposal, (b) by Ambros concurrently with Ambros' entry into a definitive agreement with respect to a Superior Offer, subject to certain requirements set forth in the Merger Agreement, or (c) in certain circumstances following termination of the Merger Agreement if an acquisition proposal with respect to Ambros had been made prior to such termination and Ambros enters into or consummates an Acquisition Transaction, as defined in the Merger Agreement, within 12 months following such termination. A termination fee of $1.9 million may become payable by Werewolf to Ambros if the Merger Agreement is terminated by (a) Ambros following certain specified events relating to a change in the recommendation of the our board of directors or certain other actions by Werewolf relating to an acquisition proposal or (b) in certain circumstances following termination of the Merger Agreement if an acquisition proposal with respect to Werewolf had been made prior to such termination and Werewolf enters into or consummates an Acquisition Transaction, as defined in the Merger Agreement, within 12 months following such termination.

These provisions could discourage a potential competing acquirer from considering or proposing an acquisition or merger, even if it were prepared to pay consideration with a higher value than that implied by the merger consideration in the Merger.

Lawsuits may be filed against the company, Ambros or any of the members of their respective boards of directors arising out of the Merger, which may delay or prevent the Merger.

Putative stockholder complaints, including stockholder class action complaints, and other complaints may be filed against the company, our board of directors, Ambros, the Ambros Board and others in connection with the Contemplated Transactions. The outcome of litigation is uncertain, and Werewolf or Ambros may not be successful in defending against any such future claims. Lawsuits that may be filed against Werewolf, our board of directors, Ambros or the Ambros Board could delay or prevent the Merger, divert the attention of Werewolf's and Ambros' management and employees from their day-to-day business and otherwise adversely affect Werewolf and Ambros financially.

The Exchange Ratio will not be adjusted based on the market price of our common stock, so the merger consideration at the Merger Closing may have a greater or lesser value than at the time the Merger Agreement was signed.

The Exchange Ratio, as defined in the Merger Agreement, is based on a formula set forth in the Merger Agreement and will not be adjusted based on changes in the trading price of our common stock. Therefore, if before the completion of the Merger the market price of our common stock declines from the market price on the date of the Merger Agreement, Ambros stockholders could receive merger consideration with a value substantially lower than the value calculated by the parties when the Exchange Ratio formula was established. Similarly, if the market price of our common stock increases before the completion of the Merger, Ambros stockholders could receive merger consideration with substantially higher value for their shares of Ambros Capital Stock. The Merger Agreement does not include a price-based termination right. We and Ambros cannot predict the trading price of our common stock at the Merger Closing.

We or Ambros may waive one or more of the conditions to the Merger.

Conditions to our or Ambros' obligations to complete the Merger may be waived, in whole or in part, to the extent permitted by law, in certain circumstances unilaterally or by agreement of Werewolf and Ambros. In the event that our board of directors, in its own reasonable discretion, determines any such waiver is not significant enough to require recirculation of the proxy statement related to the special meeting of Werewolf stockholders and re-solicitation of the Werewolf stockholders, it will have the discretion to complete the Merger without seeking further stockholder approval, which decision may have a material adverse effect on our stockholders. For example, it is a condition to the consummation of the Merger that the existing shares of our common stock remain continuously listed on Nasdaq through the Merger Closing and that the shares of our common stock to be issued in the Merger and the Concurrent PIPE Financing, including the shares issuable upon exercise of the pre-funded warrants to acquire our common stock with an exercise price of $0.001 per share, or Merger Pre-Funded Warrants, or the PIPE Pre-Funded Warrants and, together with the Merger Pre-Funded Warrants, the Pre-Funded Warrants, be approved for listing on the Nasdaq Capital Market, or Nasdaq, subject to official notice of issuance. If we and Ambros agree to waive this requirement and their respective boards of directors elect to proceed with the Merger Closing, Nasdaq may notify the combined company of its determination to delist the combined company's securities based upon the failure to satisfy the initial inclusion criteria in the Nasdaq application. The combined company may appeal the determination to a hearings panel but such appeal may not stay the suspension and delisting action.

If we do not successfully consummate the Merger or another strategic transaction, our board of directors may decide to pursue a dissolution and liquidation of Werewolf. In such an event, the amount of cash available for distribution to our stockholders will depend heavily on the timing of such liquidation as well as the amount of cash that will need to be reserved for commitments and contingent liabilities, as to which we can give you no assurance.

There can be no assurance that the Merger will be completed. If the Merger is not completed, our board of directors may decide to pursue a dissolution and liquidation of Werewolf. In such an event, the amount of cash available for distribution to our

stockholders will depend heavily on the timing of such decision and, ultimately, such liquidation, since the amount of cash available for distribution continues to decrease as we fund our operations while pursuing the Merger. In addition, if our board of directors were to approve and recommend, and our stockholders were to approve, a dissolution and liquidation of Werewolf, we would be required under Delaware law to pay its outstanding obligations, as well as to make reasonable provision for contingent and unknown obligations, prior to making any distributions in liquidation to stockholders. Our commitments and contingent liabilities may include obligations under our employment and related agreements with certain employees that provide for severance and other payments following a termination of employment occurring for various reasons, including a change in control of Werewolf, litigation against Werewolf, various claims and legal actions arising in the ordinary course of business and other unexpected and/or contingent liabilities. As a result of this requirement, a portion of our assets would need to be reserved pending the resolution of such obligations.

In addition, we may be subject to litigation or other claims related to a dissolution and liquidation of Werewolf. If a dissolution and liquidation were to be pursued, our board of directors, in consultation with Werewolf's advisors, would need to evaluate these matters and make a determination about a reasonable amount to reserve. Accordingly, holders of our common stock could lose all or a significant portion of their investment in the event of liquidation, dissolution or winding up of Werewolf. A liquidation would be a lengthy and uncertain process with no assurance of any value ever being returned to our stockholders.

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

Substantial doubt exists as to our ability to continue as a going concern.

As of September 30, 2026, we had cash and cash equivalents of $41.9 million and an accumulated deficit of $495.1 million. We expect to incur substantial operating losses and negative cash flows from operations for the foreseeable future. There is substantial doubt about our ability to continue as a going concern for at least twelve months from the date of the condensed consolidated financial statements included herein, and we expect continuing operations beyond the near term will require additional liquidity. We have not established a source of revenue to fund operating activities and we have no dedicated source of liquidity available to us other than through our Sales Agreement, or the Sales Agreement, with Leerink Partners LLC, or Leerink Partners, pursuant to which we are entitled to offer and sell shares of our common stock, or the ATM Offering. We have been in the past and are currently subject to General Instruction I.B.6 of Form S-3, which may limit our ability to sell shares of our common stock through the ATM Offering for the foreseeable future. We may also be required to reduce our current spending requirements where possible.

If we utilize our capital resources more quickly than anticipated or are unable to obtain additional funding or engage in strategic alternatives to support any future development activities, we may have to significantly curtail, delay, reduce or eliminate any research and development programs we may pursue, which could materially adversely affect our business, financial condition, and results of operations. If we are unable to successfully mitigate the conditions which raise substantial doubt about our ability to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements, and it is likely that investors will lose all or part of their investment, or our board of directors may conclude that it is in the best interest of our stockholders to cease normal operations and wind down the company through bankruptcy or dissolution proceedings. In such case, we would be required to pay our obligations and set aside funds for reserves prior to making any distribution to stockholders and there would be no assurances that there would be any assets remaining available for distribution to stockholders in such event.

Our ability to continue operations is dependent on consummating the Merger on a timely basis. If the Merger is not completed, we will need additional funding and may be required to significantly reduce or discontinue our operations, pursue another strategic transaction or pursue a dissolution and liquidation of Werewolf.

Based on our current operating plan, we do not expect that our existing cash resources will be sufficient to fund our operations for at least twelve months from the date of the condensed consolidated financial statements included herein. Accordingly, our ability to continue operations is dependent on consummating the Merger on a timely basis. We have incurred, and expect to continue to incur, significant expenses in connection with the Merger, and our cash resources will continue to decrease as we fund our operations and pursue completion of the Merger. There can be no assurance that the Merger will be completed on the anticipated timeline or at all.

If the Merger is not completed, we will need to obtain additional capital to continue our operations. Such additional capital may not be available to us on acceptable terms, or at all. In addition, we may seek to pursue another strategic transaction, which could include a sale of Werewolf, a business combination or merger, a sale or divestiture of assets or proprietary technologies, or licensing or collaboration arrangements. There can be no assurance that we would be able to raise sufficient additional capital or identify, negotiate or consummate another strategic transaction on a timely basis, on favorable terms or at all. If we are unable to do so, we may be required to significantly reduce or discontinue our operations or our board of directors may determine to pursue a dissolution and liquidation of Werewolf. In any such event, our future business, prospects, financial

position and operating results could be materially adversely affected, and holders of our common stock could lose all or a significant portion of their investment.

The strategic review process we commenced in February 2026 resulted in, among other things, our entry into the Merger Agreement. As a result, our efforts are currently focused on completing the Merger rather than continuing a general process to explore strategic alternatives. If the Merger is not completed, however, our board of directors may consider other strategic alternatives, subject to our then-available cash resources and other circumstances. There can be no assurance that any such alternative would be available or successfully consummated.

We have a limited operating history, have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future.

We are an early-stage biopharmaceutical company with a limited operating history upon which our business and prospects can be evaluated. We commenced operations in 2017. To date, we have focused primarily on organizing and staffing our company; business planning; raising capital; developing and optimizing our platform technology; identifying potential product candidates; enhancing our intellectual property portfolio; undertaking research, preclinical studies, and clinical trials; and enabling manufacturing for our development programs. Although we have completed certain early-stage clinical trials and clinical trials, we have not yet demonstrated an ability to successfully complete any pivotal clinical trials, obtain regulatory approvals, manufacture a commercial-scale product, or arrange for a third party to do so on our behalf, or conduct the sales and marketing activities necessary for successful product commercialization. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biopharmaceutical products.

We have incurred significant operating losses since our inception and have not yet generated any product revenue. If any product candidates we may develop are not successfully developed and approved, we may never generate any product revenue. Our net loss was $19.7 million for the nine months ended September 30, 2026. As of September 30, 2026, we had an accumulated deficit of $495.1 million. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially if and as any product candidates advance through preclinical studies and into and through clinical trials, and as we may need to expand our clinical, regulatory, quality and manufacturing capabilities in connection with such activities. If we obtain marketing approval for any product candidate, we will incur significant commercialization expenses for marketing, sales, manufacturing and distribution. We may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives. We will need to develop commercial capabilities if we obtain marketing approval for any product candidate, and we may not be successful in doing so. The net losses we incur may fluctuate significantly from quarter to quarter and year to year.

We have no products approved for commercial sale and have not generated any revenue from product sales. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it.

To date, we have not generated any revenue from our product candidates or product sales, we do not expect to generate any revenue from the sale of products for a number of years and we may never generate revenue from the sale of products. Our ability to generate product revenue depends on a number of factors, including, but not limited to, our ability to:

- successfully complete preclinical studies;
- successfully submit investigational new drug application, or IND, submissions to the U.S. Food and Drug Administration, or the FDA or comparable foreign regulatory authorities for any future product candidates;
- successfully enroll subjects in and complete clinical trials;
- initiate and successfully complete all safety and efficacy studies to obtain U.S. and foreign regulatory approval for our product candidates;
- establish clinical and commercial manufacturing capabilities or make arrangements with third-party manufacturers for clinical supply and commercial manufacturing;
- obtain and maintain patent and trade secret protection or regulatory exclusivity for our product candidates;
- launch commercial sales of our products, if and when approved, whether alone or in collaboration with others;
- obtain and maintain acceptance of the products, if and when approved, by patients, the medical community and third-party payors;
- effectively compete with other therapies;
- obtain and maintain healthcare coverage and adequate reimbursement;
- enforce and defend intellectual property rights and claims; and

- maintain a continued acceptable safety profile of our products following approval.

Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we are unable to accurately predict the timing or amount of expenses we may incur in connection with these activities prior to generating product revenue. In addition, we may never succeed in these activities and, even if we do, may never generate revenues that are significant enough to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, undertake research and development efforts, diversify any product candidates we may develop or even continue our operations. A decline in the value of our company could also cause our stockholders to lose all or part of their investment.

We will need to obtain substantial additional funding to finance our operations and any development and commercialization activities we may pursue with respect to product candidates. If we are unable to raise this capital when needed, we may be forced to delay, reduce or eliminate any research and development programs we may pursue or other operations.

Identifying potential product candidates and conducting preclinical testing and clinical trials is a time-consuming, expensive and uncertain process that takes years to complete, and we may never generate the necessary data or results required to obtain regulatory approval and achieve product sales.

We do not have cash and cash equivalents sufficient to complete development of any product candidate. Accordingly, we will be required to obtain further funding through public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. Adequate additional financing may not be available to us on acceptable terms, or at all. Our failure to raise capital as and when needed, on acceptable terms or at all, would have a negative effect on our financial condition and our ability to develop and commercialize product candidates, and otherwise pursue our business strategy, and we may be forced to delay, reduce or eliminate any research and development programs we may pursue or future commercialization efforts.

In addition, our cash forecasts are based on assumptions that may prove to be wrong, and we could use our available capital resources earlier than we currently expect. Changing circumstances could cause us to consume capital significantly faster than we currently anticipate, and we may need to seek additional financing sooner than planned. 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 future capital requirements, both short-term and long-term, will depend on many factors, including:

- the scope, progress, timing, costs and results of researching and developing any product candidates;
- the costs associated with attracting, hiring and retaining skilled personnel and consultants;
- the cost of manufacturing any product candidates for clinical trials and, if we are able to obtain marketing approval, for commercial sale;
- the costs of any third-party products used in any combination clinical trials we may conduct that are not covered by such third parties or other sources;
- the timing of, and the cost involved in, obtaining marketing approval for any product candidates, and our ability to obtain marketing approval and generate revenue from any potential commercial sales of such product candidates;
- the cost of building a sales force in anticipation of product commercialization and the cost of commercialization activities for any product candidates if we receive marketing approval, including marketing, sales and distribution costs;
- the potential emergence of competing therapies and other adverse market developments;
- the amount and timing of any payments we may be required to make pursuant to our license agreement with Harpoon Therapeutics, Inc. or other future license agreements or collaboration agreements;
- our ability to establish future collaborations, licensing or other arrangements and the financial terms of any such agreements, including the timing and amount of any future milestone, royalty or other payments due under any such agreement;
- the costs involved in preparing, filing, prosecuting, maintaining, expanding, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- any product liability or other lawsuits related to our product candidates;
- the extent to which we in-license or acquire other products and technologies;

- general economic conditions, including inflation and the imposition of new or revised global trade tariffs;
- the costs of operating as a public company;
- our ability to complete the transfer of the EMD Transferred Assets technology to EMD; and
- our ability to consummate the Merger on a timely basis.

We do not have any committed external source of funds, and adequate additional financing may not be available to us on acceptable terms, or at all. In addition, our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions both inside and outside the U.S. 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 any research-stage programs or clinical trials we may pursue, future commercialization efforts or other operations.

Our revenue, if any, will be derived from sales of products that we do not expect to be commercially available for a number of years, if at all. If we obtain marketing approval for any product candidates that we develop, we expect to incur significant commercialization expenses related to product sales, marketing, distribution and manufacturing. Some of these expenses may be incurred in advance of marketing approval and could be substantial.

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

Unless and until we can generate a substantial amount of product revenue, we expect to seek additional capital through a combination of public or private equity offerings, debt financings, collaborations and licensing arrangements or other sources. Our issuance of additional securities, whether equity or debt, or the possibility of such issuance, may cause the market price of our common stock to decline, and our stockholders may not agree with our financing plans or the terms of such financings. To the extent that we raise additional capital through the sale of equity or convertible debt securities, our stockholders' ownership interests will be diluted and the terms of these securities may include liquidation or other preferences that adversely affect our stockholders' rights. The incurrence of indebtedness would result in payment obligations and could require us to comply with certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to declare dividends, limitations on our ability to acquire or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through collaborations and licensing arrangements with third parties, we may have to relinquish valuable rights to our product candidates or related technologies or grant licenses on terms unfavorable to us. In addition, securing additional financing would require a substantial amount of time and attention from our management and may divert a disproportionate amount of their attention away from day-to-day activities, which may adversely affect our management's ability to oversee any development activities we may pursue.

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

Changes in tax laws or in their implementation or interpretation may adversely affect our business or financial condition. The Tax Cuts and Jobs Act, or the TCJA, as amended by the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act, significantly revised the Code. The TCJA, among other things, contains significant changes to corporate taxation, including the reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21% and, for taxable years beginning after December 31, 2020, the limitation of the deduction for net operating losses, or NOLs, to 80% of current year taxable income for losses arising in taxable years beginning after December 31, 2017 (though any such NOLs may be carried forward indefinitely but no longer carried back). In addition, beginning in 2022, the TCJA eliminated the option to deduct research and development expenditures currently and generally required corporations to capitalize and amortize them over five years or 15 years (for expenditures attributable to foreign research).

In addition to the CARES Act, as part of Congress's response to the COVID-19 pandemic, economic relief legislation was enacted in 2020 and 2021 containing tax provisions. The Inflation Reduction Act, or the IRA, which was signed into law in August 2022, also introduced new tax provisions, including a one percent excise tax imposed on certain stock repurchases by publicly traded companies, which generally applies to any acquisition of stock by the publicly traded company (or certain of its affiliates) from a stockholder of the company in exchange for money or other property (other than stock of the company itself), subject to a de minimis exception. Thus, the excise tax could apply to certain transactions that are not traditional stock repurchases.

In July 2025, the One Big Beautiful Bill Act, or the OBBBA, which implements certain U.S. tax law changes that may impact our business, was enacted into law. The OBBBA modified and made permanent several provisions of the TCJA, including reductions in scheduled increases for the rate of taxation of foreign income, restoration of the immediate deductibility of U.S. research and development expenses for taxable years beginning after December 31, 2024, and reinstatement of 100% bonus depreciation for qualified capital assets. The OBBBA did not modify the 80% limitation on the use of NOLs described above. The effects of the OBBBA on our business and the healthcare industry in general are not yet known. Regulatory guidance under

the OBBBA and other recent tax legislation is and continues to be forthcoming, and such guidance could ultimately increase or lessen their impact on our business and financial condition. Congress may also enact additional legislation, some of which could have an impact on us. In addition, it is uncertain if and to what extent various states will conform to the OBBBA and additional tax legislation.

Our ability to utilize our NOL carryforwards and certain other tax attributes may be limited.

We have incurred substantial losses during our history. We do not anticipate generating revenue from sales of products for the foreseeable future, if ever, and we may never achieve profitability. As of December 31, 2025, we had federal and state NOL carryforwards of $215.3 million and $153.7 million, respectively. Under Section 382 of the Code, if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage point change (by value) in the ownership of its equity by certain stockholders over a three-year period), the corporation's ability to use its pre-change NOL carryforwards and other pre-change tax attributes to offset its post-change income may be limited. As a result of our prior private placement financings or other transactions, we have experienced ownership changes on June 10, 2019, August 2, 2019, and August 31, 2022, and we may in the future experience ownership changes as a result of subsequent changes in our stock ownership for purposes of Section 382. Following the approval of each of the Werewolf Stockholder Matters, the Merger will result in an ownership change for us and, accordingly, our NOL carryforwards and certain other tax attributes will be subject to limitations (or disallowance) on their use after completion of the Merger. Furthermore, our ability to utilize NOLs of Ambros that we will acquire as a result of the Merger may be subject to limitations. As a result, if we earn net taxable income, our ability to use our pre-change NOL carryforwards and other pre-change tax attributes to offset U.S. federal taxable income is subject to limitations, which could result in increased future tax liability to us and could have an adverse effect on our future results of operations. There is also a risk that due to regulatory changes, such as suspension of the use of NOLs, or for other unforeseen reasons, our existing NOLs and other tax attributes could expire or otherwise become unavailable to offset future income tax liabilities. As described above in *"Changes in tax laws or in their implementation or interpretation could adversely affect our business and financial condition,"* the TCJA, as modified by subsequent legislation, including most recently the OBBBA, includes changes to U.S. federal tax rates and rules governing NOL carryforwards that may significantly impact our ability to utilize NOLs to offset taxable income in the future. In addition, state NOLs generated in one state cannot be used to offset income generated in another state. For these reasons, we may be unable to use a material portion of our NOLs and other tax attributes.

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

Any product candidates we may develop will require successful completion of preclinical and clinical development before we can seek regulatory approval.

Our ability to generate product revenue, which we do not expect will occur for many years, if ever, will depend heavily on the successful development and eventual commercialization of product candidates, which may never occur. We currently generate no revenue from sales of any product, and we may never be able to develop or commercialize a marketable product.

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

Any development efforts we may pursue could be limited to a small number of cancer types and we may forego or delay pursuit of opportunities in other cancer types that may prove to have greater potential. Likewise, we may forego or delay the pursuit of opportunities with other potential product candidates that may prove to have greater commercial potential.

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

Preclinical development is uncertain. Any preclinical programs we may pursue may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize such programs on a timely basis or at all, which would have an adverse effect on our business.

Risk of failure for preclinical product candidates is high. Before we can commence clinical trials for any preclinical product candidates we may develop, we must complete extensive preclinical testing and studies that support INDs in the United States, or similar applications in other jurisdictions. We cannot be certain of the timely completion or outcome of any preclinical testing and studies we may conduct and cannot predict if the FDA or other regulatory authorities will accept any proposed clinical programs or if the outcome of such preclinical testing and studies will ultimately support the further development of such programs. As a result, we cannot be sure that we will be able to successfully submit INDs or similar applications for any

preclinical programs we may pursue on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing clinical trials to begin.

Preclinical studies and clinical trials are expensive, time-consuming and difficult to design and implement, and involve uncertain outcomes. Furthermore, results of earlier preclinical studies and clinical trials may not be predictive of results of future preclinical studies or clinical trials.

The risk of failure for any product candidates we may develop is high. It is impossible to predict when or if any such product candidates will successfully complete preclinical studies or clinical trials evaluating their safety and effectiveness in humans or will ultimately receive regulatory approval. To obtain the requisite regulatory approvals to market and sell any such product candidates, we must demonstrate through extensive preclinical studies and clinical trials that such product candidates are safe and effective in humans for use in each target indication. Preclinical and clinical testing is expensive and can take many years to complete, and the outcome is inherently uncertain. Failure can occur at any time during the preclinical or clinical trial process. The outcome of preclinical testing and early clinical trials may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Many companies in the biopharmaceutical and biotechnology industries have suffered significant setbacks in late-stage clinical trials after achieving positive results in early-stage development and we cannot be certain that we will not face similar setbacks. These setbacks have been caused by, among other things, preclinical findings made while clinical trials were underway, or safety or efficacy observations made in preclinical studies and clinical trials, including previously unreported adverse events. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their products.

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

We may encounter substantial delays in the commencement or completion, or termination or suspension, of any clinical trials we may conduct, which could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.

Before obtaining marketing approval from regulatory authorities for the sale of any product candidates we may develop, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidate for its intended indications. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. We may experience numerous unforeseen events during or as a result of clinical trials that could delay or prevent our ability to receive marketing approval or commercialize product candidates, including:

- we may be unable to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to obtain regulatory authorizations to commence a clinical trial;
- we may experience issues in reaching a consensus with regulatory authorities on trial design;
- regulators or institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with prospective trial sites and prospective contract research organizations, or CROs, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- clinical trial sites may deviate from a trial protocol or drop out of a trial or fail to conduct the trial in accordance with regulatory requirements;
- the number of subjects required for clinical trials of our product candidates may be larger than we anticipate or subjects may fail to enroll or remain in clinical trials at the rate we expect;
- subjects that enroll in our studies may misrepresent their eligibility or may otherwise not comply with the clinical trial protocol, resulting in the need to drop the subject from the trial, increase the needed enrollment size for the clinical trial or extend its duration;
- subjects may choose an alternative treatment for the indication being studied in any clinical trial we may conduct, or participate in competing clinical trials;
- subjects may experience severe or unexpected product-related adverse effects;

- clinical trials of our product candidates may produce unfavorable, inconclusive, or clinically insignificant results;
- we may decide to, or regulators or IRBs or ethics committees may require us to, make changes to a clinical trial protocol or conduct additional preclinical studies or clinical trials, or we may decide to abandon product development programs;
- we may need to add new or additional clinical trial sites;
- our third-party contractors, including those manufacturing our product candidates or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we may experience manufacturing delays, and any changes to manufacturing processes or third-party contractors that may be necessary or desired could result in other delays;
- we or our third-party contractors may experience delays due to complications associated with public health crises, supply chain delays, or other issues;
- the cost of preclinical testing and studies and clinical trials of any product candidates may be greater than we anticipate or greater than our available financial resources;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate or we may not be able to obtain sufficient quantities of combination therapies for use in clinical trials;
- reports may arise from preclinical or clinical testing of other cancer therapies that raise safety or efficacy concerns about our product candidates; and
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond the clinical trials and testing that we contemplate, if we are unable to successfully complete clinical trials or other testing of our product candidates, if the results of these clinical trials or tests are unfavorable or are only modestly favorable or if there are safety concerns associated with any of our product candidates, we may:

- incur additional unplanned costs;
- be required to suspend, vary or terminate clinical trials;
- be delayed in obtaining marketing approval, if at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing or other requirements;
- be required to perform additional clinical trials to support approval;
- have regulatory authorities withdraw, suspend or vary their approval of the product or impose restrictions on its distribution, such as in the form of a modified risk evaluation and mitigation strategy, or REMS, or comparable foreign strategy;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- have the product removed from the market after obtaining marketing approval;
- be subject to lawsuits; or
- experience damage to our reputation.

Conducting clinical trials in foreign countries, as we may do for any product candidates we may develop, presents additional risks that may delay completion of any such clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

Moreover, principal investigators for any clinical trials we may conduct may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required

to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authorities, as the case may be, and may ultimately lead to the denial of marketing approval of one or more product candidates.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

Similarly, the regulatory landscape related to clinical trials in the European Union, or the EU, has evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. The CTR introduces, among other changes, a centralized process that only requires the submission of a single application to all member states concerned, coordinated review procedures, expanded reporting and increased transparency obligations. In addition, both recently adopted legislation and pending legislative initiatives will impact regulatory procedures for medicinal products. Key developments include:

- On December 11, 2025, the European Commission, the Parliament and the European Council reached a political agreement on a comprehensive overhaul of EU pharmaceutical legislation, or the Pharma Package. The reform has been under negotiation since the European Commission submitted its proposal in April 2023. This package-comprised of a new directive and regulation to replace existing legislation-aims to modernize the EU regulatory framework. Following endorsement of the compromise texts by the Council's Committee of Permanent Representatives, or COREPER, and approval by the European Parliament's Committee on Public Health, or SANT, in March 2026, the proposed revisions must now be formally adopted by the Council of the EU and the European Parliament in plenary, currently anticipated by fall 2026. The reform encompasses a broad range of measures, including changes to regulatory exclusivity, incentives to combat antimicrobial resistance, intellectual property exemptions for generic medicines, orphan products, and marketing authorization procedures. The new framework is expected to enter into force in late 2026 and to be subject to transitional arrangements, with full application not anticipated before 2028; and
- Regulation (EU) 2021/2282 on health technology assessment, or the HTA Regulation, entered into application on January 12, 2025, introducing a single EU-level submission file for joint clinical assessments. The HTA Regulation initially applies to new active substances for oncology products and advanced therapy medicinal products, and will expand to orphan medicinal products in January 2028 and to all centrally authorized medicinal products by 2030.

Other legislative initiatives include the proposed SPC Regulation revision, the proposed Critical Medicines Act (for which a provisional political agreement was reached in May 2026), and the proposed Biotech Act.

If we are not able to adapt to these and other changes in existing requirements or the adoption of new requirements or policies governing clinical trials, our development plans may be impacted.

In addition to the factors above, we may make formulation or manufacturing changes to our product candidates, in which case we may need to conduct additional preclinical studies to bridge our modified product candidates to earlier versions, which may be costly, time-consuming and may not be successful at all.

Our failure to successfully initiate and complete any clinical trials we may conduct with respect to product candidates and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market any such product candidates would significantly harm our business. We cannot provide assurances that any such clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure such clinical trials. Significant preclinical study or clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize product candidates, which may harm our business and results of operations. In addition, many of the factors that cause, or lead to, delays of clinical trials may ultimately lead to the denial of regulatory approval of product candidates.

If we experience delays or difficulties in the enrollment of patients in clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in any clinical trials we may conduct for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the study until its conclusion. The enrollment of patients depends on many factors, including:

- the severity of the disease under investigation;
- the patient eligibility and the inclusion and exclusion criteria defined in the protocol;
- the size and health of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- 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 for the indications we are investigating;
- our ability to obtain and maintain patient consents;
- our ability to monitor patients adequately during and after treatment;
- the risk that patients enrolled in clinical trials will drop out of the trials before completion; and
- factors we may not be able to control, including the impacts of public health crises, which may limit the availability of patients, principal investigators or staff, or clinical sites.

In addition, any clinical trials we may conduct may compete with other clinical trials for product candidates that are in the same therapeutic areas as product candidates we may develop, and this competition could reduce the number and types of patients available to us, because some patients who might have opted to enroll in a trial we conduct may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, to the extent we conduct clinical trials, we may conduct them at the same clinical trial sites that some of our competitors use, which could reduce the number of patients who are available for such trials at those clinical trial sites.

Our inability to enroll a sufficient number of patients in any clinical trials we may conduct would result in significant delays or might require us to abandon one or more clinical trials altogether. Enrollment delays in any such clinical trials may result in increased development costs for product candidates, slow down or halt the product candidate development and approval process and jeopardize our ability to seek and obtain the marketing approval required to commence product sales and generate revenue, which would cause the value of our Company to decline and limit our ability to obtain additional financing, if needed.

Product candidates we may develop may cause undesirable or unexpectedly severe side effects that could delay or prevent their regulatory approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any.

Undesirable or unexpectedly severe side effects caused by our product candidates could cause us to interrupt, delay or halt preclinical studies or could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. It is likely that, as is the case with many treatments for cancer, there may be side effects associated with the use of our product candidates. Results of our trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated, and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Treatment-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly.

Further, by design, clinical trials rely on a sample of the potential patient population. With a limited number of patients and limited duration of exposure, rare and severe side effects of our product candidates may only be uncovered when a significantly larger number of patients is exposed to the product candidate. If our product candidates receive marketing approval and we or

others identify undesirable side effects caused by such product candidates after such approval, a number of potentially significant negative consequences could result, including:

- regulatory authorities may require the addition of labeling statements, such as a "black box" warning or a contraindication;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- regulatory authorities may require a REMS plan to mitigate risks, or comparable foreign tools, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- we may be required to change the way such product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the product candidates;
- we may be subject to regulatory investigations and government enforcement actions;
- regulatory authorities may withdraw, vary or limit their approval of such product candidates;
- we may decide to remove such product candidates from the marketplace;
- we could be sued and held liable for injury caused to individuals exposed to or taking our product candidates; and
- we may suffer reputational harm.

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

Interim topline and preliminary data from any clinical trials we may conduct and 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 publish interim topline or preliminary data from any clinical trials we may conduct. Interim data from clinical trials that we may conduct are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or "topline" data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data previously published. As a result, interim and preliminary data should be viewed with caution until the final data are available. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects.

We have in the past, and may in the future, develop product candidates in combination with third-party products, some of which may still be in development, and we will have limited or no control over the safety, supply, regulatory status or regulatory approval of such products.

Our ability to develop and ultimately commercialize product candidates used in combination with third-party products will depend on our ability to access such products on commercially reasonable terms for clinical trials and their availability for use with our commercialized product, if approved. We cannot be certain that any commercial relationships we establish will provide us with a steady supply of such products on commercially reasonable terms or at all. Any failure to enter into and maintain successful commercial relationships, or the expense of purchasing such third-party products in the market, may delay our development timelines, increase our costs and jeopardize our ability to develop product candidates as commercially viable therapies. If any of these occur, our business, financial condition, operating results, or prospects may be materially harmed.

Moreover, the development of product candidates for use in combination with another product or product candidate may present challenges that are not faced for single agent product candidates. Checkpoint inhibitors have been shown to have adverse events, including immune-related adverse events involving the lung, liver and other organ systems, which may limit the maximum dose in any clinical trials we may conduct or otherwise negatively impact any combination clinical trials we may conduct. In addition, the FDA or comparable foreign regulatory authorities may require us to use more complex clinical trial designs in order to evaluate the contribution of each product and product candidate to any observed effects. It is possible that the results of such trials could show that any positive previous trial results are attributable to the third-party product and not our product candidate. Developments related to the third-party product may also impact any such clinical trials for the combination as well as our commercial prospects should we receive regulatory approval. Such developments may include changes to the third-party product's safety or efficacy profile, changes to the availability of the third-party product, quality, and manufacturing and supply issues with respect to the third-party product.

If we are able to obtain marketing approval, the FDA or comparable foreign regulatory authorities may require that products used in conjunction with each other be cross-labeled for combined use. To the extent that we do not have rights to the third-party product, this may require us to work with such third party to satisfy such a requirement. We would also continue to be

subject to the risks that the FDA or comparable foreign regulatory authorities could revoke approval of the third-party product used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with such product. Similarly, if any third-party products we may use in combination with product candidates are replaced as the standard of care for the indications we choose for any such product candidates, the FDA or comparable foreign regulatory authorities may require us to conduct additional clinical trials. The occurrence of any of these risks could result in our own products, if approved, being removed from the market or being less successful commercially.

If we pursue additional therapeutic opportunities or product candidates in the future, we may not be successful in identifying or developing such opportunities or product candidates.

Although we may in the future explore other therapeutic opportunities in addition to the product candidates that we have historically developed, we may fail to identify or discover viable new product candidates for clinical development for a number of reasons. If we fail to identify additional potential product candidates, our business could be materially harmed.

Research programs to pursue the development of product candidates and to identify new product candidates and disease targets require substantial technical, financial and human resources whether or not they are ultimately successful. Any research programs we may pursue may initially show promise in identifying potential indications and/or product candidates, yet fail to yield results for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential indications and/or product candidates;
- potential product candidates may, after further study, be shown to have harmful adverse effects or other characteristics that indicate they are unlikely to be effective products; or
- it may take greater human and financial resources than we will possess to identify additional therapeutic opportunities for our product candidates or to develop suitable potential product candidates through internal research programs, thereby limiting our ability to develop, diversify and expand our product portfolio.

Accordingly, there can be no assurance that we will ever be able to identify additional therapeutic opportunities for product candidates or to develop suitable additional product candidates through internal research programs, which could materially adversely affect our future growth and prospects.

We may become exposed to costly and damaging liability claims, either when testing product candidates in the clinic or following commercial sale, and any product liability insurance we may obtain may not cover all damages from such claims.

We are exposed to potential product liability risks that are inherent in the research, development, manufacturing, marketing and use of biopharmaceutical products. The use of product candidates by us in clinical trials, and any sale of approved products in the future, may expose us to liability claims. For example, we may be sued if our product candidates cause or are perceived to cause injury or are found to be otherwise unsuitable during clinical trials, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability or a breach of warranties. Claims could also be asserted under state consumer protection acts.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a product, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical trials or after approval thereof, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or cease the development or commercialization of our product candidates or any products for which we may have received marketing approval. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- delay or termination of clinical trials;
- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants or difficulties in recruiting new trial participants;
- initiation of investigations by regulators;
- costs to defend or settle the related litigation;
- a diversion of management’s time and our resources;

- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- significant negative financial impact; and
- the inability to commercialize any of our product candidates, if approved.

Although we will seek to procure and maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. As the expense of insurance coverage is increasing, we may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be materially harmed.

We have never commercialized a product candidate and we may lack the necessary expertise, personnel and resources to successfully commercialize any products that receive regulatory approval, either on our own or together with collaborators.

We have never commercialized a product candidate. We currently have no sales force or marketing or distribution capabilities. To achieve commercial success of our product candidates, if any are approved, we will have to develop our own sales, marketing and supply capabilities or outsource these activities to one or more third parties. Even if we obtain approval in one jurisdiction, we may never obtain or commercialize any product in any other jurisdiction, which would limit our ability to realize their full market potential.

Factors that may affect our ability to commercialize our product candidates on our own include our ability to recruit and retain adequate numbers of effective sales and marketing personnel and obtain access to or persuade adequate numbers of physicians to prescribe our product candidates, as well as any unforeseen costs we may incur in connection with creating an independent sales and marketing organization. Developing a sales and marketing organization requires significant investment, is time-consuming and could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization in the United States, the EU or other key global markets. To the extent we need to rely upon one or more third parties, we may have little or no control over the marketing and sales efforts of those third parties and our revenue from product sales may be lower than if we had commercialized our product candidates ourselves. We will also face competition in any search for third parties to assist us with sales and marketing efforts for our product candidates. If we are unable to build our own distribution and marketing capabilities or to find suitable partners for the commercialization of our product candidates, we may have difficulties generating revenue from them.

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

The development and commercialization of new drug and biologic products is highly competitive. We have faced, and will face, competition with respect to any product candidates that we may seek to develop or commercialize from major pharmaceutical, specialty pharmaceutical and biotechnology companies, among others. There are other companies working to develop immunotherapies for the treatment of cancer including divisions of pharmaceutical and biotechnology companies of various sizes. Some of these competitive therapies are based on scientific approaches that are the same as or similar to approaches we may pursue, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

If we develop product candidates for the treatment of cancer, we may not receive marketing approval for any such product candidates. There are already a variety of available therapies marketed for cancer and some of the currently approved therapies are branded and subject to patent protection, and others are available on a generic basis. Many of these approved therapies are well-established and widely accepted by physicians, patients and third-party payors. Insurers and other third-party payors may also encourage the use of generic products. If any product candidates we may develop are approved, they may be priced at a significant premium over competitive generic products. This may make it difficult to successfully commercialize such product candidates, including in combination with or as alternatives to existing therapies. Competition may further increase with advances in the commercial applicability of technologies and greater availability of capital for investment in these industries.

We are aware of a number of companies that are developing cytokines as immunotherapies, as well as different modalities, including monoclonal antibodies, cell therapies, oncolytic viruses and vaccines.

Our competitors may succeed in developing, acquiring or licensing, on an exclusive basis, products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. We may also compete with these organizations in establishing clinical trial sites and patient registration for clinical

trials, as well as in recruiting and retaining qualified scientific and management personnel, which could negatively affect our level of expertise and our ability to execute our business plan.

Many of our competitors, either alone or with their collaborators, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical and clinical testing, obtaining regulatory approvals and reimbursement and marketing approved products than we do. Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel product candidates or to in-license novel product candidates that could make any product candidates we develop less competitive or obsolete. Smaller or early-stage companies may also prove to be significant competitors, including through collaborative arrangements with large and established companies. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. The availability of competing products could limit the demand and the price we are able to charge for product candidates we commercialize, if any. The inability to compete with existing or subsequently introduced products would harm our business, financial condition and results of operations.

The sizes of the potential markets for any product candidates we may develop are difficult to estimate and, if any of our assumptions are inaccurate, the actual markets for such product candidates may be smaller than our estimates.

The potential market opportunities for our product candidates are difficult to estimate and, if our product candidates are approved, will ultimately depend on, among other things, the indications for which our product candidates are approved for sale, any products with which our product candidates are co-administered, the success of competing therapies and therapeutic approaches, acceptance by the medical community, patient access, product pricing and reimbursement. Our estimates of the potential market opportunities for our product candidates are predicated on many assumptions, which may include industry knowledge and publications, third-party research reports and other surveys. Although we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain, and their reasonableness has not been assessed by an independent source. If any of the assumptions proves to be inaccurate, the actual markets for our product candidates could be smaller than our estimates of the potential market opportunities.

The successful commercialization of any product candidates we may develop will depend in part on the extent to which we obtain and maintain favorable coverage, adequate reimbursement levels and pricing policies with third-party payors.

The availability and adequacy of coverage and reimbursement by third-party payors, including governmental healthcare programs such as Medicare and Medicaid, managed care organizations, and private health insurers, are essential for most patients to be able to afford prescription medications such as our product candidates, if approved. Our ability to achieve acceptable levels of coverage and reimbursement for products by third-party payors will have an effect on our ability to successfully commercialize our product candidates. We cannot be sure that coverage and reimbursement in the United States, the EU or elsewhere will be available for our product candidates, if approved, or any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for pharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs or biologics when an equivalent generic drug, biosimilar or a less expensive therapy is available. For example, the U.S. Department of Health and Human Services, or HHS, imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. In addition, HHS has been empowered to negotiate the price of certain single-source drugs that have been on the market for at least seven years and certain single-source biological products that have been on the market for at least eleven years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year, up to 20 products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per-unit basis. It is possible that a third-party payor may consider our product candidates as substitutable and only offer to reimburse patients for the less expensive product. Even if we show improved efficacy or improved convenience of administration with our product candidates, pricing of existing third-party therapeutics may limit the amount we will be able to charge for our product candidates. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates, if approved. Even if our product candidates are approved and we obtain coverage for our product candidates by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. Interim reimbursement levels for new medicines, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Net prices for medicines may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of medicines from countries where they may be sold at lower prices than in the United States. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our product candidates, if approved, and may not be able to obtain a satisfactory financial return on our product candidates.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. The regulations that govern marketing approvals, pricing and reimbursement for new medicines vary widely from country to country. In the United States, third-party payors play an important role in determining the extent to which new drugs and biologics will be covered. The Medicare and Medicaid programs increasingly are used as models in the United States for how third-party payors develop their coverage and reimbursement policies for drugs and biologics. Some third-party payors may require pre-approval of coverage for new or innovative devices or pharmaceutical therapies before they will reimburse healthcare providers who use such therapies. We cannot predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our product candidates, if approved.

No uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor and coverage and reimbursement by one payor does not guarantee coverage and reimbursement by another payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

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

If any product candidate we develop receives marketing approval, whether as a single agent or in combination with other therapies, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, hospitals, cancer treatment centers, third-party payors, and others in the medical community. For example, cancer treatments like chemotherapy, radiation therapy and certain existing immunotherapies are well established in the medical community, and doctors may continue to rely on these therapies. If the product candidates we develop do not achieve an adequate level of acceptance, we may not generate significant product revenues and we may not become profitable.

The degree of market acceptance of any product, if approved for commercial sale, will depend on a number of factors, including:

- its efficacy, safety and potential advantages compared to alternative treatments;
- the prevalence and severity of any side effects;
- the product's convenience and ease of administration compared to alternative treatments;
- the clinical indications for which the product is approved;
- the willingness of the target patient population to try a novel treatment and of physicians to prescribe such treatments;
- the recommendations with respect to the product in guidelines published by scientific organizations;
- the ability to obtain sufficient third-party insurance coverage and adequate reimbursement, including, if applicable, with respect to the use of the product as a combination therapy;
- the strength of marketing, sales and distribution support;
- the effectiveness of our sales and marketing efforts;
- the approval of other new products for the same indications; and
- our ability to offer the product for sale at competitive prices.

If we obtain marketing approval for a product but such product does not achieve an adequate level of market acceptance, we may not generate or derive significant revenue from that product and our business, financial condition and results of operations may be adversely affected.

Risks Related to Our Dependence on Third Parties

If we pursue preclinical studies or clinical trials, we expect to rely on third parties to conduct them. If these third parties do not successfully carry out their contractual duties or meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval of or commercialize any product candidates.

If we pursue preclinical studies or clinical trials, we expect to depend upon third parties, including independent investigators and CROs, to conduct such studies and trials. We may need to negotiate budgets and contracts with CROs and trial sites, and

any such third parties may terminate their engagements with us at any time, any of which may result in delays to any development timelines and increased costs.

Our reliance on third parties for any research and development activities we may pursue would reduce our control over these activities but would not relieve us of our responsibility to ensure that each trial is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties would not relieve us of our regulatory responsibilities. We and these third parties would be required to comply with Good Laboratory Practice, or GLP, requirements for preclinical studies, current Good Clinical Practices, or GCP, requirements for clinical trials, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these GLP and GCP requirements through periodic inspections of trial sponsors, clinical investigators and trial sites. If we or any of these third parties fail to comply with applicable GLP or GCP requirements, the clinical data generated in any clinical trials we may conduct may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate such trials or perform additional preclinical studies or clinical trials before approving our marketing applications. We cannot be certain that, upon inspection, such regulatory authorities will determine that any preclinical studies or clinical trials we may conduct comply with GLP and/or GCP requirements. In addition, any clinical trials we may conduct must be conducted with products produced under current Good Manufacturing Practice, or GMP, requirements.

Any failure by us or such third parties to comply with applicable regulations may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any such third party violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting clinical trials on our behalf will not be our employees and, except for remedies that may be available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to any such clinical trials. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other product development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to applicable clinical protocols or regulatory requirements or for other reasons, any clinical trials we may conduct may be extended, delayed or terminated, and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize product candidates. As a result, our financial results and the commercial prospects for product candidates could be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any relationships we may establish with third-party CROs or others terminate, we may not be able to enter into arrangements with alternative CROs or other third parties or to do so on commercially reasonable terms. Switching or adding additional CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new CRO begins work. As a result, delays may occur, which could materially impact clinical development timelines. We would need to carefully manage any relationships with CROs, and there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We have supplied and may continue to supply and otherwise support third party research, including investigator-initiated clinical trials. Investigator-initiated clinical trials pose similar risks as those set forth elsewhere in this section relating to our internally-sponsored clinical trials. We have less control over the protocols, administration or conduct of these trials, including follow-up with patients and ongoing collection of data after treatment. The conduct or findings of these trials may have a negative impact on our development programs notwithstanding that we have little involvement or control over these trials. As a result, we are subject to additional risks associated with the way investigator-initiated trials are conducted. In particular, we may be named in lawsuits that would lead to increased costs associated with legal defense. Additional risks include difficulties or delays in communicating with investigators or administrators, procedural delays and other timing issues and difficulties or differences in interpreting data. Third-party investigators may design clinical trials with clinical endpoints that are more difficult to achieve, or in other ways that increase the risk of negative clinical trial results compared to clinical trials that we may design on our own. Negative results in investigator-initiated clinical trials could have a material adverse effect on our efforts to obtain regulatory approval for our product candidates and the public perception of our product candidates. As a result, our lack of control over the conduct and timing of and communications with the FDA and other regulatory authorities regarding investigator-sponsored trials may expose us to additional risks and uncertainties, many of which are outside our control, and the occurrence of which could adversely affect the commercial prospects for our product candidates.

The manufacturing of drugs and biologics is complex and we do not have our own clinical manufacturing capabilities. We expect to rely on third parties to produce preclinical, clinical and commercial supplies for any product candidates we develop.

We do not own manufacturing facilities capable of producing drug and biologic products at clinical scale. We have in the past experienced delays in receiving preclinical product supplies from third-party manufacturers and there can be no assurance that product supplies from third parties will not in the future be limited or interrupted, be of satisfactory quality or be available at acceptable prices. Additionally, the process of manufacturing drugs and biologics is complex, highly regulated, and subject to multiple risks. The manufacture of drugs and biologics is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes could result in reduced production yields, product defects, other supply disruptions and higher costs. If microbial, viral or other contaminations are discovered at the facilities of any contract manufacturing organizations, or CMOs, we may engage, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials, result in higher costs of our product and adversely affect our business.

To support the manufacture of our products, any CMOs we may engage would conduct substantial analytical testing of drug substance and vialed drug product. If such CMOs are unable to supply us with sufficient clinical grade quantities of product candidates, and we are unable to timely establish an alternate supply from one or more third-party contract manufacturers, we would experience delays in any development efforts we may pursue as we seek to locate and qualify new manufacturers. In particular, any replacement of a CMO could require significant effort and expertise because there may be a limited number of qualified replacements or capacity could be limited at each of the qualified replacements. Additionally, contract manufacturers may rely on single-source suppliers for certain raw materials for any preclinical or clinical product supplies we may require. If suppliers are delayed or unable to supply sufficient raw materials to manufacture product for any preclinical studies or clinical trials we may conduct, we may experience delays in any development efforts we may pursue as materials are obtained or we locate and qualify new raw material manufacturers. If we are unable to procure sufficient supplies of third-party products needed for any clinical trials we may conduct, we may be required to purchase such supplies on the open market, which may result in significant additional expense.

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

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

- inability to meet our product specifications and quality requirements consistently;
- inability to initiate or continue preclinical studies or clinical trials of product candidates under development;
- delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and quality issues, including those related to scale-up of manufacturing;
- failure to comply with GMP and similar foreign standards;
- reliance on a limited number of sources, and in some cases, single sources for product components and raw materials, such that if we are unable to secure a sufficient supply of these product components and raw materials, we will be unable to manufacture and sell our future product candidate in a timely fashion, in sufficient quantities or under acceptable terms;
- lack of qualified backup suppliers for those components and raw materials that are purchased from a sole or single-source supplier;
- inability to negotiate manufacturing agreements with third parties under commercially reasonable terms;

- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- disruption of operations by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier or the issuance of an FDA Form 483 notice or warning letter;
- carrier disruptions or increased costs that are beyond our control;
- failure to deliver our products under specified storage conditions and in a timely manner; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

Some of these events could be the basis for FDA action, including injunction, recall, seizure or total or partial suspension of production, any of which could result in a failure to begin or a requirement to stop any clinical trials we may conduct. In addition, any CMOs and suppliers we may engage would be subject to FDA inspections from time to time. Failure by such CMOs and suppliers to pass such inspections and otherwise satisfactorily complete the FDA approval regimen with respect to a product candidate may result in regulatory actions such as the issuance of FDA Form 483 notices of observations, warning letters or injunctions or the loss of operating licenses. In addition, such CMOs and suppliers would be subject to numerous environmental, health and safety laws and regulations, including those governing the handling, use, storage, treatment and disposal of waste products, and failure to comply with such laws and regulations could result in significant costs associated with civil or criminal fines and penalties for such third parties. Based on the severity of the regulatory action, our supply of clinical or commercial product and packaging and other services could be interrupted or limited, which could harm our business.

In addition, any CMOs we may engage may be engaged with other companies to supply and manufacture materials or products for such companies, which would also expose such suppliers and CMOs to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may also affect the regulatory clearance of a contract supplier's or CMO's facility, which could impact the contract supplier's or CMO's ability to manufacture product for us.

We may in the future seek to enter into collaborations or other similar arrangements for product candidates. If we are unable to enter into such collaborations, or if these collaborations are not successful, our business could be adversely affected.

We may evaluate and, as deemed appropriate, enter into collaborations in the future on an asset-by-asset basis to maximize the value of any product candidates or technologies we may develop. For example, in April 2022, we entered into a Collaboration Agreement with Jazz Pharmaceuticals Ireland Limited, or Jazz, and the agreement, the Jazz Collaboration Agreement, pursuant to which we granted Jazz certain licenses to develop and commercialize products containing our Interferon alpha, or IFNα, INDUKINE molecule, JZP898, or the 898 Program, as well as products containing certain isolated recombinant polypeptides comprising IFNα that meet specified criteria. In May 2026, we terminated the Jazz Collaboration Agreement and we entered into an asset purchase agreement or the Jazz Purchase Agreement with Jazz, pursuant to which we sold to Jazz the 898 Program. We may enter into other collaborations in connection with WTX-124 or WTX-330 technology or product candidates we may develop. Such collaborations may include the development and commercialization of product candidates or the commercialization of product candidates that are approved for marketing outside the United States. Potential collaborators include large and mid-size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. We have limited capabilities for product development and do not yet have any capability for commercialization. Accordingly, we may enter into collaborations with other companies to provide us with important technologies and funding for any programs or platform technology we may pursue. We will face significant competition in seeking appropriate collaborators. We may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for any 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 such product candidates as having the requisite potential to demonstrate safety and efficacy. We may also be restricted under future license agreements from entering into agreements on certain terms or at all with potential collaborators.

Future collaborations involving any product candidates we may develop may pose significant risks to us, including the following:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on

clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;

- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- 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;
- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or products, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products;
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws resulting in civil or criminal proceedings;
- our payment obligations to our licensors may be greater than the amounts our collaborators are obligated to pay us or the amounts they actually pay us;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays in or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- collaborators may not provide us with timely and accurate information regarding development, regulatory or commercialization status or results, which could adversely impact our ability to manage any development efforts we may pursue, accurately forecast financial results or provide timely information to our stockholders regarding any out-licensed product candidates;
- if a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on any applicable product development or commercialization program could be delayed, diminished or terminated; and
- collaborations may be terminated, including for the convenience of the collaborator, and, if terminated, we may find it more difficult to enter into future collaborations or be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Any collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. In addition, all of the risks relating to product development, regulatory approval and commercialization described herein will apply to the activities of any of our collaborators.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for any product candidates we develop or for any proprietary technologies we have developed or may develop, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize product candidates and technology similar or identical to such product candidates and technology, and our ability to successfully commercialize any product candidates we may develop, and our technology may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to WTX-124, WTX-330 and related technologies, including their respective components, formulations, combination therapies, methods used to manufacture them and methods of treatment and development that are important to our business. If we do not adequately protect our intellectual property rights, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our

proprietary position, we file or in-license patent applications in the United States and abroad related to WTX-124, WTX-330 and related technologies that are important to our business; we also license and may in the future license or purchase additional patents and patent applications filed by others. Following the EMD Asset Sale, our patent portfolio relating to WTX-124 and WTX-330 and related technologies includes patents and patent applications that we own or license pursuant to the license agreement that we entered into on August 14, 2026, with EMD pursuant to which EMD granted us an exclusive, field limited license to certain patents included in the assets transferred as part of the EMD License Agreement. If we are unable to secure or maintain patent protection with respect to WTX-124, WTX-330 and related technologies and any proprietary products and technology we develop, our business, financial condition, results of operations and prospects could be materially harmed.

If the scope of the patent protection we or our potential licensors obtain is not sufficiently broad, we may not be able to prevent others from developing and commercializing technology and products similar or identical to ours. The degree of patent protection we require to successfully compete in the marketplace may be unavailable or severely limited in some cases and may not adequately protect our rights or permit us to gain or keep any competitive advantage. We cannot provide any assurances that any of our patents have, or that any of our pending patent applications that mature into issued patents will include, claims with a scope sufficient to protect our product candidates or otherwise provide any competitive advantage. In addition, to the extent that we license intellectual property in the future, we cannot provide assurances that those licenses will remain in force. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Furthermore, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available; however, the life of a patent, and the protection it affords, is limited. 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.

Our patents and pending patent applications, if issued, may not provide us with any meaningful protection or prevent competitors from designing around our patent claims to circumvent our patents by developing similar or alternative technologies or therapeutics in a non-infringing manner. For example, a third party may develop a competitive therapy that provides benefits similar to one or more of our product candidates but that uses a formulation and/or a device that falls outside the scope of our patent protection. If the patent protection provided by the patents and patent applications we hold or pursue with respect to our product candidates is not sufficiently broad to impede such competition, our ability to successfully commercialize our product candidates could be negatively affected, which would harm our business.

Patent positions of life sciences companies can be uncertain and involve complex factual and legal questions. No consistent policy governing the scope of claims allowable in the field of engineered therapeutic proteins has emerged in the United States. The scope of patent protection in jurisdictions outside of the United States is also uncertain. Changes in either the patent laws or their interpretation in any jurisdiction in which we seek patent protection may diminish our ability to protect our inventions, maintain and enforce our intellectual property rights; and, more generally, may affect the value of our intellectual property, including the narrowing of the scope of our patents and any that we may license.

The patent prosecution process is complex, expensive, time-consuming and inconsistent across jurisdictions. We may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent rights at a commercially reasonable cost or in a timely manner. In addition, we may not pursue or obtain patent protection in all relevant markets. It is possible that we will fail to identify important patentable aspects of our research and development efforts in time to obtain appropriate or any patent protection. While we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development efforts, including, for example, our employees, external academic scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose our confidential or proprietary information before a patent application is filed, thereby endangering our ability to seek patent protection. In addition, publications of discoveries in the scientific and scholarly literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Consequently, we cannot be certain that we were the first to file for patent protection on the inventions claimed in our patents or pending patent applications.

The issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Pending patent applications cannot be enforced against third parties 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 any patent applications that we may license in the future will result in patents being issued. Further, the scope of the invention claimed in a patent application can be significantly reduced before the patent is issued, and this scope can be reinterpreted after issuance. Even if patent applications we currently own or that we may license in the future issue as patents, they may not issue in a form that will provide us with adequate protection to prevent competitors or other third parties from competing with us, or otherwise provide us with a competitive advantage. Any patents that eventually issue may be challenged, narrowed or invalidated by third parties. Consequently, we do not know whether WTX-124, WTX-330 or related technologies will be protectable or remain protected by valid and enforceable patent rights. Our competitors or other third parties may be able to evade our patent rights by developing

new products that are similar to our product candidates, biosimilars of our product candidates, or alternative technologies or products in a non-infringing manner.

The issuance or grant of a patent is not irrefutable as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. There may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim. We may in the future become subject to a third-party pre-issuance submission of prior art or opposition, derivation, revocation, re-examination, post-grant and *inter partes review*, or IPR, or interference proceeding and other similar proceedings challenging our patent rights or the patent rights of others in the U.S. Patent and Trademark Office, or the USPTO, or other foreign patent office. An unfavorable determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or extinguish our ability to manufacture or commercialize products without infringing third-party patent rights.

In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our owned and in-licensed patents and patent applications may in the future be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interest in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we or our licensors may need the cooperation of any such co-owners of our owned and in-licensed patents in order to enforce such patents against third parties, and such cooperation may not be provided to us or our licensors. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects.

If our efforts to protect the proprietary nature of the intellectual property related to our technologies and product candidates are not adequate, we may not be able to compete effectively in our market.

Biotechnology and pharmaceutical companies generally, and we in particular, compete in a crowded competitive space characterized by rapidly evolving technologies and aggressive defense of intellectual property. 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.

We rely upon a combination of patents, confidentiality agreements, trade secret protection and license agreements to protect the intellectual property related to our technologies and our product candidates. Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements and product candidates, thus eroding our competitive position in our market. We, or any future partners, collaborators, or licensees, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position.

It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments, or PTA. If we or our partners, collaborators, licensees or licensors fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our partners, collaborators, licensees or licensors are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such patents may be invalid and/or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business.

We seek or plan to seek patent protection for WTX-124, WTX-330 and related technologies by filing and prosecuting patent applications in the United States and other countries as appropriate. However, we cannot predict:

- if and when patents will issue;
- if patents will issue with claims that cover our product candidates;
- the degree and range of protection any issued patents will afford us against competitors including whether third parties will find ways to invalidate or otherwise circumvent our patents;
- whether any of our intellectual property will provide any competitive advantage;

- whether any of our patents that may be issued may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or otherwise may not provide any competitive advantage;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; or
- whether we will need to initiate or defend litigation or administrative proceedings which may be costly regardless of whether we win or lose.

Additionally, we cannot be certain that the claims in our pending patent applications covering WTX-124, WTX-330 and related technologies will be considered patentable by the USPTO, or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries.

The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in issued patents with claims that cover our product candidates or technology or uses thereof in the United States or in other foreign countries. Even if patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patents and patent applications we hold with respect to our product candidates or technology is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our product candidates. Further, if we encounter delays in any clinical trials we may conduct, the period of time during which we could market our product candidates under patent protection would be reduced. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. Furthermore, for U.S. applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. We cannot be certain that we are the first to invent the inventions covered by pending patent applications and, if we are not, we may be subject to priority disputes. We may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications. Various post-grant review proceedings, such as IPR, post-grant review, or PGR, and derivation proceedings, are available and may be pursued by any interested third party in the USPTO to challenge the patentability of claims issued in patents to us or our licensors. No assurance can be given as to the outcome of any such proceedings. No assurance can be given that if challenged, our patents would be declared by a court to be valid or enforceable or that even if found valid and enforceable, a competitor's technology or product would be found by a court to infringe our patents. We may analyze patents or patent applications of our competitors that we believe are relevant to our activities, and consider that we are free to operate in relation to our product candidates, but our competitors may achieve issued claims, including in patents we consider to be unrelated, which block our efforts or may potentially result in our product candidates or our activities infringing such claims. The possibility exists that others will develop products which have the same effect as our products on an independent basis which do not infringe our patents or other intellectual property rights, or will design around the claims of patents that we have had issued that cover our products.

Recent or future patent reform legislation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents. In March 2013, under the Leahy-Smith America Invents Act, or the America Invents Act, the United States moved from a "first to invent" to a "first-to-file" system. Under a "first-to-file" system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to a patent on the invention regardless of whether another inventor had made the invention earlier. The America Invents Act includes a number of other significant changes to U.S. patent law, including provisions that affect the way patent applications are prosecuted, redefine prior art and establish a USPTO-administered post-grant review system that has affected patent litigation. The America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make or use polypeptides or nucleic acids that are similar to our product candidates or components of our product candidates but that are not covered by the claims of our patents;
- the active biological ingredients in our product candidates will eventually become commercially available in biosimilar products, and no patent protection may be available with regard to formulation or method of use;
- we or our licensors, as the case may be, may fail to meet our obligations to the U.S. government in regards to any patents and patent applications funded by U.S. government grants, leading to the loss of patent rights;

- we or our licensors, as the case may be, might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that our pending patent applications will not result in issued patents;
- it is possible that there are prior public disclosures that could invalidate our or our licensors' patents, as the case may be, or parts of our or their patents;
- it is possible that others may circumvent our owned or in-licensed patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- the laws of foreign countries may not protect our or our licensors', as the case may be, proprietary rights to the same extent as the laws of the United States;
- the claims of our owned or in-licensed issued patents or patent applications, if and when issued, may not cover our product candidates or technology;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, may be narrowed in scope, or be held invalid or unenforceable as a result of legal challenges by third parties;
- the inventors of our owned or in-licensed patents or patent applications may become involved with competitors, develop products or processes which design around our patents, or become hostile to us or the patents or patent applications on which they are named as inventors;
- it is possible that our owned or in-licensed patents or patent applications omit individual(s) that should be listed as inventor(s) or include individual(s) that should not be listed as inventor(s), which may cause these patents or patents issuing from these patent applications to be held invalid or unenforceable;
- we have engaged in scientific collaborations in the past and will continue to do so in the future, and such collaborators may develop adjacent or competing products to ours that are outside the scope of our patents;
- we may not develop additional proprietary technologies for which we can obtain patent protection;
- it is possible that product candidates or technology we develop may be covered by third parties' patents or other exclusive rights; or
- the patents of others may have an adverse effect on our business.

Our proprietary position in part depends upon patents that are manufacturing, formulation or method-of-use patents, which may not prevent a competitor or other third party from using the same product candidate for another use.

Composition of matter patents for biological and pharmaceutical products are generally considered to be the strongest form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of making or method of use. We cannot be certain that the claims in our pending patent applications, including those claims covering the composition of matter of our product candidates, will be considered patentable by the USPTO or by patent offices in foreign countries, or that the claims in any of our patents that have issued or may issue will be considered valid and enforceable by courts in the United States or foreign countries. Furthermore, in some cases, we may not be able to obtain issued claims covering compositions of matter relating to our product candidates, and instead may need to rely on filing patent applications with claims covering a method of use and/or method of manufacture. Method of use patents protect a specified method of using a product, such as a method of use for treating a particular medical indication. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their products for our targeted indications, physicians may prescribe these products "off-label" for those uses that are covered by our method of use patents. Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent by enforcing patent rights or otherwise. There can be no assurance that any such patent applications will issue as granted patents, and even if they do issue, such patent claims may be insufficient to prevent third parties, such as our competitors, from utilizing our technology. Any failure to obtain or maintain patent protection with respect to our product candidates could have a material adverse effect on our business, financial condition, results of operations, and prospects.

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

In addition to the protection afforded by patents, we seek to rely on trade secret protection, confidentiality agreements, and license and other agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information, or technology that is not covered by patents. We cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

Courts outside the United States are sometimes less willing to protect trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. For example, certain aspects of WTX-124 and WTX-330 and related technologies and know-how are based on unpatented trade secrets that are not publicly disclosed. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology.

Thus, we may not be able to meaningfully protect our trade secrets. It is our practice to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual or entity during the course of the party's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual, and which are related to our business or research and development or made during normal working hours, on our premises or using our equipment or proprietary information, are our exclusive property. In addition, we take other appropriate precautions, such as physical and technological security measures, to guard against misappropriation of our proprietary technology by third parties. We have also adopted policies and conduct training that provides guidance on our expectations, and our advice for best practices, in protecting our trade secrets. However, we cannot provide assurance that these agreements and policies will not be breached by our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors and that our trade secrets and other proprietary and confidential information will not be disclosed publicly or to competitors.

These risks are heightened due to our reliance on third parties, including third-party CROs and CMOs, for certain aspects of our business. The activities conducted by our third-party vendors require us to share our trade secrets with them, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Third-party claims of intellectual property infringement may prevent or delay our product discovery and development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, reexamination, and other post-grant proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that any product candidates we may develop and/or proprietary technologies infringe their intellectual property rights. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in fields in which we may develop product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that product candidates we may develop may give rise to claims of infringement of the patent rights of others. Moreover, it is not always clear to industry participants, including us, which patents cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications filed in these fields, there may be a risk that third parties may allege they have patent rights encompassing product candidates, technologies or methods we may develop.

If a third party claims that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property claims which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;

- substantial damages for infringement, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third party's rights, and, if the court finds that the infringement was willful, we could be ordered to pay treble damages and the patent owner's attorneys' fees;
- a court prohibiting us from developing, manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third party licenses its product rights to us, which it is not required to do;
- if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights for our products; and
- redesigning our product candidates or processes so they do not infringe third-party intellectual property rights, which may not be possible or may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting preclinical and clinical trials and other development activities in the United States is not considered an act of infringement. If any product candidate we develop is approved by the FDA, a third party may then seek to enforce its patent by filing a patent infringement lawsuit against us. For example, we have received, and we may in the future receive, correspondence from third parties or their legal counsel disclosing that such third party owns patents that may encompass one or more of our product candidates. It is also possible that a third party may file a lawsuit against us alleging infringement of its patents. The outcome of any such proceeding is uncertain and would likely result in the expenditure of significant financial resources and the diversion of management's time and resources, which could harm our business. While we do not believe that any claims that could otherwise have a materially adverse effect on the commercialization of our product candidates are valid and enforceable, we may be incorrect in this belief, or we may not be able to prove it in litigation. In this regard, patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. There may be issued third-party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Patent applications can take many years to issue. There may be currently pending patent applications which may later result in issued patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by our activities. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our product candidates, constructs or molecules used in or formed during the manufacturing process, or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize product candidates.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, could involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available on commercially reasonable terms or at all. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

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

Our development of product candidates may require the use of proprietary rights held by third parties and the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights. Similarly, efficient production or delivery of our product candidates may also require specific compositions or methods, and the rights to these may be owned by third parties. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary or important to our business operations. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all, which would harm our business. We may need to cease use of the compositions or methods covered by such third-party intellectual property rights and may need to seek to develop alternative approaches that do not infringe on such intellectual property rights which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we 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 develop or license replacement technology. Moreover, the specific components, such as linkers and antibody fragments, that will be used with our product candidates may be covered by the intellectual property rights of others.

Additionally, we may collaborate with or sponsor research at academic institutions to accelerate our preclinical research or development under written agreements with these institutions. In certain cases, these institutions may provide us with an option to negotiate a license to any of the institution's rights in technology resulting from the collaboration or sponsorship. Regardless of such option, we may be unable to negotiate a license within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. If we are unable to successfully obtain rights to required third-party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of such program and our business and financial condition could suffer.

The licensing and acquisition of third-party intellectual property rights is a competitive area, and companies, which may be more established, or have greater resources than we do, may also be pursuing strategies to license or acquire third-party intellectual property rights that we may consider necessary or attractive in order to commercialize our product candidates. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

If we breach our license agreements, it could have a material adverse effect on our commercialization efforts for our product candidates.

A portion of our patent portfolio is in-licensed. As such, we are a party to license agreements and certain aspects of our business depend on patents and/or patent applications owned by other companies or institutions. We rely on a license from EMD for certain patent rights related to WTX-124 and WTX-330. Our rights with respect to in-licensed patents and patent applications may be lost if the applicable license agreement expires or is terminated or if we fail to satisfy the obligations under the license agreement. If we are unable to maintain these patent rights for any reason, our ability to develop and commercialize our product candidates could be materially harmed.

Our licensors may not successfully prosecute certain patent applications, the prosecution of which they control, under which we are licensed and on which our business depends. Even if patents issue from these applications, our licensors may fail to maintain these patents, may decide not to pursue litigation against third-party infringers, may fail to prove infringement, or may fail to defend against counterclaims of patent invalidity or unenforceability.

Risks with respect to parties from whom we have obtained intellectual property rights may also arise out of circumstances beyond our control. In spite of our best efforts, our licensors might conclude that we have materially breached our intellectual property agreements and might therefore terminate the intellectual property agreements, thereby removing our ability to market products covered by these intellectual property agreements or requiring us to enter into costly and time-consuming litigation. If any such litigation is unsuccessful, our intellectual property agreements may be terminated. In addition, if the underlying patents fail to provide the intended market exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products similar or identical to ours.

If our intellectual property agreements are terminated, our former licensors and/or assignors may be able to prevent us from utilizing the technology covered by the licensed or assigned patents and patent applications. Such an event may require us to develop design-around approaches, which may be expensive and time-consuming, if possible at all. Any of these outcomes could have a material adverse effect on our competitive business position and our financial condition, results of operations and our business prospects.

Patent term may be inadequate to protect our competitive position on our products for an adequate amount of time.

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. Depending upon the timing, duration and conditions of FDA marketing approval of our product candidates, one or more of our United States patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, referred to as the Hatch-Waxman Amendments, and similar legislation in the European Union. The Hatch-Waxman Amendments permit a patent term extension of up to five years for a patent covering an approved product as compensation for effective patent term lost during product development and the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval. Only one patent may be extended, and only those claims covering the approved drug, a method for using it, or a method for manufacturing it, may be extended. However, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents or otherwise fail to satisfy applicable requirements. Moreover, the length of the extension could be less than we request. If we are unable to obtain patent term extension or the term of any such extension is less than we request, the period during which we can enforce our patent rights for that product will be shortened and our competitors may obtain approval to market competing products sooner. As a result, our revenue from applicable products could be reduced and could have a material adverse effect on our business.

Further, recent judicial decisions in the U.S. raised questions regarding the award of PTA for patents in families where related patents have issued without PTA. Thus, it cannot be said with certainty how PTA will be viewed in the future and whether patent expiration dates may be impacted.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. To counter infringement or unauthorized use, we may be required to file lawsuits with infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

Post-grant proceedings provoked by third parties or brought by the USPTO may be necessary to determine the validity or priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could result in a loss of our current patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms, or at all. Litigation or post-grant proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. 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.

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

Some of our patent applications have been granted or may be granted or allowed in the future. We cannot be certain that an allowed patent application will become an issued patent. There may be events that can cause the allowance of a patent application to be withdrawn. For example, after a patent application has been allowed, but prior to being issued, material that could be relevant to patentability may be identified. In such circumstances, the applicant may pull the application from allowance in order for the USPTO to review the application in view of the new material. We cannot be certain that the USPTO will re-allow the application in view of the new material. Further, periodic maintenance fees on any issued patent are due to be

paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process and following the issuance of a patent. We rely on our outside counsel and other professionals or our licensing partners to pay these fees due to the USPTO and non-U.S. government patent agencies and to help us comply with other procedural, documentary and other similar requirements and we are also dependent on our licensors to take the necessary action to comply with these requirements with respect to our licensed intellectual property. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

Issued patents covering product candidates we may develop or our technology could be found invalid or unenforceable if challenged in court or the USPTO.

If we or one of our licensors initiate legal proceedings against a third party to enforce a patent covering one of our product candidates or our technology, the defendant could counterclaim that the patent covering our product candidate or technology, as applicable, is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace, and there are numerous grounds upon which a third party can assert invalidity or unenforceability of a patent. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, IPR, PGR and equivalent proceedings in foreign jurisdictions (such as opposition proceedings). Such proceedings could result in revocation or amendment to our patents in such a way that they no longer cover our product candidates or technology. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we, our patent counsel and the patent examiner were unaware during prosecution. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, or if we are otherwise unable to adequately protect our rights, we would lose at least part, and perhaps all, of the patent protection on our product candidates or technology. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize or license our technology and product candidates.

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

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time-consuming and inherently uncertain. In addition, the United States continues to adapt to wide-ranging patent reform legislation that became effective starting in 2012. Moreover, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. 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 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 our existing patents and patents that we might obtain in the future. For example, in the case *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.,* the U.S. Supreme Court held that certain claims to DNA molecules are not patentable. While we do not believe that any of the patents owned or licensed by us will be found invalid based on this decision, we cannot predict how future decisions by the courts, Congress or the USPTO may impact the value of our patents. Similarly, changes in the patent laws of other jurisdictions could adversely affect our ability to obtain and effectively enforce our patent rights, which would have a material adverse effect on our business and financial condition.

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

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, 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

products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Most of our patent portfolio is at the very early stage. We will need to decide whether and in which jurisdictions to pursue protection for the various inventions in our portfolio prior to applicable deadlines.

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

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

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

We generally enter into confidentiality and intellectual property assignment agreements with our employees, consultants, and contractors. These agreements generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusive property. However, those agreements may not be honored and may not effectively assign intellectual property rights to us. Moreover, there may be some circumstances where we are unable to negotiate for such ownership rights. Disputes regarding ownership or inventorship of intellectual property can also arise in other contexts, such as collaborations and sponsored research. If we are subject to a dispute challenging our rights in or to patents or other intellectual property, such a dispute could be expensive and time-consuming. If we were unsuccessful, we could lose valuable rights in intellectual property that we regard as our own.

We may be subject to damages resulting from claims that we or our employees have wrongfully used or disclosed confidential information of our competitors or are in breach of non-competition or non-solicitation agreements with our competitors.

Many of our employees were previously employed at other pharmaceutical companies, including our competitors or potential competitors, in some cases until recently. We may be subject to claims that we or our employees have inadvertently or otherwise used or disclosed trade secrets or other confidential information of these former employers or competitors. In addition, we have been and may in the future be subject to claims that we caused an employee to breach the terms of his or her non-competition or non-solicitation agreement. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. If our defense to those claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Any litigation or the threat thereof may adversely affect our ability to hire employees. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product candidates, which could have an adverse effect on our business, results of operations and financial condition.

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

Our trademarks or trade names may be challenged, infringed, circumvented, declared generic or determined to be infringing on other marks. We rely on both registration and common law protection for our trademarks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During the trademark registration process, we may receive Office Actions from the USPTO objecting to the registration of our trademark. Although we would be given an opportunity to respond to those objections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and/or to seek the cancellation of registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected.

Numerous factors may limit any potential competitive advantage provided by our intellectual property rights.

The degree of future protection afforded by our intellectual property rights, whether owned or in-licensed, is uncertain because intellectual property rights have limitations, and may not adequately protect our business, provide a barrier to entry against our competitors or potential competitors, or permit us to maintain our competitive advantage. Moreover, if a third party has intellectual property rights that cover the practice of our technology, we may not be able to fully exercise or extract value from our intellectual property rights. The factors that may limit any potential competitive advantage provided by our intellectual property rights include:

- pending patent applications that we own or license may not lead to issued patents;
- patents, should they issue, that we own or license, may not provide us with any competitive advantages, or may be challenged and held invalid or unenforceable;
- others may be able to develop and/or practice technology that is similar to our technology or aspects of our technology but that is not covered by the claims of any of our owned or in-licensed patents, should any such patents issue;
- third parties may compete with us in jurisdictions where we do not pursue and obtain patent protection;
- we (or our licensors) might not have been the first to make the inventions covered by a pending patent application that we own or license;
- we (or our licensors) might not have been the first to file patent applications covering a particular invention;
- others may independently develop similar or alternative technologies without infringing our intellectual property rights;
- we may not be able to obtain and/or maintain necessary licenses on reasonable terms or at all;
- third parties may assert an ownership interest in our intellectual property and, if successful, such disputes may preclude us from exercising exclusive rights, or any rights at all, over that intellectual property;
- we may not be able to maintain the confidentiality of our trade secrets or other proprietary information;
- we may not develop or in-license additional proprietary technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

Should any of these events occur, they could significantly harm our business and results of operation.

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

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

The research, testing, manufacturing, labeling, approval, selling, marketing, promotion and distribution of products are subject to extensive regulation by the FDA and comparable foreign regulatory authorities. We are not permitted to market any product candidates we may develop in the United States or in other countries until we receive approval of a new drug application, or an NDA, or biologics license application, or a BLA, from the FDA or marketing approval from applicable regulatory authorities outside the United States. Any such product candidates would be subject to the risks of failure inherent in development. We have not submitted an application for or received marketing approval for any product candidate in the United States or in any other jurisdiction. Our company has no experience in filing and supporting the applications necessary to gain marketing approvals and expects to rely on third-party CROs to assist us in this process if we pursue such applications.

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

In addition, changes in marketing approval policies during the development period, changes in or the enactment or promulgation of additional statutes, regulations or guidance or changes in regulatory review for each submitted product

application may cause delays in the approval or rejection of an application. Regulatory authorities have substantial discretion in the approval process and varying interpretations of the data obtained from preclinical and clinical testing, including based on trial design, quality of trial conduct, analysis of trial results, and the overall persuasiveness of the results, could delay, limit or prevent marketing approval of a product candidate. 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. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Further, under the Pediatric Research Equity Act, NDAs and BLAs must contain data to assess the safety and effectiveness of the product for the claimed indication in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective, unless the sponsor receives a deferral or waiver from the FDA. A deferral may be granted for several reasons, including a finding that the product or therapeutic candidate is ready for approval for use in adults before pediatric trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric trials begin. The applicable legislation in the EU also requires sponsors to either conduct clinical trials in a pediatric population in accordance with a Pediatric Investigation Plan approved by the Pediatric Committee of the European Medicines Agency, or the EMA, or to obtain a waiver or deferral from the conduct of these studies by this Committee. For any of our product candidates for which we are seeking regulatory approval in the U.S. or the EU, we cannot guarantee that we will be able to obtain a waiver or alternatively complete any required studies and other requirements in a timely manner, or at all, which could result in associated reputational harm and subject us to enforcement action.

Under the current presidential administration, there have been significant and wide-ranging reforms to federal policy and the federal government. In particular, as in recent preceding presidential administrations, pricing and reimbursement reform is a focus of reform efforts. Other healthcare reform efforts or other actions under the current presidential administration may adversely affect the development of new therapies, access to healthcare coverage or the funding of healthcare benefits, although the full impact of such efforts or actions cannot be predicted. For example, the Congressional Budget Office has estimated that Medicaid provisions in the OBBBA, including restrictions in eligibility and funding for Medicaid, as well as changes to the healthcare marketplace, will increase the number of uninsured by 16 million by 2034.

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

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

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

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

In addition, foreign regulatory authorities may change their approval policies and new regulations may be enacted. For instance, the EU pharmaceutical legislation is currently undergoing a complete overhaul, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's Pharma Package was published on April 26, 2023. This package-comprised of a new directive and regulation to replace existing legislation-aims to modernize the EU regulatory framework. On December 11, 2025, the European Commission, the Parliament and the

European Council reached a political agreement. Following endorsement of the compromise texts by COREPER and approval by SANT in March 2026, the Council of the EU formally adopted its position in September 2026. The reform now requires approval by the European Parliament, currently anticipated in late 2026, upon which the legislation will be published in the Official Journal of the EU. The reform encompasses a broad range of measures, including changes to regulatory exclusivity, incentives to combat antimicrobial resistance, intellectual property exemptions for generic medicines, orphan products, and marketing authorization procedures. The new framework is expected to enter into force in late 2026 and to be subject to transitional periods with full application after 24 months, i.e., late 2028. The revisions may have a significant impact on the pharmaceutical industry and our business in the long term.

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

We may not be able to obtain orphan drug designation or orphan drug exclusivity for any product candidates we may develop and, even if we do, that exclusivity may not prevent the FDA or the European Commission from approving competing products.

Regulatory authorities in some jurisdictions, including the United States and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a product as an orphan drug if it is a drug or biologic 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 for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for such disease or condition will be recovered from sales in the United States of such product. Generally, a product with orphan drug designation only becomes entitled to orphan drug exclusivity if it receives the first marketing approval for the indication for which it has such designation, in which case the FDA will be precluded from approving another marketing application for the same product for that indication for the applicable exclusivity period. The applicable exclusivity period is seven years in the United States.

We may seek orphan drug designations for our product candidates and may be unable to obtain such designations. Even if we do secure such designations and orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different products can be approved for the same condition. Further, the FDA can subsequently approve the same drug for the same condition if the FDA concludes that the later product is clinically superior in that it is shown to be safer, to be more effective or, in unusual cases, to make a major contribution to patient care. Finally, orphan drug exclusivity may be lost and this may occur if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition or for other reasons.

It is also possible that current or future litigation or action by Congress could change the scope of available orphan exclusivity. Any changes to the orphan drug provisions could change our opportunities for, or likelihood of success in obtaining, orphan drug exclusivity and could materially adversely affect our business, financial condition, results of operations, cash flows and prospects.

We do not know if, when, or how the FDA or Congress may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

In addition, to obtain orphan drug designation in the EU, we would need to demonstrate that (1) the product is intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions; (2) either (a) such conditions affect not more than five in 10,000 persons in the EU when the application is made, or (b) the product without the benefits derived from orphan status, would not generate sufficient return in the EU to justify the necessary investment in developing the medicinal product; and (3) there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the EU or, if such method exists, the medicinal product will be of significant benefit to those affected by that condition. The period of market exclusivity is ten years during which the EMA cannot accept another marketing authorization application or accept an application to extend for a similar product and the European Commission cannot grant a marketing authorization for the same indication for a period of ten years. The period of market exclusivity may be extended by two years for orphan medicinal products that have also complied with an agreed Pediatric Investigation Plan. No extension to any supplementary protection certificate can be granted on the basis of pediatric studies for orphan indications. The period of market exclusivity may, however, be reduced to six years if, at the end of the fifth year, it is established that the product no longer meets the criteria on the basis of which it received orphan medicinal product designation, including where it can be demonstrated on the basis of available evidence that the original orphan medicinal product is sufficiently profitable not to justify maintenance of market exclusivity or where the prevalence of the condition has increased above the threshold.

Additionally, a marketing authorization may be granted to a similar medicinal product with the same orphan indication during the 10-year period if: (i) the applicant consents to a second original orphan medicinal product application, (ii) the manufacturer of the original orphan medicinal product is unable to supply sufficient quantities; or (iii) the second applicant can establish that its product, although similar, is safer, more effective or otherwise clinically superior to the original orphan medicinal product. There is no assurance that we would be able to meet that standard for any of our product candidates. Further, if we do obtain orphan drug designation for a candidate product in the EU, we will not be able to maintain that designation if we are not able to show, to the satisfaction of the EU regulatory authorities, that the candidate product is of significant benefit to patients over available commercial products for the indication in the EU and any additional products that are ahead of our product candidate in clinical development for the indication. In addition, the Pharma Package discussed above includes proposed changes to the EU orphan medicinal product framework that may modify the length of orphan market exclusivity and change the way in which market exclusivity is awarded to drugs with more than one approved orphan indication. The Pharma Package is subject to formal adoption by the European Parliament and Council and, if adopted, could alter the exclusivity protections currently available for orphan designated products in the EU.

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

Any product candidate for which we obtain marketing approval will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post-marketing information and reports, registration and listing requirements, GMP requirements relating to quality control and manufacturing, quality assurance and corresponding maintenance of records and documents, and requirements regarding the distribution of samples to physicians and recordkeeping. In addition, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post-marketing testing and surveillance to monitor the safety or efficacy of the product, including the requirement to implement a risk evaluation and mitigation strategy.

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

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

Further requirements, including post-approval requirements, apply to the approval of products in the EU. The holder of a marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of medicinal products. These include: compliance with the EU's stringent pharmacovigilance or safety reporting rules, which can impose post-authorization studies and additional monitoring obligations; the manufacturing of authorized medicinal products, for which a separate manufacturer's license is mandatory; and the marketing and promotion of

medicinal products, which are strictly regulated in the EU and are also subject to EU member state laws. Moreover, much like the Anti-Kickback Statute prohibition in the United States, the provision of benefits or advantages to physicians and other health care professionals to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is also prohibited in the EU. Interactions between pharmaceutical companies and health care professionals are governed by strict laws, such as national anti-bribery laws of European countries, national sunshine rules, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment. The failure to comply with these and other EU requirements can also lead to significant penalties and sanctions.

Accordingly, if we receive marketing approval for one or more of our product candidates, we will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we fail to comply with these requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any products could be limited, which could adversely affect our ability to achieve or sustain profitability.

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

The regulations relating to the promotion of products for unapproved uses are complex and subject to substantial interpretation by the FDA, national competent authorities of EU Member States and other government agencies. In September 2021, the FDA published final regulations which describe the types of evidence that the agency will consider in determining the intended use of a pharmaceutical product. Physicians may nevertheless prescribe our products off-label to their patients in a manner that is inconsistent with the approved label. We intend to implement compliance and training programs designed to ensure that our sales and marketing practices comply with applicable regulations. Notwithstanding these programs, the FDA or other government agencies may allege or find that our practices constitute prohibited promotion of our products for unapproved uses. We also cannot be sure that our employees will comply with our Company policies and applicable regulations regarding the promotion of products for unapproved uses.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific communications concerning their products in certain circumstances. For example, in January 2025, the FDA published final guidance outlining its policies governing the distribution of scientific information to healthcare providers about unapproved uses of approved products. The final guidance calls for such communications to be truthful, non-misleading and to include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about the unapproved use of the approved product. If a company engages in such communications consistent with the guidance's recommendations, the FDA indicated that it will not treat such communications as evidence of unlawful promotion of a new intended use for the approved product. In addition, under some relatively recent guidance from the FDA and the Pre-Approval Information Exchange Act signed into law as part of the Consolidated Appropriations Act of 2023, companies may also promote information that is consistent with the prescribing information and proactively speak to formulary committee members of payors regarding data for an unapproved product or unapproved uses of an approved product. We may engage in these discussions and communicate with healthcare providers, payors and other constituencies in compliance with all applicable laws, regulatory guidance and industry best practices. We will need to carefully navigate the FDA's various regulations, guidance and policies, along with recently enacted legislation, to ensure compliance with restrictions governing promotion of our products.

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

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU Member States' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. General requirements for advertising and promotion of medicinal products, such as direct-to-consumer advertising of prescription medicinal products, are established in EU law. However, the details are governed by regulations in individual EU Member States and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics, or SmPC, which may require approval by the competent national authorities in connection with an MA. The SmPC is the document that provides information to physicians and other healthcare professionals concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU.

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

We may seek certain designations for any product candidates we may develop, including Breakthrough Therapy, Fast Track and Priority Review designations, but we might not receive such designations, and even if we do, such designations may not lead to a faster development or regulatory review or approval process.

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

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

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

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

We may seek PRIME designation in the EU for one or more product candidates we may develop, but we might not receive such designations and, even if we do, such designations may not lead to a faster development or regulatory review or approval process.

In the EU, we may seek PRIME designation for our product candidates in the future. PRIME is a voluntary program aimed at enhancing the EMA's role to reinforce scientific and regulatory support in order to optimize development and enable accelerated assessment of new medicines that are of major public health interest with the potential to address unmet medical needs. The program focuses on medicines that target conditions for which there exists no satisfactory method of treatment in the

EU or even if such a method exists, it may offer a major therapeutic advantage over existing treatments. PRIME is limited to medicines under development and not authorized in the EU and the applicant intends to apply for an initial marketing authorization application through the centralized procedure. To be accepted for PRIME, a product candidate must meet the eligibility criteria in respect of its major public health interest and therapeutic innovation based on information that is capable of substantiating the claims.

The benefits of a PRIME designation include the appointment of a rapporteur from the Committee for Medicinal Products for Human Use to provide continued support and help to build knowledge ahead of a marketing authorization application, early dialogue and scientific advice at key development milestones, and the potential to qualify products for accelerated review, meaning reduction in the review time for an opinion on approvability to be issued earlier in the application process. PRIME designation enables an applicant to request parallel EMA scientific advice and health technology assessment advice to facilitate timely market access. Even if we receive PRIME designation for any of our product candidates, the designation may not result in a materially faster development process, review or approval compared to conventional EMA procedures. Further, obtaining PRIME designation does not assure or increase the likelihood of EMA's grant of a marketing authorization.

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

We may seek approval of any of our product candidates using the FDA's accelerated approval pathway. A product may be eligible for accelerated approval if it treats a serious or life-threatening condition, generally provides a meaningful advantage over available therapies, and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, or IMM, that is reasonably likely to predict an effect on IMM or other clinical benefit (i.e., an intermediate clinical endpoint). The FDA or other applicable regulatory agency makes the determination regarding whether a surrogate endpoint is reasonably likely to predict long-term clinical benefit.

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

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

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

Further, there can be no assurance that we will satisfy all FDA requirements, including new provisions, that govern accelerated approval. For example, with passage of the FDORA in December 2022, Congress modified certain provisions governing accelerated approval of drug and biologic products. Specifically, the new legislation authorized the FDA to require a sponsor to have its confirmatory clinical trial underway before accelerated approval is awarded and to submit progress reports on its post-approval studies to FDA every six months until the study is completed. Moreover, FDORA established expedited procedures authorizing FDA to withdraw an accelerated approval if certain conditions are met, including where a required confirmatory study fails to verify clinical benefit or evidence demonstrates that the product is not shown to be safe or effective under its conditions of use. The FDA may also use such procedures to withdraw an accelerated approval if a sponsor fails to conduct any

required post-approval study of the product with due diligence. The new procedures include the provision of due notice and an explanation for a proposed withdrawal, and opportunities for hearing. We will need to fully comply with these and other requirements in connection with the development and approval of any product candidate that qualifies for accelerated approval.

In the EU, a "conditional" marketing authorization may be granted in cases where all the required safety and efficacy data are not yet available. A conditional marketing authorization is subject to conditions to be fulfilled for generating missing data or ensuring increased safety measures. A conditional marketing authorization is valid for one year and has to be renewed annually until fulfillment of all relevant conditions. Once the applicable conditions are fulfilled, a conditional marketing authorization can become a "standard" marketing authorization. However, if the conditions are not fulfilled within the timeframe set by the European Commission, the marketing authorization will cease to be renewed.

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

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

If we pursue a BLA or an NDA, we or any contract manufacturer we engage must supply all necessary documentation in support of the application on a timely basis and must adhere to the FDA's GLP and GMP regulations enforced through its facilities inspection program and other requirements. The facilities and quality systems of any third-party contractors we may engage must pass a pre-approval inspection for compliance with the applicable regulations as a condition of regulatory approval of any product candidate. In addition, the regulatory authorities may, at any time, audit or inspect a manufacturing facility involved with the preparation of any product candidates we may develop or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If these facilities do not pass a pre-approval plant inspection, FDA approval of the products will not be granted. Comparable requirements and related risks apply abroad.

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

Despite our efforts to audit and verify regulatory compliance, one or more of our third-party contractors may be found on regulatory inspection by the FDA, or other comparable foreign regulatory authorities to be noncompliant with cGMP regulations. If we or any third-party manufacturers we may engage fail to maintain regulatory compliance, the FDA and comparable foreign regulatory authorities can impose regulatory sanctions including, among other things, shutdown of the third-party vendor or invalidation of product lots or processes, fines, injunctions, civil penalties, delays, suspension, variation or withdrawal of approvals, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, refusal to approve a pending application for a new product, or revocation of a pre-existing approval. Any such consequence could significantly and adversely affect supplies of our products, if approved, and would severely harm our business, financial condition and results of operations.

We may in the future conduct clinical trials for product candidates at sites outside the United States. The FDA may not accept data from trials conducted in such locations and the conduct of trials outside the United States could subject us to additional delays and expense.

We may in the future conduct one or more clinical trials with trial sites that are located outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with GCPs. The FDA must be able to validate the data from the trial through an onsite inspection if necessary and the data must be applicable to the U.S. population and U.S. medical practice. In addition, while these clinical trials are subject to the applicable local laws, the FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations. There can be no assurance that the FDA will accept data from clinical trials conducted outside of the United States. If the FDA does not accept the data from any

trial that we conduct outside the United States, it would likely result in the need for additional trials, which would be costly and time-consuming and delay or permanently halt our development of product candidates.

In addition, the conduct of clinical trials outside the United States could have a significant adverse impact on us or the trial results. Risks inherent in conducting international clinical trials include:

- clinical practice patterns and standards of care that vary widely among countries;
- non-U.S. regulatory authority requirements that could restrict or limit our ability to conduct any clinical trials;
- administrative burdens of conducting clinical trials under multiple non-U.S. regulatory authority schemes;
- foreign exchange rate fluctuations; and
- diminished protection of intellectual property in some countries.

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

In the United States and foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. We expect that current laws, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we may receive for any approved products. If reimbursement of our products is unavailable or limited in scope, our business could be materially harmed.

The 2010 Patient Protection and Affordable Care Act, or the ACA, substantially changed the way healthcare is financed by both governmental and private insurers and continues to significantly impact the U.S. pharmaceutical industry.

The ACA has been subject to litigation challenging its provisions, and such litigation is likely to continue with uncertain results. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect until fiscal year 2032 unless additional congressional action is taken.

Since enactment of the ACA, there have been, and continue to be, numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, on July 4, 2025, the OBBBA, was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired ACA subsidies.

In the EU, on 12 January 2025, the HTA Regulation entered into application. The HTA Regulation initially applies to new active substances for oncology products and advanced therapy medicinal products, and will expand to orphan medicinal products in January 2028 and to all centrally authorized medicinal products by 2030. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products as well as certain high-risk medical devices, and provide the basis for cooperation at the EU level for joint clinical assessments in these areas. It permits EU member states to use common HTA Regulation tools, methodologies, and procedures across the EU, and requires them to rely on EU-level joint clinical assessment reports for the clinical components of their national HTA evaluations. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement. As implementation of the HTA Regulation is phased in and key methodological and procedural guidance continues to evolve, there remains uncertainty regarding the evidence requirements, timing, and impact of joint clinical assessments on national reimbursement processes. The new framework may result in additional or differently structured evidentiary expectations, misalignment between assessment and regulatory timelines, or delays in national decisions.

Current and future legislative efforts may limit the costs for our products, if and when they are licensed for marketing, and that could materially impact our ability to generate revenues.

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

In addition, in October 2020, HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program to import certain prescription products from Canada into the U.S. That regulation was challenged in a lawsuit by the Pharmaceutical Research and Manufacturers of America, or PhRMA, but the case was dismissed by a federal district court in February 2023 after the court found that PhRMA did not have standing to sue HHS. Several states have passed laws allowing for the importation of products from Canada. For example, on June 15, 2026, the FDA approved Colorado's Section 804 Importation Program proposal to import certain products from Canada for specific state healthcare programs. It is unclear how this and Florida's similar program, approved by the FDA in 2024, will be implemented and whether they will overcome potential legal, regulatory, or industry challenges in the United States and/or Canada.

On April 15, 2025, President Trump issued an Executive Order that directs HHS to take steps to reduce the prices of pharmaceutical products. The executive order repeats many of the proposals advanced during the first Trump administration, including directing the FDA to streamline and improve its existing importation program so as to make it easier for states to obtain approval without sacrificing the safety or quality of pharmaceutical products. With respect to the IRA's Medicare drug pricing program, the executive order, among other things, calls for alignment in "the treatment of small molecule prescription drugs with that of biological products, ending the distortion that undermines relative investment in small molecule prescription drugs, coupled with other reforms to prevent any increase in overall costs to Medicare and its beneficiaries."

Subsequently, on May 12, 2025, President Trump issued an additional executive order, or the Additional Order, calling on pharmaceutical manufacturers to voluntarily reduce the prices of medicines in the U.S. The Additional Order directs the Secretary of HHS to communicate most-favored-nation, or MFN, price targets to pharmaceutical manufacturers to bring prices in line with comparably developed nations. Since the Additional Order, the Trump administration has continued to exert pressure on pharmaceutical manufacturers to implement MFN pricing. For example, the current administration has announced agreements with certain pharmaceutical companies, depending on the agreement, that require the manufacturers to offer, through a direct-to-consumer platform, or TrumpRx, U.S. patients and Medicaid programs prescription MFN pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Additionally, on December 23, 2025, Centers for Medicare & Medicaid Services, or CMS, issued two proposed rules that, if implemented, would introduce two mandatory payment models, the Global Benchmark for Efficient Drug Pricing and Guarding U.S. Medicare Against Rising Drug Costs models, where manufacturers of certain Medicare Part B and Medicare Part D products would be assessed rebates if the prices for such products exceed those paid in economically comparable countries. On October 2, 2026, CMS issued a final rule implementing the Global Benchmark for Efficient Drug Pricing, or GLOBE, model, and the five-year performance period is scheduled to begin on April 1, 2027. The Guarding U.S. Medicare Against Rising Drug Costs, or GUARD, model has not been finalized and is proposed to begin on January 1, 2027. Further, on April 2, 2026, President Trump issued an executive order establishing a tariff framework for imported patented pharmaceuticals and related inputs, with more favorable rates and/or exceptions tied to MFN pricing and domestic manufacturing commitments. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand MFN pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical products available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. It remains to be seen how these pricing initiatives will affect the broader pharmaceutical industry.

At the U.S. state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Another emerging trend at the state level is the establishment of prescription product affordability boards, some of which will prospectively permit certain states to establish upper payment limits for products that the state has determined to be "high-cost." Prescription product affordability boards in several states have begun identifying products for affordability reviews and issuing information requests to manufacturers to determine whether upper payment limits may be justified. In addition, regional health care authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription product and other health care programs. These measures could reduce the ultimate demand for our products, once approved, or put pressure on our product pricing. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures. This may be increasingly true with respect to products approved pursuant to the accelerated approval pathway. State Medicaid programs and other payers are developing strategies and implementing significant coverage barriers, or refusing to cover these products outright, arguing that accelerated approval products have insufficient or limited evidence despite meeting the FDA's standards for accelerated approval.

Finally, outside the United States, in some nations, including those of the EU, the pricing of prescription pharmaceuticals is subject to governmental control and access, and reimbursement schemes vary widely from country to country. For example,

some EU Member States may restrict the range of products for which their national health insurance systems provide reimbursement. Other countries may control the prices of medicinal products for human use or allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or our collaborators may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. This Health Technology Assessment, or HTA, process is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU Member States. The HTA Regulation discussed above introduces key changes to this process, which are intended to boost cooperation among Member States in assessing health technologies, including new medicinal products. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

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

Healthcare providers, physicians, and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Any future arrangements we may have with healthcare providers, third-party payors, and customers will subject 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 may conduct clinical research or market, sell and distribute any products for which we obtain marketing approval. These include, but are not limited to, the following:

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

False Claims Laws. The federal false claims laws and civil monetary penalties laws, including the federal civil False Claims Act, impose criminal and civil penalties, including those from civil whistleblower or qui tam actions against individuals or entities for, 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 or record material to a false claim or avoiding, decreasing or concealing an obligation to pay money to the federal government.

HIPAA. The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program.

HIPAA and HITECH Act. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or the HITECH Act, also imposes obligations on certain types of individuals and entities, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.

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

Transparency Requirements. The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, with specific exceptions, to report annually to CMS information related to payments and other transfers of value made to U.S.-licensed physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and certain other U.S.-licensed healthcare providers and U.S. teaching hospitals, as well as information regarding ownership and investment interests by physicians and their immediate family members. Applicable manufacturers are also required to report such information regarding its payments and other transfers of value to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives during the previous year.

Analogous State and Foreign Laws. Analogous state and foreign fraud and abuse laws and regulations, such as state and foreign anti-kickback and false claims laws, and transparency laws, may apply to sales or marketing arrangements, and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and some state and local laws require certain regulatory licenses to manufacture or distribute products commercially and/or the registration of pharmaceutical sales representatives in the jurisdiction. Additionally, some state and foreign laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the government, in addition to requiring manufacturers to report information related to

payments to physicians and other healthcare providers or marketing expenditures. Many state and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The provision of benefits or advantages to physicians to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of medicinal products is prohibited in the EU. Payments made to physicians in certain EU member states must be publicly disclosed. Moreover, agreements with physicians often must be the subject of prior notification and approval by the physician's employer, his or her competent professional organization and/or the regulatory authorities of the individual EU member states. These requirements are provided in the national laws, industry codes or professional codes of conduct applicable in the EU member states. Failure to comply with these requirements could result in reputational risk, public reprimands, administrative penalties, fines or imprisonment.

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

Compliance with state, national and international privacy and data security requirements could result in additional costs and liabilities to us or inhibit our ability to collect and process data globally, and the failure to comply with such requirements could subject us to a variety of harms, including significant fines and penalties, litigation and reputational damage, any of which may have a material adverse effect on our business, financial condition or results of operations.

We, and the third parties with whom we work, are and may become subject to data privacy and protection laws and regulations, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information, including comprehensive regulatory systems in the U.S., EU and United Kingdom. The regulatory framework for the collection, use, safeguarding, sharing, transfer and other processing of information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Failure to comply with any of these laws and regulations could result in enforcement action against us (including fines and other penalties), claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, "process") personal information and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, sensitive third-party data, and other sensitive data the Company may process (e.g., business plans, transactions, financial information, etc.).

In the United States, there are numerous federal and state laws and regulations related to the privacy and security of personal information that may be applicable to our current and future activities. For instance, a wide range of enforcement agencies at both the state and federal levels can review companies for privacy and data security concerns based on general consumer protection laws. The FTC and state Attorneys General are aggressive in reviewing privacy and data security protections for consumers. For example, the FTC has focused on the unpermitted processing of health and genetic data, including through enforcement actions, and has expanded the types of privacy violations that it interprets to be "unfair" under Section 5 of the Federal Trade Commission Act, as well as the types of activities it views to trigger the Health Breach Notification Rule (which the FTC also has the authority to enforce). We will need to account for the FTC's evolving rules and guidance for proper privacy and data security practices in order to mitigate our risk for a potential enforcement action, which may be costly. If we are subject to a potential FTC enforcement action, we may be subject to a settlement order that requires us to adhere to very specific privacy and data security practices, which may impact our business. We may also be required to pay fines as part of a settlement (depending on the nature of the alleged violations). If we violate any consent order that we reach with the FTC, we may be subject to additional fines and compliance requirements.

In addition to consumer protection laws, a broad range of privacy-related legislation has been introduced at both the federal and, especially, state levels. For example, the California Consumer Privacy Act, or the CCPA, which went into effect on January 1, 2020, imposes many requirements on businesses that process the personal information of California residents, including requiring businesses to provide notice to data subjects regarding the information collected about them and how such

information is used and shared, and providing data subjects the right to request access to such personal information and, in certain cases, request the deletion of such personal information.

In addition to California, many other states have passed comprehensive privacy laws that are currently in effect or will go into effect in the coming years. Like the CCPA, these laws create obligations related to the processing of personal information, as well as special obligations for the processing of "sensitive" data (which includes health data in some cases). Although these and similar laws often have exemptions for personal information collected in the context of clinical trials, some provisions of these laws may apply to our business activities. Other states are and will be considering these laws in the future, and Congress has also continued to consider passing a federal privacy law. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

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

In addition to the risks associated with enforcement activities by government authorities, there also is the threat of consumer class actions related to these laws and the overall protection of personal information. Even if we are not determined to have violated the law, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and our business.

In addition to the United States, there are significant privacy and data security laws that apply in Europe and other countries. For example, the European Union's General Data Protection Regulation, or the EU GDPR, and the United Kingdom's, or the UK, GDPR, or the UK GDPR, and collectively, the GDPR, impose strict requirements for processing personal data. For example, the collection, use, disclosure, transfer, or other processing of personal information, including personal health data, regarding individuals who are located in the European Economic Area, or the EEA, is subject to the GDPR. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal information, including strict rules on the transfer of personal information to countries outside the EU, including the United States. The GDPR also permits data protection authorities to require destruction of improperly gathered or used personal information and/or impose substantial fines for violations of the GDPR, which can be up to four percent of annual global revenues or 20 million Euros, whichever is greater, and it also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR provides that EU member states may make their own further laws and regulations limiting the processing of personal information, including genetic, biometric or health data. As a result, there is increased scrutiny on the extent to which clinical trial sites located in the EEA should apply the GDPR to transfers of personal information from such sites to countries that are considered to lack an adequate level of data protection, such as the United States. Similar obligations and risks are associated with the United Kingdom's version of the GDPR. The requirements and uncertainty around this and other data protection and data transfer regimes have the potential to impact our business.

These evolving compliance and operational requirements related to privacy and data protection impose significant costs that are likely to increase over time. Preparing for and complying with such requirements is rigorous and time-intensive. It requires significant resources and a review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that process or transfer personal information, and may require us to modify our data processing practices and policies, divert resources from other initiatives and projects, and restrict the way products and services involving data are offered. Further, current and future laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from any clinical trials we may conduct, could require us to change our business practices and put in place additional compliance mechanisms, interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business, and could lead to government enforcement actions, private litigation and significant fines and penalties against us. Any of these events could have a material adverse effect on our business, financial condition, results of operations and prospects.

We are subject to U.S. and certain foreign export control, import, sanctions, anti-corruption, and anti-money laundering laws with respect to our operations and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

We are subject to export control and import laws and regulations, including the U.S. Export Administration Regulations, U.S. Customs regulations, various economic and trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control, the U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, and other state and national anti-bribery and anti-money laundering laws in countries in which we conduct activities. Anti-corruption laws are interpreted broadly and

prohibit companies and their employees, agents, third-party intermediaries, joint venture partners and collaborators from authorizing, promising, offering or providing, directly or indirectly, improper payments or benefits to recipients in the public or private sector. We may have direct or indirect interactions with officials and employees of government agencies or government-affiliated hospitals, universities and other organizations. In addition, we may engage third-party intermediaries to promote any clinical research activities we may pursue abroad and/or to obtain necessary permits, licenses, and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

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

Changes in and uncertainty surrounding U.S. and international trade policies could have a material adverse impact on our business, financial condition and results of operations.

As a result of numerous changes in tariffs and trade restrictions that have been announced and/or implemented by the Trump administration since taking office, and other countries in response to Trump administration actions, and the underlying uncertainty currently surrounding international trade, we could experience a negative impact on our costs of materials or supply chain disruptions and delays. If, in connection with any development activities we may pursue, we are unable to obtain necessary raw materials or product components in sufficient quantity and in a timely manner due to disruptions in the global supply chain caused by macroeconomic events and conditions, the development, testing and clinical trials of any product candidates we may develop may be delayed or rendered infeasible, and regulatory approval or commercial launch of any resulting product may be delayed, which could significantly harm our business. We cannot yet predict the effect of recently imposed U.S. tariffs, or of possible future U.S. tariffs, including, but not limited to, tariffs on pharmaceuticals, pharmaceutical ingredients, including finished drug products, medical countermeasures, critical inputs such as active pharmaceutical ingredients and key starting materials, and derivative products of those items, on imports, or the extent to which other countries will impose quotas, duties, tariffs, taxes or other similar restrictions upon imports or exports in the future, nor can we predict future trade policy or the terms of any renegotiated trade agreements and their impact on our business.

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

Trade tensions and conflicts between the United States and China have been escalating in recent years and, as such, we could be exposed to the possibility of product supply disruption and increased costs and expenses in the event of changes to the laws, rules, regulations and policies of the governments of the United States or China, or as a result of geopolitical unrest or unstable economic conditions. Certain Chinese biotechnology companies may become subject to trade restrictions, sanctions, other regulatory requirements or proposed legislation by the U.S. government, which could restrict or even prohibit our ability to work with such entities, thereby potentially disrupting the supply of material to us. For example, in February 2024, U.S. lawmakers called for investigations into and the imposition of possible trade sanctions against certain Chinese biotechnology companies, including WuXi AppTec and WuXi Biologics over alleged ties to the Chinese military. Sustained uncertainty about or further escalating trade and political tensions between the United States and China may prevent or hinder the export of materials or technical information between us and third parties, such as pharmaceutical partners, or could result in trade or retaliatory restrictions that may hinder or potentially inhibit our ability to rely on any contract development and manufacturing organizations or other service providers that operate in China. These third parties may voluntarily require compliance or supply chain requirements that go above and beyond potential legislation to address perceived risk of "pass through," which would make it difficult for us to operate our business.

In December 2025, Congress enacted a law that, subject to certain grandfather provisions, will prohibit U.S. federal agencies from procuring or obtaining "biotechnology equipment or services" from certain Chinese companies designated as "biotechnology companies of concern." It will also prohibit U.S. federal agencies from entering into, extending or renewing contracts with any entity that either uses biotechnology equipment or services provided by a designated biotechnology company of concern in performance of the contract or enters into any contract with a third party that requires either party to use biotechnology equipment or services produced or provided by a biotechnology company of concern. It also prohibits an executive agency from obligating or expending a loan or grant to procure biotechnology equipment or services produced or

provided by a designated biotechnology company of concern. Regulatory or legislative action taken by the U.S. government to impose restrictions on transactions with China, like the restrictions described above, could have the potential to severely restrict the ability of companies like ours to contract with Chinese biotechnology companies of concern, which could have adverse effects on any development of product candidates we may pursue and our business operations.

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

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 harm our business.

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

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials; however, 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 addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair any research, development or production efforts we may pursue. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

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

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, consultants and vendors and, to the extent we engage them, CROs, commercial partners and principal investigators. Misconduct by these parties could include intentional failures to comply with FDA regulations or the regulations applicable in the EU and other jurisdictions, provide accurate information to the FDA, the European Commission and other regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements.

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

The biopharmaceutical industry is subject to extensive regulatory obligations and policies that may be subject to change, including due to judicial challenges, election cycles, and resulting regulatory updates and changes in policy priorities.

In June 2024, the U.S. Supreme Court issued an opinion in *Loper Bright Enterprises v. Raimondo* holding that courts reviewing agency action pursuant to the Administrative Procedure Act "must exercise their independent judgment" and "may not defer to an agency interpretation of the law simply because a statute is ambiguous." The decision has impacted how lower courts evaluate challenges to agency interpretations of law, including those by the FDA, HHS, CMS and other agencies with significant oversight of the biopharmaceutical industry. This is likely to increase both the frequency of such challenges and their odds of success by eliminating one way in which the government previously prevailed in such cases. As a result, significant regulatory policies will be subject to increased litigation and judicial scrutiny.

In addition, federal agency activities, priorities, leadership, policies, rulemaking, communications, spending and staffing may be significantly impacted by election cycles and legislative developments. For example, the current presidential administration aims to significantly reduce government spending through cuts to federal healthcare programs and reductions in the workforces of key government agencies, such as the FDA, HHS and CMS. Efforts by the current administration to limit federal agency budgets or personnel may result in reductions to agency budgets, employees and operations. The administration and agencies have also made abrupt announcements about new or changed regulatory policies, such as policies related to use of artificial intelligence ("AI") to review product applications. Additionally, any federal government shutdowns may prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews or other regulatory activities, and may significantly impact the ability of the FDA to timely review and process any regulatory submissions we may make. These developments may lead to slower response times and longer review periods, potentially affecting any development of product candidates we may pursue or our ability to obtain regulatory approval for any such product candidates. Any resulting changes in regulation may result in unexpected delays, increased costs, or other negative impacts on our business that are difficult to predict.

Risks Related to Our Business Operations, Employee Matters and Managing Growth

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

We are highly dependent on the management, research and development, clinical, financial and business development expertise of our executive officers, as well as the other members of our scientific and clinical teams. Although we have employment offer letters which outline the terms of employment with each of our executive officers, each of them may terminate their employment with us at any time. As such, these employment offer letters do not guarantee our retention of our executive officers for any period of time. We do not maintain "key person" insurance for any of our employees.

Recruiting and retaining qualified scientific and clinical personnel and, if we are successful in obtaining marketing approval for any product candidates, sales and marketing personnel, would be critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of any research, development and commercialization objectives we may pursue and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and other key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain regulatory approval for and commercialize product candidates. We are based in the Boston area, a region that is home to many other biopharmaceutical companies as well as many academic and research institutions, resulting in fierce competition for qualified personnel. Furthermore, to the extent we hire personnel from competitors, we may be subject to allegations that they have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output. We may also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we may rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating any research and development strategy we may pursue. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to attract and retain high-quality personnel as needed, our ability to pursue our growth strategy will be limited, and could harm our business, prospects, financial condition and results of operations.

Our business could be negatively affected by cyberattacks or a deficiency in our cybersecurity.

A cyberattack or similar incident could occur and result in information theft, data corruption, operational disruption, damage to our reputation, or financial loss. We are increasingly dependent on information technology systems and infrastructure, including mobile technologies and third-party service providers, to operate our business. Our technologies, systems, networks, or other proprietary information, and those of our vendors, suppliers and other business partners, may become the target of cyberattacks or information security breaches that could result in the unauthorized release, gathering, monitoring, misuse, loss, or destruction of proprietary and other information, or could otherwise lead to the disruption of our business operations. The risk of a security

breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. Moreover, certain cyber incidents, such as advanced persistent threats, may remain undetected for an extended period and could lead to disruptions in critical systems or the unauthorized release of confidential or otherwise protected information. These events could lead to financial loss and other adverse consequences, for instance due to remedial actions, loss of business, disruption of operations, damage to our reputation, or potential liability. Our systems and insurance coverage for protecting against cybersecurity risks may not be sufficient. Furthermore, as cyberattacks continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any vulnerability to cyberattacks.

Our computer systems and data, or those of any third-party with whom we work, such as research institution collaborators, CROs and other contractors or consultants, may fail or suffer security breaches, which could lead to a range of adverse consequences for us.

Despite the implementation of security measures, our internal computer systems and those of any third parties with whom we work, such as CROs and other contractors, vendors and consultants, may be vulnerable to damage from cybersecurity threats, including attempts to gain unauthorized access to and to harm sensitive or confidential information and networks, insider threats, and ransomware. These vulnerabilities may be heightened as a result of flexible work arrangements.

Investigations into and remedial efforts in connection with any security incidents, even those with immaterial impact, can be costly and time-consuming and could be material, or cause significant disruption, to our business. For example, the loss of clinical trial data from any clinical trials we may conduct could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we may rely on third parties for research and development, the manufacture and supply of drug product and drug substance and to conduct clinical trials. We depend on these third parties to implement adequate controls and safeguards to protect against, detect, report and remediate cybersecurity incidents. If they fail to do so or are otherwise impacted by security incidents, we may suffer financial and other harm, including to our information, operations, performance, and reputation. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary information, we could incur liability and any further development and commercialization of product candidates could be delayed.

Cybersecurity threats, both on premises and in the cloud, are evolving and include, but are not limited to: malicious software, destructive malware, ransomware, attempts to gain unauthorized access to systems or data, disruption to operations, critical systems or denial of service attacks; unauthorized release of confidential, personal or otherwise protected information; corruption of data, networks or systems; harm to individuals; and loss of assets. In addition, we could be impacted by cybersecurity threats or other disruptions or vulnerabilities found in products or services we use that are provided to us by third parties, for instance via supply chain attacks. The techniques used by criminal elements and state-sponsored actors to attack computer systems are sophisticated, change frequently and may originate from less regulated and remote areas of the world. As a result, we may not be able to address these techniques proactively or implement adequate preventative measures. These events, if not prevented or effectively mitigated, could damage our reputation, require remedial actions and lead to loss of business, regulatory actions, potential liability and other financial losses.

Certain data breaches may also be required to be reported to affected individuals and various government and/or regulatory agencies, under provisions of HIPAA, as amended by the HITECH Act, other U.S. federal and state laws, and requirements of non-U.S. jurisdictions, including the EU Data Protection Directive, and financial penalties may also apply.

Our insurance policies may not be adequate to compensate us for the potential losses arising from security breaches, failures or disruptions of our infrastructure, catastrophic events and disasters or otherwise. 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 defending a suit, regardless of its merit, could be costly and divert management's attention.

Business disruptions and unfavorable economic conditions could seriously harm our business, future revenue and financial condition, and could increase our costs and expenses.

We depend on our employees, consultants and other service providers, including any contract manufacturers and CROs we may engage, for the continued operation of our business. Our or their operations could be significantly disrupted by earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, ice and snowstorms, extreme weather conditions, medical epidemics or pandemics, wars or other armed conflicts, geopolitical tensions or trade wars, terrorist attacks, and other natural or man-made disasters or business interruptions, for which we are, and they may be, predominantly self-insured. To the extent we develop product candidates and rely on third-party contract manufacturers to produce them, our ability to obtain clinical supplies for such product candidates could be disrupted if the operations of these suppliers were affected by a man-made or natural disaster or other business interruption. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses.

In addition, unfavorable economic conditions both inside and outside the U.S., including, without limitation, heightened inflation, capital market volatility, interest rate and currency rate fluctuations, any potential economic slowdown or recession, banking disruptions, public health crises and geopolitical events, including trade wars or civil or political unrest (such as the ongoing war between Ukraine and Russia and conflict in the Middle East), have resulted in a significant disruption of global financial markets. If the disruption persists or deepens, we could experience an increase in our costs and expenses, including an increase in financing costs, and restrictions on our access to potential sources of future capital. If we are unable to raise additional capital when needed or on attractive terms, our business, financial condition, stock price and results of operations could be adversely affected, and we could be forced to delay, reduce or altogether terminate one or more future research and development programs. Further, we hold our cash and cash equivalents that we use to meet our working capital and operating expense needs in deposit accounts at multiple financial institutions, and if a financial institution in which we hold such funds fails or is subject to significant adverse conditions in the financial or credit markets, we could be subject to a risk of loss of all or a portion of any uninsured funds or be subject to a delay in accessing all or a portion of such uninsured funds. Any such loss or lack of access to these funds could adversely impact our short-term liquidity and ability to meet our operating expense obligations. In addition, there is a risk that one or more service providers, manufacturers and other partners on which we may rely may not survive such difficult economic times, which could directly affect our ability to attain our operating goals. Any of the foregoing could harm our business, future revenue and financial condition.

A variety of risks associated with marketing any product candidates we may develop internationally, if approved, could materially adversely affect our business.

We may 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:

- regulatory requirements in foreign countries that differ from those in the United States;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign 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;
- complexities associated with managing multiple payor reimbursement regimes, government payors or patient self-pay systems;
- 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 geopolitical actions, including war and terrorism.

Any of these factors could harm our future international expansion and operations and, consequently, our results of operations.

We may engage in other strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time, we may engage in other strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of intellectual property, products or technologies. Additional potential transactions that we may consider in the future include a variety of business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any future transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our financial condition, liquidity and results of operations. Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of management. In addition, the integration of any business that we may acquire

in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits of the acquisition. Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

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

We have received notices from Nasdaq that we are not in compliance with the minimum bid price requirement for continued listing, and our common stock may be delisted if we do not regain compliance.

We are required to comply with the continued listing requirements of Nasdaq including, among other things, maintaining a minimum closing bid price of $1.00 per share, referred to as the minimum bid price requirement. On February 4, 2026, we received a deficiency letter, or the Nasdaq Deficiency Notice, from the Nasdaq Listing Qualifications Department, or the Nasdaq Staff, notifying us that we had failed to meet the minimum bid price requirement. In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided an initial period of 180 calendar days, which expired on August 3, 2026, to regain compliance with the minimum bid price requirement. We did not regain compliance during this initial compliance period.

Following the expiration of the initial compliance period, Nasdaq granted us an additional 180-calendar-day period, expiring on February 1, 2027, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of our common stock must be at least $1.00 per share for a minimum of 10 consecutive business days during this additional compliance period, at which time the Nasdaq Staff will provide written notification to us that we have regained compliance with the minimum bid price requirement, unless the Nasdaq Staff exercises its discretion to extend this ten-day period pursuant to Nasdaq Listing Rule 5810(c)(3)(H).

We have not regained compliance with the minimum bid price requirement. There can be no assurance that we will regain compliance during the additional compliance period. If we do not regain compliance by the expiration of the additional compliance period, the Nasdaq Staff will notify us that our common stock is subject to delisting, which determination we may appeal to a Nasdaq Hearings Panel. Our common stock would remain listed pending the panel's decision, although there can be no assurance that any such appeal would be successful.

Any delisting of our common stock from Nasdaq would have a material adverse effect on the market for, and liquidity and price of, our common stock and would adversely affect our ability to raise capital on terms acceptable to us, or at all. Delisting from Nasdaq could also have other negative consequences, including, without limitation, the potential loss of confidence by investors, customers and employees and fewer business development opportunities. Delisting would also make it more difficult for Werewolf stockholders to sell their shares of our common stock in the public market.

The price of our common stock could be subject to volatility related or unrelated to our operations.

The price of our common stock is likely to be volatile. For example, from January 1, 2025, until November 9, 2026, the closing price of our common stock has ranged from $0.31 to $2.19. The stock market in general and the market for biotechnology and pharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at an attractive price or at all. The market price for our common stock may be influenced by many factors, including:

- adverse results from preclinical studies;
- the commencement, enrollment or results of any clinical trials we may conduct, or changes in the development status of our product candidates;
- adverse results from, delays in initiating or completing, or termination of clinical trials;
- unanticipated serious safety concerns related to the use of our product candidates;
- clinical trial results from, or regulatory approval of, a competitor's product candidate;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- any delay in our regulatory filings for our product candidates and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- lower than expected market acceptance of our product candidates following approval for commercialization;
- adverse developments concerning our manufacturers;
- our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices;
- introduction of new products or services by our competitors;

- changes in financial estimates by us or by any securities analysts who might cover our stock;
- conditions or trends in our industry;
- our cash position;
- sales of our common stock by us or our stockholders in the future;
- adoption of new accounting standards;
- ineffectiveness of our internal controls;
- changes in the market valuations of similar companies;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biotechnology and pharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- investors' general perception of our company and our business;
- recruitment or departure of key personnel;
- overall performance of the equity markets;
- trading volume of our common stock;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies and product candidates;
- significant lawsuits, including patent or stockholder litigation;
- proposed changes to healthcare laws or pharmaceutical pricing in the United States or foreign jurisdictions, or speculation regarding such changes;
- general political and economic conditions, including the imposition of new or revised global trade tariffs; and
- other events or factors, many of which are beyond our control.

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

If securities or industry analysts do not publish or cease publishing research or reports about our company, or if they issue unfavorable or inaccurate research regarding our business, our share price and trading volume could decline.

The trading market for our common stock relies, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not have research control over these analysts. There can be no assurance that existing analysts will continue to cover us or that new analysts will begin to cover us. There is also no assurance that any covering analysts will provide favorable coverage. Although we have obtained coverage, if one or more of the analysts covering us downgrade our common stock or publish unfavorable or inaccurate research about our business, our stock price may decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

We have broad discretion regarding use of our cash and cash equivalents, and we may use them in ways that do not enhance our operating results or the market price of our common stock.

Our management has broad discretion in the application of our cash and cash equivalents. We could utilize our cash and cash equivalents in ways our stockholders may not agree with or that do not yield a favorable return, if any, and our management might not apply our cash and cash equivalents in ways that ultimately increase the value of our stockholders' investments. If we do not utilize our cash and cash equivalents in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

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

We currently anticipate that we will retain future earnings for the development, operation and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future.

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

As a public company, we incur significant legal, accounting and other expenses that we did not previously incur as a private company. The Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, Nasdaq listing requirements, and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel have and will need to continue to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs, particularly as we hire additional financial and accounting employees to meet public company internal control and financial reporting requirements and will make some activities more time-consuming and costly compared to when we were a private company.

We are continually evaluating these rules and regulations and cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. These rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If, notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting. However, while we remain an emerging growth company or a smaller reporting company with less than $100.0 million in annual revenue, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we are engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, including through hiring additional financial and accounting personnel, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses in our internal control over financial reporting, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

In the past, we have identified material weaknesses in our internal control over financial reporting, and if we are unable to implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and completeness of our financial reports, and the market price of our common stock may be materially adversely affected.

In the past, we have identified material weaknesses in our internal control over financial reporting. All material weaknesses previously identified have been fully remediated.

If, in the future we have a material weakness in our internal controls over financial reporting, we may not detect errors on a timely basis and our consolidated financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company, we are required to file accurate and timely quarterly and annual reports with the SEC under the Exchange Act. Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from the Nasdaq Capital Market or other adverse consequences that would materially harm our business. In addition, we could become subject to investigations by the stock exchange on which our securities are listed, the SEC, and other regulatory authorities, and become subject to litigation from

investors and stockholders, which could harm our reputation and our financial condition, or divert financial and management resources from our core business.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock.

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. As discussed above, we have identified material weaknesses in the past which have since been remediated. However, our remediation of previous material weaknesses may not prevent any future deficiency in our internal control over financial reporting. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could harm our business and have a negative effect on the trading price of our stock.

We are required to disclose changes made in our internal controls and procedures on a quarterly basis, and our management is required to assess the effectiveness of these controls annually. However, for as long as we are an emerging growth company under the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012 or a smaller reporting company with less than $100.0 million in annual revenue, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404. We could be an emerging growth company for up to five years. An independent assessment of the effectiveness of our internal control over financial reporting could detect problems that our management's assessment might not. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation, which could have a negative effect on the trading price of our stock.

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

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

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

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

- establish a classified board of directors such that only one of three classes of directors is elected each year;
- allow the authorized number of our directors to be changed only by resolution of our board of directors;
- limit the manner in which stockholders can remove directors from our board of directors;
- establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our board of directors;

- require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent;
- limit who may call stockholder meetings;
- authorize our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors; and
- require the approval of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast to amend or repeal specified provisions of our certificate of incorporation or bylaws.

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

Our restated certificate of incorporation designates the Court of Chancery of the State of Delaware, or the Court of Chancery and the federal district courts of the United States of America as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers and employees and increase the costs to our stockholders of bringing such claims.

Our restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if the Court of Chancery of the State of Delaware does not have jurisdiction, the federal district court for the District of Delaware) will be the sole and exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, employees or stockholders to our company or our stockholders;
- any action asserting a claim arising pursuant to any provision of the DGCL or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; or
- any action asserting a claim arising pursuant to any provision of our certificate of incorporation or bylaws (in each case, as they may be amended from time to time) or governed by the internal affairs doctrine.

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

These exclusive forum provisions may limit the ability of our stockholders to bring a claim in a judicial forum that such stockholders find favorable for disputes with us or our directors, officers or employees, and increase the costs to such stockholders of bringing such a claim, either of which may discourage such lawsuits against us and our directors, officers and employees. If a court were to find either exclusive forum provision contained in our restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving such action in other jurisdictions, all of which could materially adversely affect our business, financial condition and operating results.

Item 6. Exhibits

Exhibit Number	Description
2.1‡	Agreement and Plan of Merger, dated as of August 21, 2026, by and among Ambros Therapeutics, Inc., Werewolf Therapeutics, Inc., and Wave Atlantis Merger Sub, Inc. (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on August 21, 2026, File No. 001-40366).
3.1	Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on May 5, 2021, File No. 001-40366).
3.2	Third Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on June 13, 2025).
10.1	Form of Werewolf Stockholder Support Agreement (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on August 21, 2026, File No. 001-40366).
10.2	Form of Ambros Stockholder Support Agreement (incorporated by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on August 21, 2026, File No. 001-40366).
10.3	Form of Ambros Lock-Up Agreement (incorporated by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on August 21, 2026, File No. 001-40366).
10.4	Form of Securities Purchase Agreement, dated as of August 21, 2026, by and among Werewolf Therapeutics, Inc. and each of the Investors listed on Exhibit A thereto (incorporated by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K, filed with the Securities and Exchange Commission on August 21, 2026, File No. 001-40366).
10.5+	Amendment of Retention Agreement, dated as of August 25, 2026, by and between the Registrant and Daniel J. Hicklin (incorporated by reference to Exhibit 10.30 to the Registrant's Registration Statement on Form S-4, filed with the Securities and Exchange Commission on September 22, 2026, File No. 333-299079).
10.6‡	Asset Purchase Agreement, dated as of August 14, 2026, by and between Werewolf Therapeutics, Inc. and EMD Serono Research & Development Institute Inc. (incorporated by reference to Exhibit 10.54 to the Registrant's Registration Statement on Form S-4/A, filed with the Securities and Exchange Commission on October 26, 2026, File No. 333-299079).
10.7‡	License Agreement, dated as of August 14, 2026, by and between Werewolf Therapeutics, Inc. and EMD Serono Research & Development Institute Inc. (incorporated by reference to Exhibit 10.55 to the Registrant's Registration Statement on Form S-4/A, filed with the Securities and Exchange Commission on October 26, 2026, File No. 333-299079).
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1†	Certifications of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL with applicable taxonomy extension information contained in Exhibits 101)

* Filed herewith.

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

‡ Certain schedules and similar attachments have been omitted pursuant to Item 601(a)(5) of Regulation S-K, and certain identified information has been excluded pursuant to Item 601(b)(10)(iv) of Regulation S-K because it is both (i) not material and (ii) the type that the Registrant customarily and actually treats as private or confidential. The Registrant agrees to furnish supplementally a copy of any omitted schedule or attachment to the Securities and Exchange Commission or its staff upon request.

+ Indicates management contract.

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.

WEREWOLF THERAPEUTICS, INC.

Date: November 13, 2026

By: /s/ Daniel J. Hicklin

Daniel J. Hicklin, Ph.D.
President, Chief Executive Officer and Director
(Principal Executive Officer)

Date: November 13, 2026

By: /s/ Michael J. Urban

Michael J. Urban
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 31.1

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

I, Daniel J. Hicklin, Ph.D., certify that:

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

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

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

4. The registrant's other certifying officer 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 13, 2026

By: /s/ Daniel J. Hicklin
Daniel J. Hicklin, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

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

I, Michael J. Urban, certify that:

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

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

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

4. The registrant's other certifying officer 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 13, 2026

By: /s/ Michael J. Urban
Michael J. Urban
Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

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

In connection with the Quarterly Report on Form 10-Q of Werewolf Therapeutics, Inc. (the "Company") for the period ended September 30, 2026 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned officers of the Company hereby certifies, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to his knowledge:

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

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

Date: November 13, 2026 By: /s/ Daniel J. Hicklin
Daniel J. Hicklin, Ph.D.
President and Chief Executive Officer
(Principal Executive Officer)

Date: November 13, 2026 By: /s/ Michael J. Urban
Michael J. Urban
Chief Financial Officer
(Principal Financial and Accounting Officer)