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DELTA REPORT

10-Q

HOWL - WEREWOLF THERAPEUTICS, IN

10-Q - MARCH 31, 2024 COMPARED TO 10-Q - SEPTEMBER 30, 2023

The following comparison report has been automatically generated

TOTAL DELTAS	1756
CHANGES	159
DELETIONS	806
ADDITIONS	791

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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, 2023 March 31, 2024

☐ **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.)**
200 Talcott Ave, 2nd Floor Watertown, Massachusetts	
(Address of principal executive offices)	**02472 (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 Global Select Market

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

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

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

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

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

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

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

As of November 10, 2023 April 29, 2024, there were 36,192,248 43,455,367 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 subsidiary, 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,” “estimate,” “expect,” “goal,” “intend,” “may,” “might,” “objective,” “ongoing,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would,” or the negative of these words or other similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among other things, statements about:

- the initiation, timing, progress and results of our research and development programs, preclinical studies and ongoing and planned 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;
- 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;
- the potential advantages of our PREDATOR platform and our ability to use our platform to identify and develop future 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;
- 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™ and INDUKINE™. 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:

- 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. We may never generate any revenue from product sales 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 complete the development and any commercialization of WTX-124, WTX-330 and any future product candidates.
- We are early in our development efforts and our current product candidates will require successful completion of preclinical and clinical development before we can seek regulatory approval for any product candidates.
- Our business is highly dependent on the success of our initial INDUKINE molecules, which are in the early stages of development and will require significant additional preclinical and clinical development before we can seek regulatory approval for and launch a product commercially.
- Our approach to the discovery and development of product candidates based on our PREDATOR platform is unproven, and we do not know whether we will be able to develop any products of commercial value.
- Manufacturing INDUKINE molecules is subject to risk since they are a novel class of multi-domain biologics that include protease cleavable linkers, and they have never been produced on a commercial scale. We may be unable to

  manufacture INDUKINE molecules at the scale needed for clinical development and commercial production on a timely basis or at all.
- 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 our clinical trials, which could result in increased costs to us, delay or limit our ability to generate revenue and adversely affect our commercial prospects.
- 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 are developing WTX-124, and could develop WTX-330 and potentially future product candidates, in combination with third-party drugs, 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 drugs.
- We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.
- We rely, and expect to continue to rely, on third parties to conduct our preclinical studies and clinical trials. 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.
- The manufacturing of biologics is complex, and we do not have our own clinical manufacturing capabilities. We will rely on third parties to produce preclinical, clinical and commercial supplies of all current and any future product candidates.
- We rely on our license agreement with Harpoon Therapeutics, Inc. for patent rights with respect to our product candidates and may in the future acquire additional third-party intellectual property rights on which we may similarly rely. We face risks with respect to such reliance,

including the risk that we could lose these rights that are important to our business if we fail to comply with our obligations under these licenses.

- 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.
- In the second quarter of 2023, past, we have identified a material weakness weaknesses in our internal control over financial reporting, and that weakness has led if we are unable to a conclusion that our implement and maintain effective internal control over financial reporting in the future, investors may lose confidence in the accuracy and disclosure controls completeness of our financial reports, and procedures were not effective as the market price of September 30, 2023. Our inability to remediate the material weakness, our discovery of additional weaknesses, and our inability to achieve and maintain effective disclosure controls and procedures and internal control over financial reporting could common stock may be materially adversely affect our results of operations, our stock price and investor confidence. affected.

PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

		September 30, 2023	December 31, 2022			
March 31, 2024					**March 31, 2024**	**December 31, 2023**
Assets	**Assets**					
Current assets:	Current assets:					
Current assets:						
Current assets:						
Cash and cash equivalents						
Cash and cash equivalents						
Cash and cash equivalents	Cash and cash equivalents	$130,058	$129,315			
Prepaid expenses and other current assets	Prepaid expenses and other current assets	3,289	3,957			
Other receivables	Other receivables	5,911	6,928			
Total current assets	Total current assets	139,258	140,200			
Property and equipment, net	Property and equipment, net	8,342	8,988			

Restricted cash and cash equivalents, net of current portion	Restricted cash and cash equivalents, net of current portion	21,019	1,214
Operating lease right of use asset	Operating lease right of use asset	7,251	8,463
Other non-current assets		516	1,380
Other assets			
Total assets	Total assets	$176,386	$160,245
Liabilities and Stockholders' Equity:			
Liabilities and stockholders' equity			
Current liabilities:	Current liabilities:		
Current liabilities:			
Current liabilities:			
Accounts payable			
Accounts payable			
Accounts payable	Accounts payable	$ 1,386	$ 1,221
Accrued expenses and other current liabilities	Accrued expenses and other current liabilities	7,967	14,152
Operating lease liability, current	Operating lease liability, current	1,605	2,084
Deferred revenue, current	Deferred revenue, current	1,814	6,532
Note payable, current	Note payable, current	1,667	—
Total current liabilities	Total current liabilities	14,439	23,989
Operating lease liability, net of current portion	Operating lease liability, net of current portion	11,352	12,600
Deferred revenue, net of current portion	Deferred revenue, net of current portion	588	1,128
Notes payable, net of discount, issuance costs, and current portion		37,564	—
Other liabilities		—	191
Note payable, net of discount, issuance costs, and current portion			
Total liabilities			

Total liabilities				
Total liabilities	Total liabilities	63,943	37,908	
Commitments and contingencies	Commitments and contingencies			Commitments and contingencies
Stockholders' equity:	Stockholders' equity:			
Preferred stock, $0.0001 par value, 5,000 shares authorized at September 30, 2023 and December 31, 2022; no shares issued or outstanding as of September 30, 2023 and December 31, 2022, respectively		—	—	
Common stock, $0.0001 par value, 200,000 shares authorized as of September 30, 2023 and December 31, 2022; 35,658 and 31,515 shares issued as of September 30, 2023 and December 31, 2022, respectively; 35,658 and 31,434 shares outstanding as of September 30, 2023 and December 31, 2022, respectively		3	3	
Preferred stock, $0.0001 par value, 5,000,000 shares authorized as of March 31, 2024 and December 31, 2023; no shares issued or outstanding as of March 31, 2024 and December 31, 2023				
Preferred stock, $0.0001 par value, 5,000,000 shares authorized as of March 31, 2024 and December 31, 2023; no shares issued or outstanding as of March 31, 2024 and December 31, 2023				
Preferred stock, $0.0001 par value, 5,000,000 shares authorized as of March 31, 2024 and December 31, 2023; no shares issued or outstanding as of March 31, 2024 and December 31, 2023				

Common stock, $0.0001 par value, 200,000,000 shares authorized as of March 31, 2024 and December 31, 2023; 43,282,371 and 39,107,048 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively			
Additional paid-in capital	Additional paid-in capital	444,510	429,039
Accumulated deficit	Accumulated deficit	(332,070)	(306,705)
Total stockholders' equity	Total stockholders' equity	112,443	122,337
Total liabilities and stockholders' equity	Total liabilities and stockholders' equity	$176,386	$160,245

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,	
	2023	**2022**	**2023**	**2022**
	Three Months Ended March 31,			
	Three Months Ended March 31,			
	Three Months Ended March 31,			
	2024			
	2024			

		2024			
Revenue:					
Revenue:					
Revenue:	Revenue:				
Collaboration revenue	Collaboration revenue	$ 5,897	$ 4,970	$ 18,442	$ 9,118
Collaboration revenue					
Collaboration revenue					
Operating expenses:					
Operating expenses:					
Operating expenses:	Operating expenses:				
Research and development	Research and development	10,838	13,070	32,127	37,902
Research and development					
Research and development					
General and administrative					
General and administrative					
General and administrative	General and administrative	4,310	4,439	13,856	14,093
Total operating expenses	Total operating expenses	15,148	17,509	45,983	51,995
Total operating expenses					
Total operating expenses					
Operating loss					
Operating loss					
Operating loss	Operating loss	(9,251)	(12,539)	(27,541)	(42,877)
Other income:	Other income:				
Other (expense) income, net		(5)	3	(1,136)	268
Interest income, net		971	593	3,312	729
Other income:					
Other income:					
Interest income					
Interest income					
Interest income					
Interest expense					
Interest expense					
Interest expense					
Other expense, net					
Other expense, net					
Other expense, net					
Total other income					
Total other income					
Total other income	Total other income	966	596	2,176	997

Net loss	Net loss	$ (8,285)	$ (11,943)	(25,365)	(41,880)
Net loss per share, basic and diluted		$ (0.23)	$ (0.40)	$ (0.72)	$ (1.48)
Net loss					
Net loss					
Net loss per common share, basic and diluted					
Net loss per common share, basic and diluted					
Net loss per common share, basic and diluted					
Weighted-average common shares outstanding, basic and diluted	Weighted-average common shares outstanding, basic and diluted	35,654	29,764	35,335	28,233
Weighted-average common shares outstanding, basic and diluted					
Weighted-average common shares outstanding, basic and diluted					

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) thousands, except share amounts)

	Common Stock		Common Stock	Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares					
Balance at December 31, 2023						
Balance at December 31, 2023						
Balance at December 31, 2023						
Issuance of common stock from at the market offering, net of issuance costs of $985						
Stock-based compensation expense						
Stock option exercises						
Net loss						
Balance at March 31, 2024						

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2022	31,515	$ 3	$429,039	$(306,705)	$ 122,337
Issuance of common stock from at the market offering, net of issuance costs of $103	3,824	—	8,610	—	8,610
Stock-based compensation expense	—	—	2,108	—	2,108
Net loss	—	—	—	(11,982)	(11,982)
Balance at March 31, 2023	35,339	3	439,757	(318,687)	121,073
Issuance of common stock from at the market offering, net of issuance costs of $31	272	—	644	—	644
Issuance of common stock under Employee Stock Purchase Plan	29	—	45	—	45
Stock-based compensation expense	—	—	1,930	—	1,930
Stock option exercises	2	—	5	—	5
Net loss	—	—	—	(5,098)	(5,098)
Balance at June 30, 2023	35,642	3	442,381	(323,785)	118,599
Issuance of common stock from at the market offering, net of issuance costs of $29	15	—	30	—	30
Stock-based compensation expense	—	—	2,097	—	2,097
Stock option exercises	1	—	2	—	2
Net loss	—	—	—	(8,285)	(8,285)
Balance at September 30, 2023	35,658	$ 3	$444,510	$(332,070)	$ 112,443

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance at December 31, 2021	27,608	$ 2	$405,680	$(252,895)	$ 152,787

	Common Stock

	Common Stock

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares				
Balance at December 31, 2022					
Balance at December 31, 2022					
Balance at December 31, 2022					

Issuance of common stock from at the market offering, net of issuance cost of $370						
Stock-based compensation expense	Stock-based compensation expense	—	—	1,745	—	1,745
Stock option exercises		46	—	129	—	129
Stock-based compensation expense						
Stock-based compensation expense						
Net loss	Net loss	—	—	—	(15,343)	(15,343)
Balance at March 31, 2022		27,654	2	407,554	(268,238)	139,318
Issuance of common stock from at the market offering, net of issuance costs of $314		801	—	3,339	—	3,339
Stock-based compensation expense		—	—	1,777	—	1,777
Stock option exercises		1	—	1	—	1
Net loss	Net loss	—	—	—	(14,594)	(14,594)
Balance at June 30, 2022		28,456	2	412,671	(282,832)	129,841
Issuance of common stock from at the market offering, net of issuance costs of $87		2,248	1	11,019	—	11,020
Stock-based compensation expense		—	—	1,936	—	1,936
Stock option exercises		32	—	93	—	93
Net loss	Net loss	—	—	—	(11,943)	(11,943)
Balance at September 30, 2022		30,736	$ 3	$425,719	$(294,775)	$ 130,947
Balance at March 31, 2023						

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,	
	2023	2022
Operating activities:		
Net loss	$ (25,365)	$ (41,880)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	6,135	5,458
Depreciation expense	1,304	687
Non-cash interest expense	181	—
Non-cash lease expense	1,212	1,265
Change in fair value of success payment liability	(1,030)	253
Amortization of debt issuance costs	60	—
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	596	(3,398)

	Three Months Ended March 31,	
	2024	2023
Operating activities:		
Net loss	$ (25,365)	$ (41,880)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	6,135	5,458
Depreciation expense	1,304	687
Non-cash interest expense	181	—
Non-cash lease expense	1,212	1,265
Change in fair value of success payment liability	(1,030)	253
Amortization of debt issuance costs	60	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	596	(3,398)

Prepaid expenses and other assets			
Other receivables	Other receivables	1,017	(4,300)
Other non-current assets		136	(1,204)
Accounts payable		241	(778)
Accrued expenses and other current liabilities		(5,338)	4,677
Accounts payable, accrued expenses and other liabilities			
Accounts payable, accrued expenses and other liabilities			
Accounts payable, accrued expenses and other liabilities			
Deferred revenue			
Deferred revenue			
Deferred revenue	Deferred revenue	(5,258)	10,801
Operating lease liability	Operating lease liability	(1,727)	(498)
Other liabilities		(191)	191
Net cash used in operating activities			
Net cash used in operating activities			
Net cash used in operating activities	Net cash used in operating activities	(28,027)	(28,726)
Investing activities:	**Investing activities:**		
Purchases of property and equipment	Purchases of property and equipment	(571)	(3,093)
Purchases of property and equipment			
Purchases of property and equipment			
Net cash used in investing activities	Net cash used in investing activities	(571)	(3,093)
Financing activities:	**Financing activities:**		
Proceeds from at the market offering of common stock, net of issuance costs			

Proceeds from at the market offering of common stock, net of issuance costs			
Proceeds from at the market offering of common stock, net of issuance costs			
Proceeds from drawdown of term loans			
Proceeds from at the market offering of common stock		9,447	14,761
Proceeds from drawdown of term loans		40,000	—
Payment of equity issuance costs		(143)	(341)
Proceeds from issuances under Employee Stock Purchase Plan		45	—
Proceeds from stock option exercises	Proceeds from stock option exercises	7	230
Proceeds from stock option exercises			
Proceeds from stock option exercises			
Net cash provided by financing activities	Net cash provided by financing activities	49,356	14,650
Net increase (decrease) in cash, cash equivalents and restricted cash and cash equivalents		20,758	(17,169)
Net cash provided by financing activities			
Net cash provided by financing activities			
Net increase in cash, cash equivalents and restricted cash and cash equivalents			
Cash, cash equivalents and restricted cash and cash equivalents—beginning of period	Cash, cash equivalents and restricted cash and cash equivalents—beginning of period	130,529	158,830

Cash, cash equivalents and restricted cash and cash equivalents—end of period	Cash, cash equivalents and restricted cash and cash equivalents—end of period	$151,287	$141,661
Reconciliation of cash, cash equivalents and restricted cash and cash equivalents to the condensed consolidated balance sheets			
Reconciliation of cash, cash equivalents and restricted cash and cash equivalents to the condensed consolidated balance sheets			
Reconciliation of cash, cash equivalents and restricted cash and cash equivalents to the condensed consolidated balance sheets			
Cash and cash equivalents			
Cash and cash equivalents			
Cash and cash equivalents			
Prepaid expenses and other current assets			
Restricted cash and cash equivalents, net of current portion			
Total cash, cash equivalents and restricted cash and cash equivalents			
Supplemental disclosure of cash flow information:	**Supplemental disclosure of cash flow information:**		
Supplemental disclosure of cash flow information:			
Supplemental disclosure of cash flow information:			
Cash paid for interest			
Cash paid for interest			

Cash paid for interest	Cash paid for interest	$ 1,646	$ —
Supplemental disclosure of non-cash investing and financing activities:	**Supplemental disclosure of non-cash investing and financing activities:**		
Purchases of property and equipment in accounts payable and accrued expenses	Purchases of property and equipment in accounts payable and accrued expenses	$ 198	$ 307
Purchases of property and equipment in accounts payable and accrued expenses			
Purchases of property and equipment in accounts payable and accrued expenses			
Issuance costs in accounts payable and accrued expenses	Issuance costs in accounts payable and accrued expenses	$ 24	$ 61
Stock option exercise receivables in prepaid expenses and other current assets		$ —	$ (7)
Leasehold improvements paid by landlord		$ —	$ 5,444

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. (“Werewolf” or the “Company”) was incorporated in the state of Delaware in October 2017. The Company is As used throughout these unaudited, condensed consolidated financial statements, the terms “Werewolf,” “we,” “us,” and “our” refer to the business of Werewolf Therapeutics, Inc., and its wholly owned subsidiary. We are an innovative biopharmaceutical company pioneering the development of therapeutics engineered to stimulate the body’s immune system for the treatment of cancer. The Company’s Our headquarters are located in Watertown, Massachusetts.

Since inception, the Company has we have devoted substantially all of its time our efforts and efforts financial resources to performing 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 activities, raising capital and recruiting management and technical staff to support these operations. The Company is 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 the Company's our product development efforts are successful, it is uncertain when, if ever, the Company we will realize significant revenue from product sales.

The Company We had cash and cash equivalents of $130.1 million $139.2 million at September 30, 2023 March 31, 2024. The Company expects We expect that its our cash and cash equivalents will enable it us to fund its our operating expenses and capital expenditure requirements for at least twelve months from the date of issuance of the condensed consolidated financial statements in this Form 10-Q. However, additional funding will be necessary beyond this point to fund future preclinical and clinical activities. The Company expects We expect to finance its our future cash needs through a combination of equity or debt financings, collaboration agreements, strategic alliances and licensing arrangements.

2. Summary of Significant Accounting Policies

Basis of Presentation and Consolidation

The accompanying condensed consolidated financial statements as of September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023, and for the three and nine months ended September 30, 2023 March 31, 2024 and 2022, 2023, have been prepared in accordance with the rules and regulations of the Securities and Exchange Commission (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 the Company's our financial position and results of its 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 the Company's our Annual Report on Form 10-K for the year ended December 31, 2022 December 31, 2023 filed with the SEC on March 23, 2023 March 7, 2024 (the "2022 "2023 Annual Report").

The information presented in the condensed consolidated financial statements and related notes as of September 30, 2023 March 31, 2024, and for the three and nine months ended September 30, 2023 March 31, 2024 and 2022, 2023, is unaudited. The December 31, 2022 December 31, 2023 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, 2023 March 31, 2024 are not necessarily indicative of the results that may be expected for the fiscal year ending December 31, 2023 December 31, 2024, or any future period.

The accompanying condensed consolidated financial statements include the accounts of Werewolf Therapeutics, Inc. and its wholly owned subsidiary, Werewolf Therapeutics Mass Securities, Inc. 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 the Company's our audited financial statements as of and for the year ended December 31, 2022 December 31, 2023, and the notes thereto, which are included in the 2022 2023 Annual Report. There have been no material changes in the Company's our significant accounting policies during the nine three months ended September 30, 2023 March 31, 2024.

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. On an ongoing basis, the Company's management evaluates its Significant estimates and judgments including, assumptions reflected in these condensed consolidated financial statements include, but are not limited to, those related to revenue recognition, accrued expenses, assumptions used in the valuation of stock-based compensation expense and income taxes. Actual results could differ from those estimates.

Recent Accounting Pronouncements

Accounting In December 2023, the FASB issued ASU No. 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures ("ASU No. 2023-09"), which enhances the transparency and decision usefulness of income tax disclosures primarily related to rate reconciliation and income taxes paid. The provisions of ASU No. 2023-09 are effective for fiscal years beginning after December 15, 2024, with early adoption permitted, and are required to be applied on a prospective basis. Our management is 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 the Company's condensed our consolidated financial statements upon adoption.

Subsequent Events

The Company has We have evaluated subsequent events and transactions that occurred in the period from 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, the Company we did not identify any subsequent events that require adjustment or disclosure in the condensed consolidated financial statements.

3. Jazz Collaboration and License Agreement

In April 2022, Detailed description of the Company entered into an contractual terms and our accounting for the agreement described below is included in our audited financial statements and notes in the 2023 Annual Report.

During the three months ended March 31, 2024, we continued to perform under our exclusive global collaboration and license agreement (the "Collaboration Agreement") with Jazz Pharmaceuticals Ireland Limited ("Jazz" ("Jazz"), pursuant to which we recognize revenue utilizing the Company granted Jazz certain licenses to develop and commercialize products containing cost-to-cost input method, which best depicts the Company's Interferon alpha ("IFNα") INDUKINE™ molecule, JZP898 (formerly WTX-613), 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, the Company is responsible for certain pre-clinical development activities with respect to JZP898 and other development activities specified in mutually agreed upon development plans. Jazz will generally reimburse the Company for the cost of such activities. Jazz will be 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"). Jazz received IND application clearance for JZP898 in July 2023.

Under the terms of the Collaboration Agreement, the Company received a non-refundable upfront cash payment of $15.0 million in April 2022 and a variable consideration payment of $5.0 million in July 2023, which is included in the overall transaction price as described below.

Milestones and Royalties

The Company is eligible to receive up to $520.0 million in development and regulatory milestones, and up to $740.0 million in sales-based milestones for all Licensed Products. In addition, the Company is eligible to receive tiered mid-single digit royalties based on Jazz's, and any of its affiliates' and sublicensees' annual net sales of Licensed Products, subject to reduction in specified circumstances.

As of September 30, 2023, the Company has not recognized any revenue related to sales-based milestones.

Accounting Analysis under ASC 606

Identification of the Contract(s)

The Company assessed the Collaboration Agreement and concluded that it represents a contract with a customer within the scope of ASC Topic 606, *Revenue from Contracts with Customers*.

Identification of Promises and Performance Obligations

The Company has concluded that the exclusive license to its intellectual property, JZP898, and the non-exclusive corresponding "know-how" are not capable of being distinct from the other promises within the contract, and as such, the Company has determined that the license and "know-how" combined with the other research and development services and supply represent performed for the customer. As a single combined performance obligation.

Determination of Transaction Price

The overall transaction price as of the inception of the contract was determined to be $32.3 million, which is comprised of the nonrefundable upfront payment of $15.0 million and the estimated costs for research services of $17.3 million. Outside of the estimated costs for research services, there is no other variable consideration included in the transaction price at inception. The Company used the most likely amount method to estimate variable consideration and estimated that the most likely amount for each potential development and regulatory milestone payment under this agreement was zero at the inception of the contract, as achievement of those milestones was uncertain and highly susceptible to factors outside the Company's control. Accordingly, all such milestone payments were excluded result, we recognize revenue from the transaction price at inception of contract. Management reevaluates the transaction price at the end of each reporting period, including developing a revised estimate for over time as research

and development services are performed. The following table summarizes research and development costs incurred and the most likely amount for each potential development and regulatory milestone, and as uncertain events are resolved or other changes revenue recognized in circumstances occur, adjusts the transaction price as necessary. Sales based royalties, including milestones based on the level of sales, were also excluded from the transaction price, as the license is deemed to be the predominant item to which the royalties relate. The Company will recognize such revenue at the later of (i) when the related sales occur, or (ii) when the connection with our performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied).

The upfront payment of $15.0 million was recorded as deferred revenue and, along with payments related to the Company's conduct of research services under the Collaboration Agreement or any development and regulatory milestones, will be recognized as revenue using an input-based measurement of actual costs incurred as a percentage of Agreement:

	Three Months Ended March 31,	
	2024	2023
	(in thousands)	
Revenue recognized	$ 742	$ 4,464
Cost incurred	$ 335	$ 2,121

The following table presents changes in our contract liabilities during the estimated total costs expected to be incurred over the expected term of conduct of the research services. The Company believes this input-based method to recognize revenue best reflects the transfer of value to Jazz. three months ended March 31, 2024:

	Balance as of December 31, 2023	Additions	Reductions	Balance as of March 31, 2024
		(in thousands)		
Contract liabilities:				
Deferred revenue	$ 1,340	$ —	$ (407)	$ 933
Total contract liabilities	$ 1,340	$ —	$ (407)	$ 933

The remaining deferred revenue is expected to be recognized as revenue over a term of approximately 2.5 2.1 years.

Recognition of Revenue

For the nine months ended September 30, 2023, using the cost-to-cost input method, which best depicts the research services performed for the customer, the Company recognized $18.4 million of revenue related to the Collaboration Agreement. During the three and nine months ended September 30, 2023, the Company determined that a variable consideration payment totaling $5.0 million was likely to be achieved and accordingly revised its estimate of the overall transaction price to include this amount. During the three and nine months ended September 30, 2023, the Company recognized a cumulative catch-up of revenue of $4.2 million related to the increase to the overall transaction price of $5.0 million, based on the cost-to-cost input method discussed above. As of September 30, 2023, there is $1.8 million and $0.6 million of current and non-current deferred revenue, respectively, related to the Collaboration Agreement. As of December 31, 2022, there was $6.5 million and $1.1 million of current and non-current deferred revenue, respectively, related to the Collaboration Agreement. All costs associated with the Collaboration Agreement are recorded in research and development expense in the condensed consolidated statements of operations.

Unbilled receivables related to the Collaboration Agreement of $0.9 $0.3 million and $4.1 million is included within other receivables in the accompanying condensed consolidated balance sheets as of September 30, 2023 and December 31, 2022, respectively. Receivables related to the Collaboration Agreement of $5.0 million and $2.8 $0.4 million are included within other receivables in the accompanying condensed consolidated balance sheets as of September 30, 2023 March 31, 2024 and December 31, 2022 December 31, 2023, respectively. Receivables related to the Collaboration Agreement of $0.4 million and $0.9 million are included within other receivables in the accompanying condensed consolidated balance sheets as of March 31, 2024 and December 31, 2023, respectively. Revenue recognized during the three months ended March 31, 2024 and 2023, includes $0.4 million and $2.3 million of revenue that was included in deferred revenue as of December 31, 2023 and 2022, respectively.

The following table presents

At the end of each reporting period, we re-evaluate our estimate of the transaction price associated with the Collaboration Agreement and determine if variable consideration previously excluded from the transaction should be included in the transaction price based on changes in circumstances, if any. During the Company's contract liabilities during the nine three months ended September 30, 2023 (in thousands):

	Balance as of December 31, 2022	Additions	Reductions	Balance as of September 30, 2023
Contract liabilities:				
Deferred revenue	$ 7,660	$ 5,000	$ (10,258)	$ 2,402
Totals	$ 7,660	$ 5,000	$ (10,258)	$ 2,402

March 31, 2024 and 2023, we did not recognize any adjustment to the transaction price associated with variable consideration previously excluded from the transaction price.

As of September 30, 2023 March 31, 2024, the Company has we have not received any royalty payments under the Collaboration Agreement.

4. Financial Instruments and Fair Value Measurements

Fair value is an exit price, representing the amount that would be received from the sale of an asset or paid to transfer a liability in an orderly transaction between market participants. Fair value is determined based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect certain market assumptions. As a basis for considering such assumptions, GAAP establishes a three-tier value hierarchy, which prioritizes the inputs used to develop the assumptions and for measuring fair value as follows: (Level 1) observable inputs such as quoted prices in active markets for identical assets; (Level 2) inputs other than the quoted prices in active markets Our assets that are observable either directly or indirectly; and (Level 3) unobservable inputs in which there is little or no market data, which requires the Company required to develop its own assumptions. This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value.

The Company's financial instruments that are be measured at fair value on a recurring basis consist of money market funds, classified as cash, cash equivalents and restricted cash and cash equivalents on the Company's our condensed consolidated balance

sheets as March 31, 2024 and a success payment liability pursuant December 31, 2023. We did not have any liabilities that are required to an amended and restated loan and security agreement (the "Loan Agreement") with Pacific Western Bank ("PWB") (see Note 7, *Term Loan*).

The Company measures the be measured at fair value on a recurring basis as of money market funds based on quoted prices in active markets for identical securities. March 31, 2024 or December 31, 2023.

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, 2023 March 31, 2024 were as follows (in thousands): follows:

	Level 1	Level 2	Level 3	Total
	Level 1	Level 2	Level 3	Total
	(in thousands)			
Assets:	Assets:			
Money market funds				
Money market funds				
Money market funds	Money market funds	$144,740	$—	$—	$144,740
Total assets	Total assets	$144,740	$—	$—	$144,740

Assets and liabilities measured at fair value on a recurring basis as of December 31, 2022 December 31, 2023 were as follows (in thousands): follows:

	Level 1	Level 2	Level 3	Total
Assets:				

Money market funds	$ 128,812	$ —	$ —	$ 128,812
Total assets	$ 128,812	$ —	$ —	$ 128,812
Liabilities				
Success payment liability	$ —	$ —	$ 570	$ 570
Total liabilities	$ —	$ —	$ 570	$ 570

The success payment liability was included within accrued expenses and other current liabilities in the accompanying condensed consolidated balance sheets as of December 31, 2022.

	Level 1	Level 2	Level 3	Total
		(in thousands)		
Assets:				
Money market funds	$ 149,294	$ —	$ —	$ 149,294
Total assets	$ 149,294	$ —	$ —	$ 149,294

There were no changes in valuation techniques during the three or nine months ended September 30, 2023. There were no liabilities measured at fair value on a recurring basis as of September 30, 2023 March 31, 2024.

Success Payment Liability

The Company was We have entered into an amended and restated loan and security agreement (the "PWB Loan Agreement") with Pacific Western Bank ("PWB"), as described below in Note 6. In conjunction with the PWB Loan Agreement, we became obligated to pay to PWB a one-time success payment of up to $1.6 million (the "Success Fee") upon the occurrence of the Company achieving certain conditions defined in the PWB Loan Agreement. Agreement (the "Success Fee Event"). The Success Fee Event (as defined in the Loan Agreement) occurred during the second quarter of 2023, resulting in the immediate payment in full of the required Success Fee (as defined in Note 7 below). Fee.

The following table reconciles Prior to the change in fair value occurrence of the Success Fee Event, we recognized a success payment liability during the nine months ended September 30, 2023 based on Level 3 inputs (in thousands):

	Nine Months Ended September 30, 2023
Balance at December 31, 2022	$ 570
Additions	—
Change in fair value	1,030
Payment at Success Event	(1,600)
Balance at September 30, 2023	$ —

The success payment liability is that was stated at fair value and was previously considered Level 3 because its fair value measurement was based, in part, on significant inputs not observed in the market. Upon completion of the Success Fee Event, we paid the Company total $1.6 million success payment and removed the corresponding financial instrument for success payment liability. We remeasured the success payment liability at each reporting date and paid immediately prior to the total $1.6 million. Prior to repayment, Success Fee Event. During the Company remeasured three months ended March 31, 2023, we recognized expense of $1.0 million associated with the liability at change in the fair value with a corresponding increase of $1.0 million recorded to other expense, net for the nine months ended September 30, 2023.

5. Restricted Cash and Cash Equivalents

The Company maintained restricted cash and cash equivalents of $21.2 million and $1.2 million at September 30, 2023 and December 31, 2022, respectively. At September 30, 2023, $20.0 million of the restricted cash and cash equivalents balance represents an obligation under the term loan facility to maintain a minimum cash balance in the Company's PWB accounts. This became effective upon imminent achievement of the funding goal as required by the terms of the Loan Agreement (see Note 7, *Term Loan*). The remaining restricted cash amounts are comprised solely of letters of credit required pursuant to the

Company's leased office spaces. The current portion of restricted cash and cash equivalents success payment liability which is included in prepaid expenses and other current assets expense, net in the accompanying condensed consolidated balance sheets for all periods presented below (in thousands): statements of operations. We had no outstanding obligation associated with the Success Fee as of March 31, 2024 or December 31, 2023.

	Nine Months Ended September 30, 2023		Nine Months Ended September 30, 2022	
	Beginning of Period	End of Period	Beginning of Period	End of Period
Cash and cash equivalents	$ 129,315	$ 130,058	$ 157,531	$ 140,450
Restricted cash and cash equivalents, current	—	210	91	—
Restricted cash and cash equivalents, net of current portion	1,214	21,019	1,208	1,211
Cash, cash equivalents and restricted cash and cash equivalents	$ 130,529	$ 151,287	$ 158,830	$ 141,661

6. 5. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities as of September 30, 2023 and December 31, 2022 were comprised as follows (in thousands): follows:

	September 30, 2023	December 31, 2022
Manufacturing	$ 1,928	$ 6,674
Contract research	1,745	2,990
Employee compensation and benefits	2,666	3,135
Professional fees	678	613
Success payment liability	—	570
Accrued interest		
Other	950	170
Total accrued expenses and other current liabilities	$ 7,967	$ 14,152

	March 31, 2024	December 31, 2023
	(in thousands)	
Manufacturing	$2,119	$2,772
Employee compensation and benefits	1,350	3,627
Contract research	915	1,049
Professional fees	910	655
Total accrued expenses and other current liabilities	$6,215	$8,860

7. 6. Term Loan

In April 2022, the Company we entered into the PWB Loan Agreement with PWB. Under the terms of the PWB Loan Agreement, PWB made available a term loan in an aggregate principal amount of up to $20.0 million ("Tranche I Loan") available at any time after the closing date until February 28, 2024 as extended to August 31, 2024 upon the satisfaction of certain conditions set forth in the PWB Loan Agreement (such date, the

“Amortization Date”). Based on the satisfaction of certain conditions defined in the PWB Loan Agreement, PWB was also obligated to make available an additional term loan in the aggregate principal amount of up to $20.0 million (“Tranche II Loan”, or collectively with the Tranche I Loan, the “Term Loans”) available at any time after the closing date until the Amortization Date upon the acceptance by the U.S. Food and Drug Administration (the “FDA”) of two investigational new drug (“IND”) submissions on or before March 31, 2023. As of September 30, 2023 March 31, 2024, the Company has we have drawn down $40.0 million of the Term Loans.

The outstanding notes payable balance under the Term Loans as of September 30, 2023 consists of the following (in thousands): following:

	September 30, 2023 March 31, 2024
	(in thousands)
Note payable	$ 40,000
Unamortized debt discount and issuance costs	(769) (585)
Net carrying amount of note payable	39,231 39,415
Less: current portion of note payable	(1,667) (11,667)
Note payable, net, less current portion	$ 37,564 27,748

Subsequent to the interest-only period, which ends on August 31, 2024, the Company is we are required to make equal monthly principal payments plus interest until the Term Loans mature on August 31, 2026. The Term Loans will bear interest on the outstanding daily balance at a floating annual rate equal to greater of: (i) 0.5% above the prime rate then in effect or (ii) 4.5%. If the prime rate changes throughout the term, the interest rate will be adjusted effective on the date of the prime rate change. All interest chargeable under the PWB Loan Agreement is computed on a 360-day year for the actual number of days elapsed, with interest payable monthly. The Company We recognized interest expense related to the PWB Loan Agreement of $0.9 $1.0 million and $1.9 $0.2 million during the three and nine months ended September 30, 2023, March 31, 2024 and 2023, respectively.

The Company did not incur interest expense following table presents the total principal payments scheduled to become due during each of the three and nine months years ended September 30, 2022. December 31:

	Principal Payments
	(in thousands)
2024 (remaining as of March 31, 2024)	$ 6,667
2025	20,000
2026	13,333
	$ 40,000

The Company was We were obligated to pay PWB a one-time fee in the event of certain corporate transactions equal to either (i) the greater of (a) $0.2 million and (b) 2.0% of the amount drawn under the Term Loans, for a transaction occurring on or before

March 31, 2023, March 31, 2023, or (ii) for any transaction occurring thereafter, the greater of (a) $0.4 million and (b) 4.0% of the amount drawn under the Term

Loans (the “Success Fee”). The Success Fee Event occurred during the second quarter of 2023, resulting in the immediate payment in full of the $1.6 million required Success Fee.

All outstanding obligations under the PWB Loan Agreement are secured by the Company’s our personal property (exclusive of any intellectual property) and are subject to acceleration in the event of default. In the event of a late payment or default, the Company is we are obligated to pay a fee equal to 5.0% of such unpaid amounts. In connection with the PWB Loan Agreement, the Company is we are required to comply with certain negative covenants, which among other things, restrict the Company us from (i) incurring future debt or granting liens, (ii) effectuating a merger or

consolidation with or into any other business organization, (iii) paying dividends or making certain other distributions, (iv) selling or otherwise transferring its our assets, (v) making investments in any entities or instruments other than certain investments specified in the PWB Loan Agreement and (vi) making capitalized expenditures in excess of 125% of the amount provided for in the annual budget approved by the our board of directors. The PWB Loan Agreement also contains standard affirmative covenants, including with respect to the issuance of audited consolidated financial statements, insurance, and maintenance of good standing and government compliance in the Company's our state of formation. On or before September 30, 2023, the Company was we were required to raise aggregate gross cash process of at least $50.0 million from the sale or issuance of the Company's our equity or from strategic partnerships or any similar transaction. From after Since receipt of those proceeds, the Company is we are required to maintain at all times at least $20.0 million of otherwise unrestricted cash in accounts with PWB, which is included within restricted cash and cash equivalents, net of current portion on the Company's our condensed consolidated balance sheet as of September 30, 2023 March 31, 2024 and December 31, 2023. On April 17, 2023, the Company we achieved the $50.0 million funding milestone, triggering the corresponding $20.0 million cash covenant, full payment of the Success Fee of $1.6 million, and the updated Amortization Date of August 31, 2024.

PWB has the right to accelerate all of our outstanding obligations of under the Company under the PWB Loan Agreement or terminate any remaining Term Loan commitments in the event of a material adverse effect on (i) the our operations, business or financial condition, of the Company, (ii) the Company's our ability to repay any portion of the Term Loans or perform any of its our other obligations under the PWB Loan Agreement, and (iii) the Company's our interest in, or the value, perfection or priority of PWB's security interest in the collateral. As of September 30, 2023, the Company had drawn both Term Loans and had $40.0 million outstanding principal.

8. 7. Common and Preferred Stock

Common Stock

The Company is We are authorized to issue 200.0 million 200,000,000 shares of common stock. Common stockholders are entitled to dividends if and when declared by the Company's our board of directors. As of September 30, 2023 March 31, 2024, no dividends on common stock had been declared by the Company. us.

On May 10, 2022, the Company we entered into a Sales Agreement (the "Sales Agreement") with Leerink Partners LLC ("Leerink" Leerink Partners"), formerly known as SVB Securities LLC, pursuant to which the Company we may offer and sell shares of its our common stock with an aggregate offering price of up to $50.0 million (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. As We were initially entitled to offer and sell shares of September 30, 2023, the Company had sold our common stock having an aggregate offering price of 7,938,848 shares under up to $50.0 million in the ATM Offering Offering. On February 9, 2024, we filed a prospectus supplement (the "Prospectus Supplement") under our shelf registration statement for the offer and sale of shares of our common stock having an offering price of up to an additional $25.0 million in the ATM Offering. Following our filing of the Prospectus Supplement, we are now entitled to offer and sell shares of our common stock with an aggregate offering price of up to $75.0 million pursuant to the Sales Agreement. During the three months ended March 31, 2024, we sold 4,169,324 shares of our common stock at an average price of $3.33 $5.05 per share for net proceeds of $25.0 million $20.1 million after deducting sales commissions and offering expenses. During the three months ended March 31, 2023, we sold 3,824,249 shares of our common stock at an average price of $2.35 per share for net proceeds of $8.6 million after deducting sales commissions and offering expenses.

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

	As of March 31, 2024	As of December 31, 2023
Shares reserved for exercises of outstanding stock options	7,450,864	5,700,070
Shares reserved for vesting of restricted stock units	361,500	361,500
Shares reserved for exercises of warrants	58,904	58,904
Shares reserved for future issuance under the 2021 Employee Stock Purchase Plan	507,113	507,113
Shares reserved for future issuance under the 2021 Stock Incentive Plan	2,110,219	1,911,660
Total shares reserved for future issuance	10,488,600	8,539,247

Preferred Stock

The Company is We are authorized to issue 5.0 million 5,000,000 shares of undesignated preferred stock in one or more series. As of September 30, 2023 March 31, 2024, no shares of preferred stock were issued or outstanding.

Shares Reserved for Future Issuance

The Company had reserved shares of common stock for issuance as follows (in thousands):

	As of September 30,	As of December 31,

	2023	2022
Shares reserved for exercises of outstanding stock options	6,480	5,244
Shares reserved for vesting of restricted stock units	317	323
Shares reserved for exercises of warrants	59	59
Shares reserved for future issuance under the 2021 Employee Stock Purchase Plan	530	244
Shares reserved for future issuance under the 2021 Stock Incentive Plan	1,281	939
Total shares reserved for future issuance	8,667	6,809

9.

8. Stock-based Compensation

2017 Stock Incentive Plan

In December 2017, the Company we adopted the 2017 Stock Incentive Plan (the (as amended and restated, the "2017 Plan"), as amended and restated, under which it we could grant incentive stock options ("ISOs"), non-qualified stock options, restricted stock awards ("RSAs"), restricted stock units ("RSUs"), stock appreciation rights and other stock-based awards to eligible employees, officers, directors and consultants. The terms of stock options and RSAs, including vesting requirements, are were determined by the our board of directors, subject to the provisions of the 2017 Plan.

2021 Stock Incentive Plan

In April 2021, the our board of directors adopted and the Company's our stockholders approved the 2021 Stock Incentive Plan (the "2021 Plan"), which became effective immediately prior to the effectiveness of the Company's our initial public offering ("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 ISOs, non-qualified stock options, RSAs, RSUs, stock appreciation rights and other stock-based awards. The Company's 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 the our board of directors, subject to the provisions of the 2021 Plan.

The Company 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 the Company 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 ended 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 outstanding common stock on such date and (ii) such amount as determined by the our board of directors. Effective January 1, 2022 and 2023, 1,380,397 and 1,575,753 As of March 31, 2024, a total of 4,911,502 additional shares respectively, were automatically have been added to the total shares reserved authorized for issuance under the 2021 Plan pursuant to this evergreen provision. in accordance with these terms.

As of September 30, 2023 March 31, 2024, there were 1,281,089 2,110,219 shares available for future issuance under the 2021 Plan.

2021 Employee Stock Purchase Plan

In April 2021, the board of directors adopted and the Company's stockholders approved the 2021 Employee Stock Purchase Plan (the "2021 ESPP"), which became effective immediately prior to the effectiveness of the IPO. The Company initially reserved 244,000 shares of common stock for future issuance under the 2021 ESPP. The 2021 ESPP provides that an additional number permits eligible employees to purchase shares of shares will automatically be added to the shares reserved for issuance on 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 fiscal year, beginning with offering period, each employee who is enrolled in the fiscal year ending December 31, 2022 and continuing for each fiscal year until, and including, the fiscal year ending on December 31, 2032. The 2021 ESPP will automatically receive an option to purchase up to a whole number of shares added of our common stock. The purchase price of each year of the shares purchased, in a given purchase period, will be equal to the lowest of (i) 488,000 shares of common stock, (ii) 1% 85% of the number lesser of shares of outstanding common stock on such date, and (iii) such amount as determined by the board of directors. Effective January 1, 2023, 315,150 additional shares were automatically added to the shares reserved for issuance under the 2021 ESPP pursuant to the evergreen provision. The Company initiated its first offering period under the 2021 ESPP in December 2022.

The 2021 ESPP provides that eligible employees may contribute up to 15% of their eligible earnings toward the semi-annual purchase of the Company's common stock. The 2021 ESPP is qualified under Section 423 of the Internal Revenue Code. The employee's purchase price is derived

from a formula based on the closing price of the a share of our common stock on (i) the first day of the offering period, versus the closing price on the last date of purchase (or, if not a trading day, on the immediately preceding trading day). The offering period under the 2021 ESPP has a duration of six months, and the purchase price with respect to each offering period beginning on or after such date is, until otherwise amended, equal to 85% of the lesser of (i) the fair market value of the Company's common stock at the commencement of the applicable six-month offering period or (ii) the fair market value last day of the Company's offering period. During the three months ended March 31, 2024 and 2023, no shares of our common stock on the purchase date. The Company estimates the fair value were purchased by participants of the common stock under the 2021 ESPP using a Black-Scholes valuation model. For the three and nine months ended September 30, 2023, the fair value of common stock awarded was estimated on the date of grant using the Black-Scholes option valuation model and the straight-line attribution approach with the following assumptions: risk-free interest rate (3.8%); expected term (0.5 years); expected volatility (92.7%); and an expected dividend yield (0%). The Company recorded less than $0.1 million of stock-based compensation under the 2021 ESPP for the three and nine months ended September 30, 2023. As of September 30, 2023, there was unrecognized stock-based compensation expense of less than $0.1 million related to the most recent ESPP offering period, which ended May 31, 2023.

ESPP.

Stock-Based Compensation Expense

Total stock-based compensation expense recognized in the condensed consolidated statements of operations was as follows (in thousands): follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	Three Months Ended March 31,			
	Three Months Ended March 31,			
	Three Months Ended March 31,			
	2024			
	2024			
	2024			
	(in thousands)			
	(in thousands)			
	(in thousands)			
Research and development				
Research and development				
Research and development	Research and development	$ 1,008	$ 909	$ 3,047	$ 2,496
General and administrative	General and administrative	1,089	1,027	3,088	2,962
General and administrative				
General and administrative				
Total stock-based compensation	Total stock-based compensation	$ 2,097	$ 1,936	$ 6,135	$ 5,458
Total stock-based compensation				
Total stock-based compensation				

RSA Activity

The Company We may, at its our discretion, repurchase unvested shares of restricted stock issued pursuant to the 2017 Plan at the initial purchase price if the employees or non-employees terminate their service relationship with the Company. us. The shares are recorded in stockholders' deficit as

they vest.

The following table summarizes RSA activity during the nine months ended September 30, 2023 (in thousands, except per share amounts):

	Shares/Units	Weighted-Average Grant Date Fair Value Per Share
Unvested at December 31, 2022	81	$ 1.38
Granted	—	$ —
Vested	(81)	$ 1.38
Forfeited	—	$ —
Unvested at September 30, 2023	—	$ —

As of September 30, 2023 December 31, 2023, there was all RSAs granted to employees or non-employees had become fully vested or had been previously forfeited. No RSAs were granted during the three months ended March 31, 2024. Accordingly, we had no unrecognized stock-based compensation expense related to unvested RSAs. RSAs as of March 31, 2024.

No RSAs vested during the three months ended September 30, 2023. The aggregate fair value of RSAs that vested during the three months ended September 30, 2022 March 31, 2023, based upon the fair values of the stock underlying the RSAs on the day date of vesting, was $0.3 million $0.1 million. The aggregate fair value of RSAs that vested during the nine months ended September 30, 2023 and 2022, based upon the fair values of the stock underlying the RSAs on the day of vesting, was $0.2 million and $1.0 million, respectively.

RSU Activity

The Company has also We have granted RSUs to its our employees under the 2021 Plan. The following table summarizes RSU activity during the nine three months ended September 30, 2023 (in thousands, except per share amounts) March 31, 2024:

	Shares/Units	Weighted-Average Grant Date Fair Value Per Share
Unvested at December 31, 2022	323	$ 4.32
Granted	—	$ —
Vested	—	$ —
Forfeited	(6)	$ 4.97
Unvested at September 30, 2023	317	$ 4.30

	Shares/Units (in thousands)	Shares/Units	Weighted-Average Grant Date Fair Value Per Share (in thousands)
Unvested at December 31, 2023			
Granted			
Vested			
Forfeited			
Unvested at March 31, 2024			

As of September 30, 2023 March 31, 2024, there was we had unrecognized stock-based compensation expense related to unvested RSUs of $0.4 million $0.3 million, which the Company expects we expect to recognize over a weighted-average period of approximately 0.5 year. 0.4 years.

No RSUs vested during the three or nine months ended September 30, 2023 March 31, 2024 or 2022. 2023.

Stock Option Activity

During the three months year ended September 30, 2022 December 31, 2022, the Company we granted performance-based stock options to certain executive officers for the purchase of an aggregate of 883,352 shares of common stock with a grant date fair value of $3.36 per share. These stock options vest would have vested only upon achievement of specified performance targets related to certain business objectives on or before December 31, 2023. As of September 30, 2023 March 31, 2023, none of these options were vested because none of the specified performance targets had been achieved. Because achievement of the specified performance targets was not deemed probable as of September 30, 2023 March 31, 2023, the Company has we did not recorded record any expense for these stock options from during the date three months ended March 31, 2023. As of issuance through September 30, 2023. During December 31, 2023, the second quarter of 2023, 101,447 of the performance-based stock options were forfeited by an executive who retired from the Company. The total unrecognized stock-based compensation expense for the remaining specified performance targets had not been achieved, and accordingly, all outstanding performance-based stock options is $2.6 million as of September 30, 2023 expired without vesting. No additional performance-based stock options have been granted during the three months ended March 31, 2024.

The fair value of stock options granted during the three and nine months ended September 30, 2023 March 31, 2024 and 2022 2023 was calculated on the date of grant using the following weighted-average assumptions:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
	Three Months Ended March 31,			
	Three Months Ended March 31,			
	Three Months Ended March 31,			
	2024			
	2024			
	2024			
Risk-free interest rate				
Risk-free interest rate				
Risk-free interest rate	Risk-free interest rate	4.3 %	2.9 %	3.9 %	2.3 %
Expected term (in years)	Expected term (in years)	6.0	9.8	6.0	7.6
Dividend yield		— %	— %	— %	— %
Expected term (in years)					
Expected term (in years)					
Expected annual dividend yield					
Expected annual dividend yield					
Expected annual dividend yield					
Expected volatility	Expected volatility	84.8 %	77.9 %	82.7 %	77.0 %
Expected volatility					
Expected volatility					

Using the Black-Scholes option pricing model, the weighted-average grant date fair value of stock options granted during the three months ended September 30, 2023 March 31, 2024 and 2022 2023 was $1.91 $3.59 and $3.35 $1.48 per share, respectively. Using the Black-Scholes option pricing model, the weighted-average grant date fair value of stock options granted during the nine months ended September 30, 2023 and 2022 was $1.56 and $5.00 per share, respectively.

The following table summarizes stock option activity during the nine three months ended September 30, 2023 March 31, 2024:

	Options Outstanding		
	Number of Options (in thousands)	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (in years)
Outstanding at December 31, 2022	5,244	$ 7.86	8.34

	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, 2023				
Granted				
Granted	Granted	1,616	$ 2.16	
Exercised	Exercised	(3)	$ 1.98	
Exercised				
Exercised				
Cancelled	Cancelled	(377)	$ 5.82	
Outstanding at September 30, 2023		6,480	$ 6.56	8.14
Exercisable at September 30, 2023		2,831	$ 7.67	7.64
Cancelled				
Cancelled				
Outstanding at March 31, 2024				
Outstanding at March 31, 2024				
Outstanding at March 31, 2024				
Exercisable at March 31, 2024				

The aggregate intrinsic fair value of stock options exercised during the three months ended September 30, 2023 and 2022 March 31, 2024 was less than $0.1 million in both periods. The aggregate intrinsic fair value of nominal. There were no stock options exercised during the nine three

months ended September 30, 2023 and 2022 was less than $0.1 million and $0.4 million, respectively. March 31, 2023.

As of September 30, 2023 March 31, 2024, there was we had unrecognized stock-based compensation expense related to unvested stock options of $11.2 million $14.1 million, which the Company expects we expect to recognize over a weighted-average period of approximately 1.7 2.6 years.

10. 9. Related Parties

In May 2022, the Company we entered into a sublease agreement with Crossbow Therapeutics, Inc. ("Crossbow"), for which entities affiliated with MPM Capital ("MPM Capital") are also beneficial owners, to sublease the entirety of its our office and laboratory space in Cambridge, Massachusetts. Luke Evnin, Ph.D., the chair of the Company's our board of directors, co-founded MPM Capital and serves as Managing Director of MPM Capital. Briggs Morrison, who serves on the Company's our board of directors, serves as Executive Partner of MPM Capital and Chief Executive Officer of Crossbow. The term of the sublease agreement commenced in June 2022 and ends ended in March 2024, with no option to extend. The Company We received cash payments under its the sublease of approximately $1.2 million $0.4 million during the nine three months ended September 30, 2023 March 31, 2024. In addition, the Company we received $0.2 million from Crossbow in June 2022 as a security deposit that is included within accrued expenses and other current liabilities in the accompanying condensed consolidated balance sheets sheet as of September 30, 2023 March 31, 2024. Following the conclusion of the sublease agreement, the security deposit is expected to be remitted to Crossbow upon satisfactory inspection of the subleased premises.

11. 10. 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, unvested RSAs, unvested RSUs and warrants to purchase common stock are considered to be potentially dilutive securities,

however the following weighted-average amounts outstanding shares of common stock equivalents were excluded from the calculation of diluted net loss attributable to common stockholders per share because their effect would be anti-dilutive (in thousands): anti-dilutive:

	September 30,	
	2023	2022
Outstanding stock options	6,480	5,279
Unvested RSAs	—	126
Unvested RSUs	317	236
Warrants to purchase common stock	59	59
Total	6,856	5,700

March 31,		March 31,	
2024		2024	2023
Outstanding stock options	Outstanding stock options		
Unvested RSUs	Unvested RSUs		
Warrants to purchase common stock	Warrants to purchase common stock		
Commons stock to be issued under the 2021 ESPP Unvested RSAs			
Total	Total		

11. Subsequent Event

On May 2, 2024, we, as borrower, entered into a loan and security agreement (the "Loan Agreement") with K2 HealthVentures LLC, or K2HV ("K2HV," and together with any other lender from time to time, as the "Lenders"); K2HV, as administrative agent for the Lenders; and Ankara Trust Company, LLC, as collateral trustee for the Lenders. The Loan Agreement provides 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 upon closing and $5.0 million from the second tranche commitment. We used the $29.5 million in net loan proceeds received at closing, together with $10.5 million in existing cash, to repay all amounts outstanding under the PWB Loan Agreement in May 2024. A third tranche commitment of up to $10.0 million is available to be drawn at our option during certain availability periods, 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. A fourth tranche commitment of up to $20.0 million is available to be drawn down at our option through May 1, 2026 or if the third tranche is funded, May 1, 2027, subject to Lender's review of our clinical, financial and operating plan and subject to Lender's consent in its sole and absolute discretion.

The term loan matures on May 1, 2028, and we are obligated to make interest only payments for the first 24 months, or 36 months if the third tranche is funded, and then interest and equal principal payments for the next 24 or 12 months, as applicable. The term loan bears 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 may 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 are entitled and certain notice requirements. We were required to pay the Lenders' certain customary fees and expenses at closing and will be required to pay additional fees that may be due upon maturity or prepayment such as final payment fees and prepayment fees.

The Lenders may elect 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, at a conversion price of the lesser of $6.32 per share and the lowest effective price per share of our next equity financing, subject to customary adjustments and 9.99% and 19.99% beneficial ownership limitations. There will be no prepayment penalty for any principal amount converted into common stock. The Loan Agreement provides the Lenders with certain piggyback registration rights with respect to the shares of common stock issuable upon conversion of term loans under the Loan Agreement.

The Loan Agreement contains customary representations and warranties, events of default and affirmative and negative covenants, including covenants that limit or restrict our ability to, among other things, dispose of assets, make changes to the 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. As security for our obligations under the 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.

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 subject to certain exceptions and conditions.

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, 2022 December 31, 2023, or the 2022 2023 Annual Report on Form 10-K, that was filed with the United States Securities and Exchange Commission, or SEC, on March 23, 2023 March 7, 2024. 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 an innovative biopharmaceutical company pioneering the development of therapeutics engineered to stimulate the body's immune system for the treatment of cancer. We are leveraging 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 molecules, are intended to activate selectively in the tumor microenvironment. Our most advanced product candidates, WTX-

124 and WTX-330, are systemically delivered, conditionally activated Interleukin-2 and Interleukin-12, respectively, INDUKINE molecules for the treatment of multiple tumor types.

In the second quarter of 2022, we received clearance from the U.S. Food and Drug Administration, or the FDA, for our investigational new drug application, or IND, for WTX-124. In the third quarter of 2022, the first patient was dosed We are currently evaluating WTX-124 in a Phase 1/1b clinical trial to evaluate WTX-124 as a monotherapy and in combination with Merck's Merck & Co., Inc.'s anti-PD-1 therapy KEYTRUDA® KEYTRUDA (pembrolizumab) in patients with immunotherapy sensitive advanced or metastatic solid tumors who have failed standard of care treatment, including checkpoint inhibitor therapy. In November 2023, we announced preliminary first-in-human clinical data from the initial monotherapy dose-escalation cohorts in the Phase 1/1b clinical trial. The preliminary data established proof of mechanism for WTX-124 and proof of concept for our INDUKINE design, and included assessments of safety and tolerability, pharmacokinetics, relevant biomarkers and preliminary antitumor activity. The preliminary data included data collected as of October 18, 2023, from 16 heavily pretreated patients from the first four monotherapy dose escalation cohorts (1, 3, 6, and 12 mg), and supported supportive of continued dose escalation. Dose escalation is ongoing in the monotherapy and combination therapy arms of the trial. Additional In the first half of 2024, we expect to report updated interim data from the monotherapy dose-escalation cohorts will inform declaration arms of the Phase 1/1b clinical trial, select a recommended dose for expansion and opening of the initiate monotherapy dose expansion arms. We expect additional interim arms, and report initial data from the monotherapy combination dose escalation arm and cohorts of the recommended dose for expansion arm in the first half of 2024. Phase 1/1b clinical trial.

In the fourth quarter of 2022, we received clearance from the FDA for our IND for WTX-330. In the first quarter of 2023, the first patient was dosed We are also currently evaluating WTX-330 in a Phase 1 clinical trial to evaluate for the safety and tolerability treatment of WTX-330 in patients with immunotherapy resistant advanced or metastatic solid tumors or lymphoma, resistant to be followed by expansion arms in relapsed/refractory tumors following treatment with checkpoint inhibitors or tumors for which checkpoint inhibitors are not approved. We announced the initiation of patient dosing in February 2023. The trial is currently open for enrollment. We plan to report initial data from the Phase 1 clinical trial in the second quarter of 2024. During the three months ended March 31, 2024, we received alignment from the U.S. Food and Drug Administration, or the FDA, on the comparability path for WTX-330 for an improved manufacturing process, which we expect to integrate into our clinical development program.

In April 2022, we entered into a global collaboration and license agreement, or the Collaboration Agreement, with Jazz Pharmaceuticals Ireland Limited, or Jazz, pursuant under which Jazz acquired exclusive global development and commercialization rights related to which we granted Jazz certain licenses to develop and commercialize products containing our Interferon alpha, (IFNα) or IFNα, INDUKINE molecule, JZP898 (formerly WTX-613), as well as products containing certain isolated recombinant polypeptides comprising IFNα that meet specified criteria which we refer (each such product, a Licensed Product). Pursuant to as the Licensed Products. Under terms of the Collaboration Agreement, we are initially responsible for certain pre-clinical preclinical development activities with respect to JZP898 and other development activities specified in mutually agreed upon development plans. Jazz will generally reimburse us for the cost of such activities. Jazz is will be responsible for all other development and commercialization activities conducted to exploit the Licensed Products, including submission of an IND to the FDA. Products. Jazz received IND application clearance from the FDA for JZP898 in July 2023. Under 2023 and initiated a Phase 1 clinical trial of JZP898 in the terms fourth quarter of 2023.

We continue to further the Collaboration Agreement, we received an upfront payment development of $15.0 million in April 2022, and we are eligible to receive cost reimbursements for research services performed under the Collaboration Agreement. We are also eligible to receive up to $520.0 million our preclinical product candidates, WTX-518, a systemically delivered, conditionally activated Interleukin-18 INDUKINE molecule in development for the treatment of cancer designed to promote activation of immune cells in the tumor microenvironment, resulting in antitumor immunity, and regulatory milestones, WTX-712, a systemically delivered, conditionally activated Interleukin-21, or IL-21, INDUKINE molecule that is being developed to minimize the severe toxicities that have been observed with recombinant IL-21 therapy and up to $740.0 million in sales-based milestones for all Licensed Products. In addition, we are eligible to receive tiered mid-single digit royalties based on Jazz's, and any of its affiliates' and sublicensees', annual net sales of Licensed Products, subject to reduction in specified circumstances.

We were incorporated and commenced operations in 2017. Since inception, we have devoted substantially all of our time and efforts to performing research and development activities, raising capital and recruiting management and technical staff to support these operations. To date, we have financed our operations primarily with proceeds from the sales of our convertible maximize clinical benefit when administered as promissory notes monotherapy or in combination with checkpoint inhibitors in refractory and/or immunologically unresponsive tumors. In April 2024, we presented preclinical data for both WTX-518 and equity securities WTX-712 at the American Association for Cancer Research Annual Meeting. Our preclinical models demonstrate that WTX-518 exhibits remarkable tumor-selective activation, resistance to IL-18BP and from the upfront payment robust immune activation, while WTX-712 acts through a unique mechanism that we received from Jazz pursuant to the terms of the Collaboration Agreement. From December 2017 to August 2018, we issued convertible promissory notes for aggregate gross cash proceeds of $11.0 million. From August 2019 to June 2020, we issued an aggregate of 80,246,565 shares of Series A preferred stock for aggregate gross cash proceeds of $44.2 million, together with conversion of all of our previously issued convertible promissory notes. In December 2020, we issued 78,222,173 shares of Series B preferred stock at a price of $0.92 per share, resulting in gross cash proceeds of $72.1 million. On May 4, 2021, we completed our initial public offering, or IPO, pursuant to which we issued and sold 7,500,000 shares of our common stock at a public offering price of $16.00 per share. We received net proceeds of approximately $109.2 million, after deducting underwriting discounts and commissions and other offering expenses payable by us. On May 10, 2022, we entered into a sales agreement, or the Sales Agreement, with Leerink Partners LLC, or Leerink (formerly known

as SVB Securities LLC),pursuant to which we may offer and sell shares of our common stock robustly activates tumor-specific T lymphocytes with an aggregate offering price expanded therapeutic window through its selective release of up to $50.0 million, which we refer to as wild-type IL-21 in the ATM Offering. As of September 30, 2023, we had sold an aggregate of 7,938,848 shares under the ATM Offering at an average price of $3.33 per share for net proceeds of $25.0 million after deducting sales commissions and offering expenses.

Due to our significant research and development expenditures, we have accumulated substantial net losses since our inception. As of September 30, 2023, we had an accumulated deficit of $332.1 million. We expect to continue to incur substantial and increasing expenses and net losses for the foreseeable future, as we continue to advance our current and future product candidates through preclinical and clinical development, manufacture drug product and drug supply, seek regulatory approval for our current and future product candidates, maintain and expand our intellectual property portfolio, hire additional research and development and business personnel and operate as a public company.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations 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. 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.

Because of the numerous risks and uncertainties associated with product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to raise capital, maintain our research and development efforts, expand our business or continue our operations at planned levels, and as a result we may be forced to substantially reduce or terminate our operations. tumor microenvironment.

Financial Operations Overview

Revenue

We have not All of our revenue has been generated any revenue to date from product sales and do not expect to do so in the near future. Collaboration Agreement with Jazz. For the nine three months ended September 30, 2023 March 31, 2024, we recognized $18.4 million $0.7 million of revenue related to revenue. Revenue from the transaction price for the Collaboration Agreement is recognized based on a cost-to-cost input method and includes upfront, milestone, and cost reimbursement payments. The Collaboration Agreement includes multiple development and regulatory and sales-based milestones, which were excluded from the transaction price at inception of which $5.9 million related the Collaboration Agreement based on our assessment that there was a high level of uncertainty of achieving the milestones. During the three months ended March 31, 2024, we re-evaluated this assessment for any milestones that continue to be excluded from the transaction price, and concluded not to recognize any adjustment to the $15.0 million upfront payment received in April 2022, $8.1 million related to costs incurred for research services to be reimbursed by Jazz, and $4.4 million related to a transaction price associated with variable consideration payment. We had $2.4 million of deferred revenue as of September 30, 2023, which is classified as either current or net of current portion in our condensed consolidated balance sheets based on previously excluded from the period over which the revenue is expected to be recognized. As of September 30, 2023, we had not received any royalty payments under the Collaboration Agreement. transaction price.

In the future, we expect to continue our ability to generate revenue from the Collaboration Agreement will depend on successfully achieving the various development and regulatory and sales-based milestones, as well as incurring costs for research activities that are reimbursable by Jazz. We may also generate revenue from product sales or other collaboration agreements, strategic alliances and licensing arrangements. We expect that our potential future revenue, if any, will fluctuate from quarter-to-quarter and year-to-year based upon our pattern of performance under the Collaboration Agreement and as a result of the timing and amount of milestones, reimbursement of costs incurred and other payments and product sales, to the extent any are successfully commercialized. If we fail to complete the development of our product candidates in a timely manner or obtain regulatory approval for them, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected.

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 for the three and nine months ended September 30, 2023 and 2022 were as follows (in thousands): follows:

		Three Months Ended September 30,		Nine Months Ended September 30,	
		2023	2022	2023	2022
		Three Months Ended March 31,			
		Three Months Ended March 31,			
		Three Months Ended March 31,			
		2024			
		2024			
		2024			
		(in thousands)			
		(in thousands)			
		(in thousands)			
WTX-330					
WTX-124	WTX-124	$ 1,318	$ 1,644	$ 1,871	$ 6,913
WTX-330		1,839	3,224	2,491	8,586
JZP898 (formerly WTX-613)		791	2,224	6,960	4,406
WTX-124					
WTX-124					
JZP898					
JZP898					
JZP898					
WTX-712	WTX-712	347	—	965	—
WTX-712					
WTX-712					

WTX-518					
WTX-518					
WTX-518					
Pre-development candidates					
Pre-development candidates					
Pre-development candidates	Pre-development candidates	760	435	2,189	1,907
Total external development costs	Total external development costs	$ 5,055	$ 7,527	$ 14,476	$ 21,812
Total external development costs					
Total external development costs					

Research and development activities are central to our business model. We expect that our research and development expenses will continue to increase substantially for the foreseeable future as we progress our clinical trials of WTX-124 and WTX-330, complete pre-clinical requirements for continue preclinical development of WTX-712 and WTX-518, and continue to discover and develop additional product candidates. As a result of our entry into the Collaboration Agreement, which commenced in April 2022, our external preclinical development costs for JZP898 will generally be reimbursed by Jazz.

The decrease in development costs during the three months ended September 30, 2023, is primarily due to a decrease in manufacturing costs incurred with contract manufacturing organizations to support the production of preclinical, current, and future clinical trial materials for WTX-124 and WTX-330 as more fully described below under “Results of Operations – Research and Development Expenses.”

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. The actual probability of success for our product candidates will depend on a variety of factors, including:

- the scope, rate of progress and expenses of our ongoing research activities as well as any preclinical studies and clinical trials, including our ongoing Phase 1/1b clinical trial for WTX-124 and Phase 1 clinical trial for WTX-330, and 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 salaries, benefits and other related costs, including stock-based compensation, for personnel in our executive, finance, people operations, business development, legal, IT information technology and administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters; professional fees for accounting, auditing, 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.

We expect that our general and administrative expenses will increase in the future as we increase our personnel headcount to support the increasing size and complexity of our research, development and manufacturing activities.

Other Income

Other (Expense) Interest Income Net

Other (expense) Interest income net consists primarily of remeasurement gains or losses attributable to changes interest earned from cash and cash equivalents and restricted cash and cash equivalents invested in the fair value of the success payment liability associated with money market funds.

Interest Expense

Interest expense represents interest incurred from our debt loan agreement with Pacific Western Bank, or PWB, and non-cash interest expense related the amortization of debt issuance costs costs.

Other Expense, Net

Other expense, net primarily consists of foreign currency gains and losses related to our debt agreement with PWB. For more information see "Liquidity and Capital Resources" below.

Interest Income, Net

Interest income, net consists of interest income earned from our cash and cash equivalents, net of interest expense incurred from our Loan Agreement with PWB. services performed by foreign vendors.

Results of Operations

Comparison of the Three Months Ended September 30, 2023 March 31, 2024 and 2022 2023

The following table summarizes our results of operations operations:

	Three Months Ended March 31,		$ Change
	2024	2023	
	(in thousands)		
Revenue:			
Collaboration revenue	$ 742	$ 4,464	$ (3,722)
Operating expenses:			
Research and development	12,908	11,706	1,202
General and administrative	4,996	4,981	15
Total operating expenses	17,904	16,687	1,217
Operating loss	(17,162)	(12,223)	(4,939)
Other income:			
Interest income	1,973	1,519	454
Interest expense	(1,003)	(172)	(831)
Other expense, net	(1)	(1,106)	1,105
Total other income	969	241	728
Net loss	$ (16,193)	$ (11,982)	$ (4,211)

Revenue

Revenue was $0.7 million for the three months ended September 30, 2023 and 2022 (in thousands):

	Three Months Ended September 30,	$ Change

	2023	2022	
Revenue:			
Collaboration revenue	$ 5,897	$ 4,970	$ 927
Operating expenses:			
Research and development	10,838	13,070	(2,232)
General and administrative	4,310	4,439	(129)
Total operating expenses	15,148	17,509	(2,361)
Operating loss	(9,251)	(12,539)	3,288
Other income:			
Other (expense) income, net	(5)	3	(8)
Interest income, net	971	593	378
Total other income	966	596	370
Net loss	$ (8,285)	$ (11,943)	$ 3,658

Revenue

Revenue was $5.9 million for the three months ended September 30, 2023 March 31, 2024, which is comprised of partial recognition of the $15.0 million upfront payment received in April 2022 upon the execution of the Collaboration Agreement with Jazz, costs incurred for research services to be reimbursed by Jazz, and revenue related to the achievement of certain variable consideration components. Comparatively, we recognized $5.0 million $4.5 million in collaboration revenue during the three months ended September 30, 2022 March 31, 2023. This $0.9 million increase $3.7 million decrease in collaboration revenue is primarily driven by a change in the transaction price higher volume of $5.0 million development activity during the three months ended September 30, 2023, upon achieving a variable consideration component included March 31, 2023 in the Collaboration Agreement, which led to an additional recognition preparation of $4.4 million during the period. This increase was partially offset by a decline in revenue recognized as a result IND submission of a decrease in research and development activities related to JZP898.

Research and Development Expenses

The following table summarizes our research and development expenses for the three months ended September 30, 2023 and 2022 (in thousands): expenses:

		Three Months Ended September 30,			Three Months Ended March 31,	
		2023	2022	$ Change		$ Change
	2024					
		(in thousands)				
		(in thousands)				
		(in thousands)				
Personnel	Personnel	$ 3,635	$ 3,652	$ (17)		
Contract research		1,188	863	325		
Manufacturing						
Clinical trial costs						

Contract research organization				
Facility costs				
Lab consumables	Lab consumables	1,202	1,020	182
Clinical trial costs		1,715	665	1,050
Manufacturing		2,152	5,999	(3,847)
Facilities		777	662	115
Other	Other	169	209	(40)
Total research and development expenses	Total research and development expenses	$10,838	$13,070	$(2,232)

Research and development expenses for the three months ended September 30, 2023 March 31, 2024 were $10.8 million $12.9 million, compared to $13.1 million $11.7 million for the three months ended September 30, 2022 March 31, 2023. The decrease increase of $2.2 million $1.2 million was primarily due to:

- $3.8 1.2 million of decreased a combined increase in manufacturing costs of $0.9 million and clinical trial costs of $0.3 million. The increases in both our manufacturing and clinical trial costs are driven by an increase of $2.3 million in costs associated with our continued development efforts of WTX-124 and WTX-330, which continue to progress through their respective clinical trials, including manufacturing to support those clinical trials. This increase was partially offset by a decrease of $2.9 million $0.9 million in contract manufacturing costs associated with candidates WTX-124 and WTX-330 as these costs were higher in the prior period as we prepared for initiation of our clinical trials; likewise, contract manufacturing costs associated with JZP898, decreased by $0.9 million as these costs which were higher in during the prior period three months ended March 31, 2023 as we prepared for IND submission of JZP898.

The decrease was partially offset by:

- $1.1 million of increased clinical trial costs, primarily driven by continued expansion of sites and enrollment for both our WTX-124 and WTX-330 trials;
- $0.3 million of increased contract research costs driven primarily by proof-of-concept (or “POC”) costs in the current period for WTX-712; JZP898; and
- $0.2 0.5 million of increased personnel costs due to the timing and valuation of stock-based awards granted to employees, combined with annual cost of living adjustments.

These increases were partially offset by a decrease of $0.4 million in lab consumables costs primarily related due to expanded a shift in priorities from discovery efforts to a higher focus on furthering the research and headcount.

development of our existing product candidates.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the three months ended September 30, 2023 and 2022 (in thousands): expenses:

	Three Months Ended September 30,		$	Three Months Ended March 31,	
	2023	2022	Change	2024	$ Change

		(in thousands)		
		(in thousands)		
		(in thousands)		
Personnel	Personnel	$2,204	$2,214	$ (10)
Professional services	Professional services	1,024	837	187
Facility costs				
Corporate insurance	Corporate insurance	330	701	(371)
Facility costs		358	324	34
IT costs		174	142	32
Information technology costs				
Other	Other	220	221	(1)
Total general and administrative expenses	Total general and administrative expenses	$4,310	$4,439	$(129)

General and administrative expenses were $4.3 million $5.0 million for each of the three months ended September 30, 2023, compared to $4.4 million for the three months ended September 30, 2022. The decrease March 31, 2024 and 2023. Significant fluctuations in general and administrative expenses include:

- $0.4 million of $0.1 million was primarily due decreased corporate insurance costs, driven by a reduction in insurance premiums in the current period, which was offset in part associated premiums; and
- $0.2 million of increased professional services costs, driven by an increase in costs incurred to protect our intellectual property. property and general corporate matters.

Interest Income

Interest income was $2.0 million for the three months ended March 31, 2024, compared to $1.5 million for the three months ended March 31, 2023. This increase in interest income was primarily a result of higher yields on our cash equivalents during the three months ended March 31, 2024 compared to the three months ended March 31, 2023.

Interest Expense

During the three months ended March 31, 2024 we recognized interest expense of $0.9 million related to the unpaid principal balance of our term loans under the loan agreement with PWB, compared to $0.2 million of interest expense recognized during the three months ended March 31, 2023. Additionally, we recognized $0.1 million of non-cash interest related to the amortization of debt issuance costs during the three months ended March 31, 2024, compared to a nominal amount of non-cash interest recognized during the three months ended March 31, 2023. The increase in the total interest expense recognized during the three months ended March 31, 2024 compared to three months ended March 31, 2023 was due to the timing of when we drew down on our term loans, which occurred on March 15, 2023. Prior to drawing down on the term loans, we incurred no interest expense.

Other (Expense) Income, Expense, Net

Other (expense) income, expense, net for the three months ended September 30, 2023 March 31, 2023 primarily consisted of $1.0 million in losses recognized for the change in the fair value of the success payment liability during the period. As the success payment liability was settled during the second quarter of 2023, we incurred no such losses during the three months ended March 31, 2024. Other expense, net for the three months ended March 31, 2024 and 2022 consisted primarily 2023 also consists of foreign currency gains and losses related to services performed by foreign vendors. No material foreign currency gains or losses were recognized in during either period.

Interest Income, Net

Interest income was $1.0 million for the three months ended September 30, 2023, compared to $0.6 million for the three months ended September 30, 2022. This increase in interest income was primarily a result of higher interest rates during the three months ended September 30, 2023 compared to the three months ended September 30, 2022.

Results of Operations

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

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

	Nine Months Ended September 30,		
	2023	2022	$ Change
Revenue:			
Collaboration revenue	$ 18,442	$ 9,118	$ 9,324
Operating expenses:			
Research and development	32,127	37,902	(5,775)
General and administrative	13,856	14,093	(237)
Total operating expenses	45,983	51,995	(6,012)
Operating loss	(27,541)	(42,877)	15,336
Other income:			
Other (expense) income, net	(1,136)	268	(1,404)
Interest income, net	3,312	729	2,583
Total other income	2,176	997	1,179
Net loss	$ (25,365)	$ (41,880)	$ 16,515

Revenue

Revenue was $18.4 million for the nine months ended September 30, 2023, which is comprised of partial recognition of the $15.0 million upfront payment received in April 2022 upon the execution of the Collaboration Agreement with Jazz, costs incurred for research services to be reimbursed by Jazz, and revenue related to the achievement of certain variable consideration components. Comparatively, we recognized $9.1 million in collaboration revenue during the nine months ended September 30, 2022. This $9.3 million increase in collaboration revenue is partially driven by a change in the transaction price of $5.0 million during the nine months ended September 30, 2023, upon achieving a variable consideration component included in the Collaboration Agreement, which led to an additional recognition of $4.4 million during the period. Additionally, we recognized an increase in revenue recognized as a result of an increase in research and development activities related to JZP898.

Research and Development Expenses

The following table summarizes our research and development expenses for the nine months ended September 30, 2023 and 2022 (in thousands):

	Nine Months Ended September 30,		
	2023	2022	$ Change
Personnel	$ 11,402	$ 10,853	$ 549
Manufacturing	5,803	14,892	(9,089)
Clinical trial costs	5,049	3,364	1,685
Contract research organization	3,624	3,556	68
Lab consumables	3,513	2,664	849
Facilities	2,170	2,108	62
Other	566	465	101
Total research and development expenses	$ 32,127	$ 37,902	$ (5,775)

Research and development expenses for the nine months ended September 30, 2023 were $32.1 million, compared to $37.9 million for the nine months ended September 30, 2022. The decrease of $5.8 million was primarily due to:

- $9.1 million of decreased manufacturing costs driven by a decrease of $7.7 million in costs incurred with contract manufacturing organizations to support the production of preclinical, current, and future clinical trial materials associated with candidates WTX-124, WTX-330, WTX-712, and JZP898, and by $1.4 million of favorable adjustments recognized during the current period upon the closeout of completed purchase orders.

The decrease was partially offset by:

- $1.7 million of increased clinical trial costs, primarily driven by continued expansion of sites and enrollment for both our WTX-124 and WTX-330 trials;
- $0.8 million of increased lab consumables costs primarily related to expanded discovery efforts and headcount; and
- $0.5 million of increased personnel costs, driven primarily by the timing and valuation of stock-based awards granted to employees.

General and Administrative Expenses

The following table summarizes our general and administrative expenses for the nine months ended September 30, 2023 and 2022 (in thousands):

	Nine Months Ended September 30,		
	2023	2022	$ Change
Personnel	$ 6,979	$ 6,728	$ 251
Professional services	3,230	2,983	247
Corporate insurance	1,461	2,150	(689)
Facilities	954	1,049	(95)
IT costs	486	444	42
Other	746	739	7
Total general and administrative expenses	$ 13,856	$ 14,093	$ (237)

General and administrative expenses were $13.9 million for the nine months ended September 30, 2023, compared to $14.1 million for the nine months ended September 30, 2022. The decrease of $0.2 million was primarily due to:

- $0.7 million of decreased corporate insurance costs, driven by a reduction in associated premiums.

The decrease was partially offset by:

- $0.3 million of increased personnel costs, including $0.1 million of increased stock-based compensation expense, due to increased headcount to support operating as a public company; and
- $0.2 million of increased professional services costs, driven by costs incurred to protect our intellectual property.

Other (Expense) Income, Net

During the nine months ended September 30, 2023, other (expense) income, net primarily consisted of $1.0 million in losses recognized for the change in the fair value of the success payment liability during the period. Comparatively, we recognized a gain of $0.3 million related to the change in the fair value of the success payment liability during the nine months ended September 30, 2022.

Interest Income, Net

Interest income was $3.3 million for the nine months ended September 30, 2023, compared to $0.7 million for the nine months ended September 30, 2022. This increase in interest income was primarily a result of higher interest rates during the nine months ended September 30, 2023 compared to the nine months ended September 30, 2022.

Liquidity and Capital Resources

Sources of Liquidity

We Since our inception in 2017, we have funded 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 $16.2 million and $12.0 million for the three months ended March 31, 2024 and 2023, respectively. As of March 31, 2024, we had an accumulated deficit of $360.3 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 through September 30, 2023 primarily through aggregate cash proceeds from convertible promissory notes, of $11.0 million, gross proceeds from private placements of our convertible preferred stock, of $116.3 million, net proceeds our initial public offering, payments from our IPO of $109.2 million, a non-refundable upfront payment of $15.0 million received in connection with Jazz under the Collaboration Agreement, $16.3 million sales of expense reimbursements and milestone receipts from Jazz pursuant to the Collaboration Agreement, net proceeds from common stock through our ATM Offering of $25.0 million at-the-market program, and the drawdown of $40.0 million of Term Loans.

Jazz Collaboration

In April 2022, we entered into the Collaboration Agreement with Jazz. Under the terms of the Collaboration Agreement, we received an upfront payment of $15.0 million our term loans. Because our product candidates are in April 2022, and we are eligible to receive cost reimbursements for research services performed under the Collaboration Agreement. In addition, we are eligible to receive up to $520.0 million in clinical development and the outcome of our efforts is uncertain, we cannot estimate the actual costs necessary to successfully complete the development and commercialization of our product candidates, or when we may achieve profitability, if at all.

We expect to continue to incur substantial and increasing expenses and net losses for the foreseeable future, as we continue to advance our current and future product candidates through preclinical and clinical development, manufacture drug product and drug supply, seek regulatory milestones, approval for our current and up future product candidates, maintain and expand our intellectual property portfolio, hire additional research and development and business personnel and operate as a public company. As a result, we expect that our accumulated deficit will also increase significantly.

As a result, we will need substantial additional funding to $740.0 million in sales-based milestones for all Licensed Products. As support our continuing operations and pursue our growth strategy. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of September 30, 2023, we 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. Our failure to raise capital or enter into such agreements as and when needed could have received $5.0 million in proceeds related to variable consideration components. In addition, we are eligible to receive tiered mid-single digit royalties based a material adverse effect on Jazz's, our business, results of operations and any of its affiliates' and sublicensees', annual net sales of Licensed Products, subject to reduction in specified circumstances. financial condition.

Term Loan Facility Facilities

In April 2022, we entered into an amended and restated loan and security agreement, or the PWB Loan Agreement, with PWB, which amended and restated in its entirety our previous loan and security agreement with PWB. Under the terms of the PWB Loan Agreement, PWB made available term loans in an aggregate principal amount of up to $40.0 million, or the Term Loans, consisting of (i) a term loan in the aggregate principal amount of up to $20.0 million available at any time until February 28, 2024 (which was extended to August 31, 2024 upon the satisfaction of certain conditions set forth in the PWB Loan Agreement), or the Amortization Date, and (ii) a term loan in the aggregate principal amount of up to $20.0 million available at any time until the Amortization Date upon the acceptance by the FDA of two IND submissions on or before March 31, 2023. On March 15, 2023, In March 2023, we drew down $40.0 million of the Term Loans.

The Term Loans bear bore interest on the outstanding daily balance at a floating annual rate equal to greater of: (i) 0.5% above the prime rate then in effect or (ii) 4.50%. If the prime rate changes changed throughout the term, the interest rate is would be adjusted effective on the date of the prime rate change. All interest chargeable under the PWB Loan Agreement is was computed on a 360-day year for the actual number of days elapsed, with interest payable monthly. The PWB Loan Agreement provides provided for interest-only payments until the Amortization Date, at which time the aggregate outstanding principal balance of the Term Loans is was required to be repaid in monthly installments on a 24-month repayment schedule. All unpaid principal and accrued and unpaid interest with respect to the Term Loans is was due and payable in full on August 31, 2026. At our option, we may were permitted to elect to prepay all, or any part, of the outstanding Term Loans at any time without premium or penalty.

We were obligated to pay PWB a one-time fee in the event of certain corporate transactions equal to either (i) the greater of (a) $200,000 and (b) 2.00% of the amount drawn under the Term Loans for a transaction occurring on or prior to March 31, 2023, or (ii) for any transaction occurring thereafter, the greater of (a) $400,000 and (b) 4.00% of the amount drawn under the Term Loans, which fee is referred to as a the Success Fee, upon the occurrence of a Success Fee Event (as defined in the PWB Loan Agreement). In April 2023, the Success Fee Event occurred and, as such, we became obligated to pay the corresponding

Success Fee to PWB, in accordance with the terms of the PWB Loan Agreement. We removed the corresponding financial instrument for the Success Fee liability and paid the total $1.6 million $1.6 million upon the occurrence of the Success Fee Event. Upon occurrence of the Success Fee Event, the Amortization Date was extended to August 31, 2024, thereby extending the due date for all unpaid principal and accrued and unpaid interest with respect to the Term Loans to August 31, 2026.

In May 2024, we repaid all amounts outstanding under the PWB Loan Agreement, using $29.5 million in net loan proceeds received under our loan agreement with K2 HealthVentures LLC, or K2HV, as described below, together with $10.5 million in existing cash. Under the PWB Loan Agreement, we were required to maintain at least $20.0 million of restricted cash in PWB accounts. As a result of the repayment, we are no longer required to maintain $20.0 million of restricted cash.

On May 2, 2024, we, as borrower, entered into a loan and security agreement, or the Loan Agreement with K2HV (we refer to K2HV, together with any other lender from time to time, as the Lenders); K2HV, as administrative agent for the Lenders; and Ankara Trust Company, LLC, as collateral trustee for the Lenders. The Loan Agreement provides 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 upon closing and $5.0 million from the second tranche commitment. A third tranche commitment of up to $10.0 million is available to be drawn at our option during certain availability periods, 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. A fourth tranche commitment of up to $20.0 million is available to be drawn down at our option through May 1, 2026 or if the third tranche is funded, May 1, 2027, subject to Lender's review of our clinical, financial and operating plan and subject to Lender's consent in its sole and absolute discretion.

The term loan matures on May 1, 2028, and we are obligated to make interest only payments for the first 24 months, or 36 months if the third tranche is funded, and then interest and equal principal payments for the next 24 or 12 months, as applicable. The term loan bears 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 may 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 are entitled and certain notice requirements. We were required to pay the Lenders' certain customary fees and expenses at closing and will be required to pay additional fees that may be due upon maturity or prepayment such as final payment fees and prepayment fees.

The Lenders may elect 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, at a conversion price of the lesser of $6.32 per share and the lowest effective price per share of our next equity financing, subject to customary adjustments and 9.99% and 19.99% beneficial ownership limitations. There will be no prepayment penalty for any principal amount converted into common stock. The Loan Agreement provides the Lenders with certain piggyback registration rights with respect to the shares of common stock issuable upon conversion of term loans under the Loan Agreement.

The Loan Agreement contains customary representations and warranties, events of default and affirmative and negative covenants, including covenants that limit or restrict 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. As security for our obligations under the Loan Agreement, we are required to comply with certain negative covenants, which among other things, restrict us from incurring future debt or granting liens, effectuating granted the

Lenders a merger or consolidation with or into any other business organization, paying dividends or making certain other distributions, selling or otherwise transferring first priority security interest on substantially all of our assets and making investments in any entities or instruments, (other than intellectual property), subject in each case, to certain exceptions specified in the Loan Agreement. The Loan Agreement also contains standard affirmative covenants, including with respect to the issuance of audited consolidated financial statements, insurance, maintenance of good standing and government compliance in our state of formation. We maintain at least $20.0 million of cash in PWB accounts, included within restricted cash and cash equivalents, net of current portion on our condensed consolidated balance sheet as of September 30, 2023, which we are required to maintain at all times pursuant to exceptions.

For additional information about the terms of the Loan Agreement. Our failure to comply with any of the foregoing covenants would result in an event of default under the Loan Agreement. Agreement, please see Part II, Item 5, "Other Information."

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, with an aggregate offering price of up to $50.0 million, which we refer to as the ATM Offering. The Sales Agreement provides that Leerink will be 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. As We were initially entitled to offer and sell shares of September 30, 2023 our common stock having an aggregate offering price of up to $50.0 million in the ATM Offering. On February 9, 2024, we had sold filed a prospectus supplement, or the Prospectus Supplement, under our shelf registration statement for the offer and sale of shares of our common stock having an offering price of up to an additional $25.0 million in the ATM Offering. Following our filing of the Prospectus Supplement, we are entitled to offer and sell shares of our common stock with an aggregate offering price of 7,938,848 up to $75.0 million pursuant to the Sales Agreement. During the three months ended March 31, 2024, we sold 4,169,324 shares under the ATM Offering of our common stock at an average price of $3.33 $5.05 per share for net proceeds of $25.0 million $20.1 million after deducting sales commissions and offering expenses.

Jazz Collaboration

As of March 31, 2024, we have received $20.0 million in payments from Jazz, excluding payments for reimbursed costs, under the terms of the Collaboration Agreement. We are eligible to receive up to an additional $515.0 million in development and regulatory milestones, and up to $740.0 million in sales-based milestones for all Licensed Products. In addition, we are eligible to receive tiered mid-single digit royalties based on Jazz's, and any of its affiliates' and sublicensees', annual net sales of Licensed Products, subject to reduction in specified circumstances.

Plan of Operation and Future Funding Requirements

We use our capital resources primarily to fund operating expenses, primarily research and development expenditures. We plan to increase our research and development expenses for the foreseeable future as we continue the preclinical and clinical development of our product candidates. At this time, due to the inherently unpredictable nature of preclinical and clinical development and given the early stage of our product candidates, we cannot reasonably estimate the costs we will incur and the timelines that will be required to complete development, obtain marketing approval and commercialize our current product candidates or any future product candidates, if at all. For the same reasons, we are also unable to predict when, if ever, we will generate revenue from product sales or whether, or when, if ever, we may achieve profitability. Clinical and preclinical development timelines, the probability of success, and development costs can differ materially from expectations. In addition, we cannot forecast which product candidates may be subject to future collaborations, when such arrangements will be secured, if at all, and to what degree such arrangements would affect our development plans and capital requirements. Further, inflation generally affects us by increasing our cost of labor and certain services. We do not believe that inflation has had a material effect on our financial statements included elsewhere in this Quarterly Report; however, our operations may be adversely affected by inflation in the future.

Due to our significant research and development expenditures, we have accumulated substantial net losses in each period since inception. We have incurred an accumulated deficit of $332.1 million through September 30, 2023. We expect to continue to incur substantial and increasing expenses and net losses for the foreseeable future, as we continue to advance our current and future product candidates through preclinical and clinical development, manufacture drug product and drug supply, seek regulatory approval for our current and future product candidates, maintain and expand our intellectual property portfolio, hire additional research and development and business personnel and operate as a public company.

As of September 30, 2023 March 31, 2024, we had cash and cash equivalents of $130.1 million $139.2 million. We also had restricted cash and cash equivalents of $21.2 million as of March 31, 2024, of which $20.0 million became unrestricted upon the repayment of the PWB Loan Agreement. We expect that our existing cash and cash equivalents will be sufficient to fund our operational expenses and capital expenditure requirements through at least the next twelve months from the date the condensed consolidated financial statements included elsewhere in this Quarterly Report are issued on November 14, 2023 May 3, 2024. We believe that our existing cash and cash equivalents at March 31, 2024, together with cash impacts of the loan refinancing, will be sufficient to fund our operational expenses and capital expenditure requirements through at least the first quarter of 2026. We have based this estimate on assumptions that may prove to be wrong, however, and we could use our capital resources sooner than we expect. Our need to raise additional funds may be accelerated if our research and development expenses exceed our current expectations, if we acquire a third party, or if we acquire or license rights to additional product candidates or new technologies from one or more third parties.

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

- 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 success of our collaboration with Jazz;
- 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 Harpoon, 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.

Our existing cash and cash equivalents will not be sufficient to complete development of WTX-124, WTX-330 or any other product candidate. candidates. Accordingly, we will be required to obtain further funding to achieve our business objectives.

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 not able to secure adequate additional funding, we may be forced to make reductions in spending, extend payment terms with suppliers, liquidate assets where possible, and/or suspend or curtail planned programs. Any of these actions could materially and adversely affect our business, financial condition, results of operations, cash flows and prospects.

Cash Flows

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

	Nine Months Ended September 30,		Three Months Ended March 31,	
	2023	2022		
	2024		2024	2023
	(in thousands)			(in thousands)

Net cash (used in) provided by:	Net cash (used in) provided by:		
Operating activities	Operating activities		
Operating activities	Operating activities	$(28,027)	$(28,726)
Investing activities	Investing activities	(571)	(3,093)
Financing activities	Financing activities	49,356	14,650
Net increase (decrease) in cash, cash equivalents and restricted cash and cash equivalents		$ 20,758	$(17,169)
Net increase in cash, cash equivalents and restricted cash and cash equivalents			

Operating Activities

Net cash used in operating activities for the nine three months ended September 30, 2023 March 31, 2024 was $28.0 million $15.3 million, compared to $28.7 million $9.9 million for the nine three months ended September 30, 2022 March 31, 2023. This decrease increase of $0.7 million $5.4 million was primarily attributable to the $16.1 million difference in the change to deferred revenue during each period. For the nine months ended September 30, 2023, deferred revenue decreased $5.3 million due to the continued progress in Jazz collaboration research, compared to an increase of $10.8 million for the nine months ended September 30, 2022 related to the non-refundable upfront cash payment at the inception of the Collaboration Agreement. This was partially offset by a decrease in net loss for the comparable periods revenue from our Collaboration Agreement of $16.5 million $3.7 million, primarily driven by increased revenue recorded under a higher volume of development activity during the Collaboration Agreement for the nine three months ended September 30, 2023 compared to the nine months ended September 30, 2022. March 31, 2023 in preparation of IND submission of JZP898, combined with an increase in research and development expenses of $1.2 million, primarily driven by our continued development efforts of our other product candidates.

Investing Activities

Net cash used in investing activities for the nine three months ended September 30, 2023 March 31, 2024 was $0.6 million $0.1 million, compared to $3.1 million $0.2 million for the nine three months ended September 30, 2022March 31, 2023. This decrease was driven by high The activity for both periods represents capital expenditures of property and equipment used in the second quarter of 2022 related to leasehold improvements for our new headquarters, which was established in May 2022.operations.

Financing Activities

Net cash provided by financing activities for the nine three months ended September 30, 2023 March 31, 2024 was $49.4 million $20.3 million, compared to $14.7 million $48.6 million for the nine three months ended September 30, 2022 March 31, 2023. Cash provided by financing activities for the nine three months ended September 30, 2023 March 31, 2024 primarily consisted of net proceeds from the $40.0 million drawdown of the Term Loans and proceeds of $9.4 million from our ATM Offering during the period. Comparatively, cash provided by financing activities for the nine three

months ended September 30, 2022 March 31, 2023 consisted primarily of $14.8 proceeds from the $40.0 million drawdown of the Term Loans combined with $8.6 million in net proceeds from our ATM Offering during the period.

Contractual Obligations

Overview

In the normal course of business, we enter into agreements with contract research organizations, or CROs, contact 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 cancelable 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.

Term Loan Facility

See *"Liquidity and Capital Resources – Sources of Liquidity – Term Loan Facility" Facilities"* for a description descriptions of our Loan Agreement. As of September 30, 2023, we had drawn the Term Loans for a total principal of $40.0 million. Upon achievement of the Loan Agreement's funding milestone, the maturity date of the Term Loans was extended to August 31, 2026. Interest-only payments are to be made until August 31, 2024, at which point the interest-only period lapses and consecutive equal payments of principal are due along with interest. The Term Loans bear interest at a floating annual rate equal to the greater of: (i) 0.5% above the prime rate then in effect or (ii) 4.5%. If the prime rate changes throughout the term, the interest rate will be adjusted effective on the date of the prime rate change. All interest chargeable under the PWB Loan Agreement is computed on a 360-day year for the actual number of days elapsed, with interest payable monthly. and our Loan Agreement.

Lease Agreements

Total estimated base rent payments over the remaining term of the In April 2019, we entered into a lease for office and laboratory space that we entered into in April 2019 as our prior headquarters are approximately $0.5 million. previous headquarters. In May 2022, we entered into a sublease agreement with Crossbow Therapeutics, Inc., or Crossbow, a related party, to sublease the entirety of this space. The rent payments we expect to receive over the remaining term of the terms for both our original lease and our sublease is approximately $0.6 million, which is greater than the rent paid by us to the landlord for the leased premises. with Crossbow is obligated to pay all real estate taxes and costs related to the subleased premises, including cost of operations, maintenance, repair, replacement, and property management. expired in March 2024.

The lease for office and laboratory space that we entered into in June 2021 commenced in May 2022. 2022 and expires in May 2030. Total estimated base rent payments over the remaining term of the lease are approximately $16.1 million. $15.0 million.

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 and judgments including, which include, but are not limited to those related to revenue recognition, accrued expenses, assumptions used in the valuation of stock-based compensation expense and income taxes. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. circumstances. Actual results could differ from those estimates under different assumptions or 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 2022 2023 Annual Report, on Form 10-K for the year ended December 31, 2022, which was filed with the SEC on March 23, 2023 March 7, 2024. During the three and nine months ended September 30, 2023 March 31, 2024, there were no material changes to our critical accounting policies from those previously disclosed.

JOBS Act Accounting Election and Smaller Reporting Company Implications

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012, as amended, or JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended, or Sarbanes-Oxley Act. Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this extended transition period, and, as a result, we will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to continue to take advantage of reduced disclosure requirements, including not being required to comply with the auditor attestation requirements of

Section 404 of the Sarbanes-Oxley Act if we are a smaller reporting company with less than $100.0 million in annual revenue.

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, 2023 March 31, 2024. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act means controls and other procedures of 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, 2023 March 31, 2024, our principal executive officer and principal financial officer concluded that, as of such date, our disclosure controls and procedures were not effective due to at the reasonable assurance level.

Remediation of Material Weakness

During the second quarter of 2023, our management identified a material weakness in our internal control controls over financial reporting, as discussed below.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis. Based on our assessment as of September 30, 2023, management concluded that our internal control over financial reporting was not effective due to a material weakness relating to design and operating deficiencies in our purchasing process, specifically related to the application of invoices to purchase orders and processes to estimate progress on open purchase orders and to identify inaccurate expense estimates within purchase orders.

Notwithstanding this Since identifying the material weakness, our management, including our chief executive officer we have taken several measures to enhance and chief financial officer, has concluded that strengthen our financial statements in this Quarterly Report present fairly, in all material respects, our financial position, results of operations and cash flows for the periods presented in accordance with accounting principles generally accepted in the United States of America. The material weakness did not result in any restatements of consolidated financial statements previously reported by us, nor were there any changes to previously released financial results.

Remediation Plan

We have implemented, and are continuing to implement, measures designed to improve internal control over financial, reporting including:

- hiring additional qualified accounting personnel, including an Assistant Controller and Senior Accountant;
- conducting a review of our procurement process and software, as well as sunsetting the historical software;
- engaging a professional accounting services firm to help us assess and commence documentation of our internal controls for complying with the Sarbanes-Oxley Act of 2002;
- strengthening, formalizing, documenting, and testing accounting processes and internal controls;
- engaging consultants to provide additional technical accounting expertise; and
- implementing procedures around our estimation processes with key vendors as well as adding analytical tools to help identify possible material errors.

The processes and controls intended to remediate the control deficiencies that led to the material weakness by, among other things, expanding managerial oversight described above have been in operation for a sufficient period of and adding process time for management to be able to

conclude that these controls to, our purchasing process, including approval and ongoing are operating effectively. As a result, management has concluded that, as of purchase orders and related invoices, and assessment of progress and estimated expenses. We have utilized and will continue to utilize financial consultants to assist with the evaluation and documentation of process controls. As of September 30, 2023 March 31, 2024, we have initiated testing of our remediation efforts, including had remediated the adoption of incremental financial policies, procedures, and internal controls. We expect our remediation efforts to continue through at least the fourth quarter of 2023. We expect to complete the remediation of the previously reported material weakness after the conclusion of testing.

weakness.

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 financial quarter covered by this Quarterly Report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. Subsequent to the identification of the material weakness described above, management has taken actions to remediate the deficiency that resulted in that material weakness.

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 Our Limited Operating History, Financial Position and Capital Requirements

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. Our approach to the discovery and development of product candidates based on our PREDATOR platform is unproven, and we do not know whether we will be able to develop any approved products of commercial value. In addition, we currently only have two product candidates that we are developing independently, WTX-124 and WTX-330, and all of our other development programs are in discovery or preclinical stages. We have not yet demonstrated an ability to successfully complete any Phase 1, Phase 2 or 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 our product candidates are not successfully developed and approved, we may never generate any product revenue. Our net loss was $8.3 million $16.2 million for the three months ended September 30, 2023 March 31, 2024. As of September 30, 2023 March 31, 2024, we had an accumulated deficit of $332.1 million $360.3 million. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially as WTX-124 and WTX-330 advance through development, and any future product candidates advance through preclinical studies and into and through clinical trials, and as we expand our clinical, regulatory, quality and manufacturing capabilities and incur additional costs associated with operating as a public company. If we obtain marketing approval for any of our product candidates, 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, 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 our ongoing and planned preclinical studies;
- successfully submit INDs investigational new drug, or IND, submissions to the U.S. Food and Drug Administration, or FDA, for any future product candidates;
- successfully complete clinical trials for WTX-124 and WTX-330;
- successfully enroll subjects in and complete future 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, maintain our research and development efforts, diversify our product candidates 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 complete the development and any commercialization of WTX-124, WTX-330 and any future product candidates. If we are unable to raise this capital when needed, we may be forced to delay, reduce or eliminate one or more of our research and development programs 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 expect to incur increasing expenses and operating losses over the next several years as we pursue clinical development of our product candidates and implement the additional infrastructure necessary to support our operations as a public reporting company. 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 WTX-124, WTX-330 or any other 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.

As of September 30, 2023 March 31, 2024, we had cash and cash equivalents of $130.1 million. $139.2 million. We expect that our existing cash and cash equivalents as of March 31, 2024 will allow us to complete the development of WTX-124 through dose escalation and expansion as a monotherapy or in combination with Merck's anti-PD-1 therapy KEYTRUDA® (pembrolizumab) pembrolizumab and the development of WTX-330 through dose escalation and expansion as a monotherapy.

Our cash and cash equivalents will not be sufficient to complete development of WTX-124, WTX-330 or any other 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 attractive terms or at all, would have a negative effect on our financial condition and our ability to develop and commercialize our current and any future product candidates, and otherwise pursue our business strategy and we may be forced to delay, reduce or eliminate our research and development programs 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 our current product candidates, or any future product candidates, including with respect to WTX-124 and WTX-330; WTX-330, or any future product candidates;
- the costs associated with attracting, hiring and retaining skilled personnel and consultants as our preclinical and clinical activities increase;
- the cost of manufacturing our lead product candidates, WTX-124 and 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, 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 Harpoon, 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.

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 one or more of our research-stage programs, clinical trials or future commercialization efforts or other operations.

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

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. For example, pursuant to the terms of our loan agreement, or the Loan Agreement, with K2 HealthVentures LLC, or K2HV, the lenders have the right to convert any portion of the outstanding principal amount of the first tranche part A term loan then outstanding into shares of our common stock, which right, if exercised, could have a dilutive impact on our stockholders' ownership interests. 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. Further, our ability to obtain additional debt financing may be limited by covenants we have made under our the Loan Agreement with K2HV, including our pledge to PWB of substantially all of our assets, other than our intellectual property, as collateral. If we raise additional funds through collaborations and licensing arrangements with third parties, we may have to relinquish valuable rights to our platform technology or product candidates 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 the development of our product candidates.

We have a term loan facility that requires us to comply with certain operating covenants and places restrictions on our operating and financial flexibility.

All outstanding obligations under the Loan Agreement are secured by our personal property (exclusive of any intellectual property), and are subject to acceleration upon an event of default. Under the Loan Agreement, we are required to comply with certain negative covenants, which among other things, restrict us from incurring future debt or granting liens, effectuating a merger or consolidation with or into any other business organization, paying dividends or making certain other distributions selling or otherwise transferring repurchasing our equity, disposing of our assets, and making investments in any entities or instruments, subject, in each case, to certain exceptions specified in the Loan Agreement. The Loan Agreement also contains standard affirmative covenants,

including with respect to the issuance of audited consolidated financial statements, insurance, and maintenance of good standing and government compliance in our state of formation. We are required to maintain at all times at least $20.0 million of otherwise unrestricted cash in accounts with PWB. Our failure to comply with any of the foregoing covenants would result in an event of default under the Loan Agreement.

Our financial obligations and contractual commitments under the Loan Agreement could have significant adverse consequences, including:

- requiring us to dedicate a portion of our cash resources to the payment of interest and principal, reducing money available to fund working capital, capital expenditures, product development and other general corporate purposes;
- increasing our vulnerability to adverse changes in general economic, industry and market conditions;
- subjecting us to restrictive covenants that may reduce our ability to take certain corporate actions or obtain further debt or equity financing;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and
- placing us at a competitive disadvantage compared to our competitors that have less debt or better debt servicing options.

Under our Loan Agreement, the occurrence of an event or circumstance that would reasonably could be expected to have a material adverse effect on our business, operations, properties, assets or condition is an event of default. If an event of default occurs and the lenders accelerate the amounts due, we may not be able to make accelerated payments, and the lenders could seek to enforce security interests in the collateral securing such indebtedness, which includes substantially all of our assets other than our intellectual property. In addition, the covenants under our Loan Agreement, the pledge of our assets as collateral and the negative pledge with respect to our intellectual property could limit our ability to obtain additional debt financing.

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 of 2017, or TCJA, as amended by the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, significantly revises revised the Internal Revenue Code of 1986, as amended, or 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%, limitation of and the tax deduction for net interest expense to 30% of adjusted taxable income (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, in each case, for losses arising in taxable years beginning after December 31, 2017 (though any such net operating losses may be carried forward indefinitely but no longer carried back). In addition, beginning in 2022, the TCJA eliminated the option to deduct research and as a result of amendments made by the CARES Act, such net operating losses arising in taxable development expenditures currently and generally requires corporations to capitalize and amortize them over five years beginning before January 1, 2021 are generally eligible or 15 years (for expenditures attributable to be carried back up to five years), one-time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. 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. Regulatory guidance under the TCJA and such additional legislation is and continues to be forthcoming, and such guidance could ultimately increase or lessen their impact on our business and financial condition. Also, as a result of the changes in the U.S. presidential administration and control of the U.S. Senate in 2021, additional tax legislation may be enacted; any such additional legislation could have an impact on us. In addition, it is uncertain if and to what extent various states will conform to the TCJA and additional tax legislation.

Our ability to utilize our net operating loss 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, 2022 December 31, 2023, we had federal and state net operating loss carryforwards of $92.1 $96.6 million and $86.1 $44.9 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 net operating loss 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. As a result, if we earn net taxable income, our ability to use our pre-change net operating loss carryforwards and other pre-change tax attributes to offset U.S. federal taxable income are 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 net operating losses, or for other unforeseen reasons, our existing net operating losses 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 amended by the CARES Act, includes changes to U.S. federal tax rates and rules governing net operating loss carryforwards that may significantly impact our ability to utilize net operating losses to offset taxable income in the future. In addition, state net operating losses 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 net operating losses and other tax attributes.

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

We are early in our development efforts and our current product candidates will require successful completion of preclinical and clinical development before we can seek regulatory approval for any product candidates.

We are early in our development efforts and have invested substantially all of our efforts and financial resources in building our PREDATOR platform and developing our initial INDUKINE molecules by leveraging our PREDATOR platform. Our lead product candidates are at or near in the beginning early stages of the clinical trial stage. development. Additionally, we have a portfolio of programs that are in even earlier stages of preclinical development and may never advance to clinical-stage development. 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 our 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.

Our business is highly dependent on the success of our initial INDUKINE molecules, which are in the early stages of development and will require significant additional preclinical and clinical development before we can seek regulatory approval for and launch a product commercially.

Our business and future success is highly dependent on our ability to obtain regulatory approval of and then successfully launch and commercialize our initial INDUKINE molecules, including our most advanced product candidates, WTX-124 and WTX-330.

Commencing clinical trials in the United States is subject to acceptance by the FDA of an IND and finalizing the trial design based on discussions with the FDA and other regulatory authorities. In the event that the FDA requires us to complete additional preclinical studies or we are required to satisfy other FDA requests prior to commencing clinical trials, the start of a clinical trial may be delayed. Even after we receive and incorporate guidance from these regulatory authorities, the FDA or other regulatory authorities could disagree that we have satisfied their requirements to commence any clinical trial or change their position on the acceptability of our trial design or the clinical endpoints selected, which may require us to complete additional preclinical studies or clinical trials or impose stricter approval conditions than we currently expect. There are equivalent processes and risks applicable to clinical trial applications in other countries, including countries in the European Union.

We may experience issues surrounding preliminary trial execution, such as delays in FDA acceptance of our INDs, revisions in trial design and finalization of trial protocols, difficulties with patient recruitment and enrollment, quality and provision of clinical supplies, or early safety signals.

We are not permitted to market any biological product in the United States until we receive approval of a Biologics License Application, or BLA, or a new drug application, or NDA, from the FDA. We have not previously submitted a BLA or an NDA to the FDA, or similar marketing application to comparable foreign regulatory authorities. A BLA or an NDA must include extensive preclinical and clinical data and supporting information to establish that the product candidate is safe, pure and potent for each desired indication. A BLA or an NDA must also include significant information regarding the chemistry, manufacturing and controls for the product, and the manufacturing facilities must complete a successful pre-license inspection.

FDA approval of a BLA or an NDA is not guaranteed, and the review and approval process is expensive and uncertain and may take several years. The FDA also has substantial discretion in the approval process. The number and types of preclinical studies and clinical trials that will be required for BLA or NDA approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to treat and the regulations applicable to any particular product candidate. Despite the time and expense associated with preclinical studies and clinical trials, failure can occur at any stage.

The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain approval of any product candidate that we develop based on the completed clinical trials.

Our ability to generate product revenues, which we do not expect will occur for many years, if ever, will depend heavily on our ability to successfully develop and commercialize WTX-124, WTX-330 and any future product candidates. The success of our product candidates will depend on several factors, including the following:

- completion of preclinical studies and clinical trials with favorable results;
- acceptance of INDs by the FDA or similar regulatory filing by comparable foreign regulatory authorities for the conduct of clinical trials of our product candidates and our proposed design of future clinical trials;
- receipt of marketing approvals from applicable regulatory authorities, including BLAs or NDAs from the FDA and maintaining such approvals;
- making arrangements with our third-party manufacturers for, or establishing, commercial manufacturing capabilities;

- maintaining an acceptable safety profile of our products following approval; and
- maintaining and growing an organization of scientists and business people who can develop our products and technology.

Generally, public concern regarding the safety of biopharmaceutical products could delay or limit our ability to obtain regulatory approval, result in the inclusion of unfavorable information in our labeling or require us to undertake other activities that may entail additional costs. We have not obtained FDA approval for any product. This lack of experience may impede our ability to obtain FDA approval in a timely manner, if at all, for WTX-124, WTX-330 or any future product candidates.

The success of our business, including our ability to finance our company and generate any revenue in the future, will primarily depend on the successful development, regulatory approval and commercialization of WTX-124, WTX-330 and any future product candidates, which may never occur. Given our early stage of development, it will be years before we are able to demonstrate the safety and efficacy of a treatment sufficient to warrant approval for commercialization, and we may never be able to do so. If we are unable to develop, or obtain regulatory approval for, or, if approved, successfully commercialize our current or any future product candidates, we may not be able to generate sufficient revenue to continue our business.

Our approach to the discovery and development of product candidates based on our PREDATOR platform is unproven, and we do not know whether we will be able to develop any products of commercial value.

The success of our business depends primarily upon our ability to discover, develop and commercialize products based on our novel PREDATOR platform. While we have had favorable preclinical study results related to WTX-124 and WTX-330, both of which we are developing by leveraging our PREDATOR platform, and have announced favorable early-stage clinical trial results related to WTX-124, we have not yet succeeded and may not succeed in demonstrating efficacy and safety for any product candidates in clinical trials or in obtaining marketing approval thereafter. We have no assurance that our PREDATOR platform will be able to produce product candidates that will successfully progress from preclinical studies into clinical development and ultimately marketing approval. We have invested substantially all of our efforts and financial resources in building our PREDATOR platform and developing our initial INDUKINE molecules by leveraging our PREDATOR platform, and our future success is highly dependent on the continued successful development of our platform and product candidates that we develop by leveraging our platform. Because all of our product candidates are based upon our PREDATOR platform, any development problems we may experience in the future related to any of our product candidates has the potential to impact the development of our other product candidates and any such development problems have the potential to cause significant delays or unanticipated costs and may ultimately not be able to be solved.

In addition, the clinical trial requirements of the FDA and other regulatory agencies and the criteria these regulators use to determine the safety and efficacy of a product candidate may vary according to the type, complexity, novelty and intended use and market of the potential products. The regulatory approval process for novel product candidates can be more expensive and take longer than for other, better known or extensively studied pharmaceutical or other product candidates. As a result, we may face a greater regulatory burden to initiate clinical trials or to obtain regulatory approval of our product candidates as compared to product candidates based on more established technology. In addition, any product candidates for which we may be able to obtain marketing approval may be subject to extensive post-approval regulatory requirements, including requirements pertaining to manufacturing, distribution and promotion. We may need to devote significant time and resources to compliance with these requirements.

Manufacturing INDUKINE molecules is subject to risk since they are a novel class of multi-domain biologics that include protease cleavable linkers, and they have never been produced on a clinical or commercial scale. We may be unable to manufacture INDUKINE molecules at the scale needed for late-stage clinical development and commercial production on a timely basis or at all, which would adversely affect our ability to conduct clinical trials and seek regulatory approvals or commercialize our programs, which would have an adverse effect on our business.

The manufacturing cell line currently in use, to develop INDUKINE manufacturing processes has not been and any future cell line that may be used, to manufacture multi-domain proteins that include our protease cleavable linkers. The presence of these linkers presents a risk that unintended proteolysis may occur during the manufacture of INDUKINE molecules and that undesired fragments may not be able to be sufficiently removed by the purification process. The novel multi-domain composition of INDUKINE molecules may present a risk due to its complexity and challenges inherent to the manufacture of biologics. As a result, the risk of delays or failure in the manufacture of our INDUKINE molecules is high. Additionally, each INDUKINE molecule that we may develop is unique, from a manufacturing perspective, so any learnings from the manufacture of other INDUKINE molecules may not apply to the manufacture of new INDUKINE molecules. Before we can commence commencing clinical trials for a new product candidate, candidates, the manufactured INDUKINE molecules must complete extensive analytical testing and be qualified for use in human studies. We cannot be certain of the timely completion or outcome of our analytical testing and suitability for human studies and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical material or if the outcome of our analytical testing will ultimately support the

further development of our programs. future programs or clinical trials. As a result, we cannot be sure that we will be able to submit INDs or similar applications for our product candidates or any future preclinical clinical programs on the timelines we expect, if at all, and we cannot be sure that the submission of INDs or similar applications will result in the FDA or other regulatory authorities allowing future clinical trials to begin. In addition, we cannot be certain that we will be able to produce product candidates at the scale required for our clinical trials and, for any approved products, commercial production on a timely basis or at all, which could also have an adverse effect on our business.

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

We have chosen to initially develop our lead product candidates, WTX-124 and WTX-330, for the treatment of advanced solid tumors and the treatment of relapsed or refractory advanced or metastatic tumors or lymphoma, respectively. Nevertheless, our development efforts will 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. Our spending on current and future research and development programs and product candidates for specific indications may not yield any commercially viable product candidates. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through collaboration, licensing or other 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. Our preclinical programs may experience delays or may never advance to clinical trials, which would adversely affect our ability to obtain regulatory approvals or commercialize these 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 our preclinical product candidates, 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 our preclinical testing and studies and cannot predict if the FDA or other regulatory authorities will accept our proposed clinical programs or if the outcome of our preclinical testing and studies will ultimately support the further development of our programs. As a result, we cannot be sure that we will be able to successfully submit INDs or similar applications for our preclinical programs on the timelines we expect, if at all, and we cannot be sure that submission of INDs or similar applications 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 our current and any future product candidates is high. It is impossible to predict when or if any of our future product candidates will successfully complete preclinical studies, or if any of our current or future product candidates will complete 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 of our product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our 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. In particular, while we have conducted certain preclinical studies of WTX-124 and WTX-330 and have entered early clinical stage development, we do not know whether either of these product candidates will perform in our clinical trials as it has performed in these prior preclinical studies. Similarly, there can be no assurance that interim or preliminary clinical data or results, including, without limitation, the preliminary Phase 1/1b clinical data reported for WTX-124, will be predictive of future clinical data or results, and there can be no assurance that success in early clinical trials will lead to success in later clinical trials. 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 our planned 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 our clinical trials, 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 our product candidates, 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 our current or future 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 for which we are developing our product candidates, or participate in competing clinical trials;
- subjects may experience severe or unexpected drug-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 such as the COVID-19 pandemic or any future pandemic;
- 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 product candidates, we may:

- incur additional unplanned costs;
- be required to suspend or terminate ongoing 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, or suspend, their approval of the drug or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy, or REMS;
- 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 our product candidates, presents additional risks that may delay completion of our 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 our clinical trials 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 of our product candidates.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. 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. For example, in December 2022 with the passage of the Food and Drug Omnibus Reform Act of 2022, Congress required sponsors to develop and submit a diversity action plan for each Phase 3 clinical trial or any other "pivotal study" of a new drug or biological product. These plans are meant to encourage the enrollment of more diverse patient populations in late-stage clinical trials of FDA-regulated products. Specifically, actions plans must include the sponsor's goals for enrollment, the underlying rationale for those goals, and an explanation of how the sponsor intends to meet them. In addition to these requirements, the legislation directs the FDA to issue new guidance on diversity action plans.

Similarly, the regulatory landscape related to clinical trials in the European Union, or EU, recently evolved. The EU Clinical Trials Regulation, or CTR, which was adopted in April 2014 and repeals the EU Clinical Trials Directive, became applicable on January 31, 2022. While the Clinical Trials Directive required a separate clinical trial application, or CTA, to be submitted in each member state, to both the competent national health authority and an independent ethics committee, the CTR introduces a centralized process and only requires the submission of a single application to all member states concerned. The CTR allows sponsors to make a single submission to both the competent authority and an ethics committee in each

member state, leading to a single decision per member state. The assessment procedure of the CTA has been harmonized as well, including a joint assessment by all member states concerned, and a separate assessment by each member state with respect to specific requirements related to its own territory, including ethics rules. Each member state's decision is communicated to the sponsor via the centralized EU portal. Once the CTA is approved, clinical study development may proceed. 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 clinical trials of our product candidates and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market any of our product candidates would significantly harm our business. We cannot provide assurances that our clinical trials will begin as planned or be completed on schedule, if at all, or that we will not need to restructure our clinical trials. Significant preclinical study or clinical trial delays could also shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do and impair our ability to successfully commercialize our 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 our 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 our clinical trials 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. We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. 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 drug candidate being studied in relation to other available therapies, including any new drugs 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 such as the COVID-19 pandemic, that which may limit the availability of patients, principal investigators or staff or clinical sites.

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

Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays or might require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our product candidates, slow down or halt our 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.

Our product candidates 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, 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 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.

The COVID-19 pandemic or any future surges, including as a result of new variants and subvariants of the virus, or a similar pandemic, epidemic, or outbreak of an infectious disease, may materially and adversely affect our business and our financial results and could cause a disruption to the development of our product candidates.

Public health crises such as the COVID-19 pandemic or similar outbreaks could adversely impact our business. In response to the COVID-19 pandemic, governments throughout the world implemented a variety of quarantines, travel restrictions and other public health and safety measures that have impacted, and may continue to impact, our operations. The ultimate extent to which COVID-19 or any future surges, including as a result of new variants and subvariants of the virus, impacts our operations, including our preclinical studies and clinical trials, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak and the actions taken to contain COVID-19 or treat its impact, among others. Any negative impact COVID-19 has on the execution of our product development plans could adversely affect our ability to timely submit INDs for product candidates, negatively affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, and have a material adverse effect on our financial results.

Effects of the COVID-19 pandemic that may delay or otherwise adversely affect our ongoing and planned preclinical activities and clinical trials as well as our business generally, include:

- delays related to COVID-19 disruptions at CROs and contract manufacturers, or in the supply chain;

- delays in receiving approval from regulatory authorities to initiate our planned clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff who, as healthcare providers, may have heightened exposure to COVID-19;
- delays or difficulties in enrolling and retaining patients in clinical trials;
- delays in clinical sites receiving the supplies and materials needed to conduct clinical trials;
- difficulties interpreting data from clinical trials due to the possible effects of COVID-19 on patients;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as clinical trial sites and hospital staff supporting the conduct of clinical trials;
- interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines; and
- interruptions, difficulties or delays arising in our existing operations and company culture as a result of many of our employees working remotely, including those hired during the COVID-19 pandemic.

Any of these effects, and other effects of the COVID-19 pandemic, including future outbreaks, the emergence of new variants and subvariants of the virus, and any future pandemic, could have a material adverse effect on our business and our results of operations and financial condition. Further, uncertainty around these and related issues could lead to adverse effects on the economy of the United States and other economies, which could impact our ability to raise the necessary capital needed to develop and commercialize our programs and product candidates.

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

From time to time, we may publish interim top-line or preliminary data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or "top-line" 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 are developing WTX-124, and could potentially develop WTX-330 and future product candidates, in combination with third-party drugs, 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 drugs.

We are developing WTX-124, and could potentially develop WTX-330 and other future product candidates, in combination with third-party cancer drugs, which may be either approved or unapproved. For example, we are conducting a clinical trial of WTX-124 both as monotherapy and in combination with Merck's anti-PD-1 therapy KEYTRUDA® (pembrolizumab). pembrolizumab. Our

ability to develop and ultimately commercialize our current product candidates, and any future product candidates, used in combination with third-party drugs will depend on our ability to access such drugs on commercially reasonable terms for clinical trials and their availability for use with our commercialized product, if approved. We cannot be certain that current or potential future commercial relationships will provide us with a steady supply of such drugs on commercially reasonable terms or at all. Any failure to maintain or enter into new successful commercial relationships, or the expense of purchasing such third-party drugs in the market, may delay our development timelines, increase our costs and jeopardize our ability to develop our current product candidates and any future 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. For example, our clinical trial for WTX-124 in combination with KEYTRUDA pembrolizumab may result in adverse events based on the combination therapy that may negatively impact the reported safety profile of the monotherapy in such clinical trials. 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 our clinical trials or otherwise negatively impact our combination clinical trials. 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 drug and not our product candidate. Developments related to the third-party drug may also impact our 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 drug's safety or efficacy profile, changes to the availability of the third-party drug, quality, and manufacturing and supply issues with respect to the third-party drug.

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 drug, 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 drug used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with such drug. Similarly, if the third-party drugs we use in combination with our product candidates are replaced as the standard of care for the indications we choose for any of our 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.

We may not be successful in our efforts to identify or discover additional product candidates.

Although we intend to explore other therapeutic opportunities in addition to the product candidates that we are currently developing, 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 our existing and planned product candidates for additional indications and to identify new product candidates and disease targets require substantial technical, financial and human resources whether or not they are ultimately successful. Our research programs 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 drugs; 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 our current 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 our 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 drug, 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.

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 European Union 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 products is highly competitive. We face competition with respect to our current product candidates and will face competition with respect to any product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical, specialty pharmaceutical and biotechnology companies among others. We compete in the segments of the pharmaceutical, biotechnology and other related markets that develop immunotherapies for the treatment of cancer. 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 our approach, and others are based on entirely different approaches. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

We are developing our initial product candidates for the treatment of cancer and have not received marketing approval for any of our 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. We expect that if our product candidates are approved, they will be priced at a significant premium over competitive generic products. This may make it difficult for us to achieve our business strategy of using our product candidates in combination with existing therapies or replacing existing therapies with our product candidates. 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 lead product candidate, WTX-124, if approved, may face competition from other Interleukin-2, or IL-2, based cancer therapies. Proleukin (aldesleukin), a synthetic protein very similar to IL-2, is approved and marketed for the treatment of metastatic renal cell carcinoma and melanoma. In addition, we are aware that a number of other companies have modified IL-2 programs in development for the treatment of cancer, including Alkermes Plc, Anaveon AG, Anwita Biosciences, Inc., Ascendis Pharma A/S, Asher Biotherapeutics, Inc., Aulos Bioscience, Inc., BioNTech SE, Cue Biopharma, Inc., DEKA Biosciences, Inc., Merck & Co., Inc., Medicenna Therapeutics Corp., Mural Oncology PLC, F. Hoffmann-La Roche AG, or Roche, Synthekine, Inc., and Xilio Therapeutics, Inc.

There are no approved IL-12 therapies currently on the market for the treatment of cancer. However, if approved, WTX-330 may face competition from other IL-12 cytokine programs in clinical and preclinical development for oncology indications, including programs from Sanofi S.A. (Amunix), DEKA Biosciences, Inc., DragonFly Therapeutics, Inc., Juno Therapeutics, Inc. (Bristol-Myers Squibb Company), Turnstone Biologics Corp. (partnered with Takeda Pharmaceutical Company Limited), Philogen S.p.A., OncoSec Medical Incorporated, Sonnet BioTherapeutics, Inc., Xilio Therapeutics, Inc., and Zymeworks Inc.

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 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 our product candidates 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 drugs would harm our business, financial condition and results of operations.

The sizes of the potential markets for our product candidates are difficult to estimate and, if any of our assumptions are inaccurate, the actual markets for our 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 drugs 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 our product candidates 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 European Union 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. 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 drug 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.

We expect the that WTX-124 and WTX-330, and other product candidates we develop, will be regulated as biological products, or biologics, and therefore they may be subject to competition sooner than anticipated.

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA, which created an abbreviated approval pathway for biologic products that are biosimilar to or interchangeable with an FDA-licensed reference biologic product. Under the BPCIA, a reference biological product is granted 12 years of non-patent exclusivity from the time of first licensure of the product, and the FDA will not accept an application for a biosimilar or interchangeable product based on the reference biological product until four years after the date of first licensure of the reference product. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a BLA for the competing product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity, and potency of the other company's product. The law is complex and is still being interpreted and implemented by the FDA. As a result, its ultimate impact, implementation, and meaning are subject to uncertainty.

We believe that any of our product candidates approved as a biologic product under a BLA should qualify for the 12-year period of exclusivity. However, there is a risk that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our investigational medicines to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Moreover, the extent to which a biosimilar, once licensed, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biologic products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing.

If competitors are able to obtain regulatory approval for biosimilars referencing our product candidates, our product candidates may become subject to competition from such biosimilars, with the attendant competitive pressure and consequences.

Risks Related to Our Dependence on Third Parties

We rely, and expect to continue to rely, on third parties to conduct our preclinical studies and clinical trials. 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.

We depend, and expect to continue to depend, upon third parties, including independent investigators and contract research organizations, or CROs, to conduct preclinical studies and clinical trials. We expect to have to negotiate budgets and contracts with CROs and trial sites, and any of these third parties may terminate their engagements with us at any time, any of which may result in delays to our development timelines and increased costs.

Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibility to ensure that each of our trials is conducted in accordance with the applicable protocol, legal and regulatory requirements and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with current Good Clinical Practices, or cGCP, 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 cGCP 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 cGCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to suspend or terminate these 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 of our clinical trials comply with the cGCP requirements. In addition, our clinical trials must be conducted with biologic product produced under current Good Manufacturing Practice, or cGMP, requirements.

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

Any third parties conducting our clinical trials 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 our 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 our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed.

If any of our relationships with these 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 our ability to meet our desired clinical development timelines. Though we plan to carefully manage our relationships with CROs, 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.

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

To date, we have produced limited quantities of our product candidates at our own facilities for preclinical evaluation. However, going forward we will rely on third-party contract manufacturers to manufacture some of our preclinical supply and all of our clinical trial supply. We do not own manufacturing facilities capable of producing drug 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 our preclinical and clinical development product supplies from third parties will not in the future be limited or interrupted, or be of satisfactory quality or continue to be available at acceptable prices. Additionally, the process of manufacturing biologics is complex, highly regulated, and subject to multiple risks. Manufacturing biologics is highly susceptible to product loss due to contamination, equipment failure, improper installation or operation of equipment, vendor or operator error, inconsistency in yields, variability in product characteristics 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 our contract manufacturing organizations, or CMOs, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials, result in higher costs of drug product and adversely affect our business.

We have engaged CMOs to provide certain services to support our clinical and preclinical development. Pursuant to the terms of separate contract manufacturing services agreements, we have engaged one CMO to provide drug substance manufacturing process development and to manufacture WTX-124 and WTX-330 drug substance to cGMP specifications for use in the further manufacture of clinical supply, a second CMO to provide drug product manufacturing process development and to manufacture clinical supply of WTX-124 and WTX-330 vialled drug product to cGMP specifications, and additional CMOs to provide drug substance and drug product manufacturing for JZP898 (formerly WTX-613). JZP898. To support the manufacture of drug substance and drug product, our CMOs will conduct substantial analytical testing of drug substance and vialled drug product. If our CMOs are unable to supply us with sufficient clinical grade quantities of WTX-124 or WTX-330, and we are unable to timely establish an alternate supply from one or more third-party contract manufacturers, we will experience delays in our development efforts as we seek to locate and qualify new manufacturers. In particular, any replacement of our CMOs 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 of the raw materials for our preclinical and clinical product supplies. If current or future suppliers are delayed or unable to supply sufficient raw materials to manufacture product for our preclinical studies and clinical trials, we may experience delays in our development efforts as materials are obtained or we locate and qualify new raw material manufacturers. Further, for our combination clinical trial of WTX-124 with KEYTRUDA (pembrolizumab), pembrolizumab, an immune checkpoint inhibitor, we will need to procure supply of KEYTRUDA pembrolizumab for use in the clinical trials. If we are unable to procure sufficient supply from third-party manufacturers or other sources, we may be required to purchase our supply of checkpoint inhibitors 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 cGMPs. In the event that any of our CMOs fail to comply with such requirements or to perform their obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third-party, which we may not be able to do on reasonable terms, if at all. The transfer of the manufacturing of 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, our reliance on third-party manufacturers exposes us to risks beyond our control, including the:

- inability to meet our drug 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 drug quality issues, including related to scale-up of manufacturing;
- failure to comply with cGMP and similar foreign standards;
- reliance on a limited number of sources, and in some cases, single sources for drug components and raw materials, such that if we are unable to secure a sufficient supply of these drug components and raw materials, we will be unable to manufacture and sell our future product candidate in a timely fashion, in sufficient quantities or under acceptable terms;

- 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, or as a result of the effects of the COVID-19 pandemic on third-party manufacturers;
- carrier disruptions or increased costs that are beyond our control;
- failure to deliver our drugs under specified storage conditions and in a timely manner; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

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

In addition, our CMOs are or may be engaged with other companies to supply and manufacture materials or products for such companies, which also exposes our 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 drug product for us.

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

A part of our strategy is to strategically evaluate and, as deemed appropriate, enter into collaborations in the future on an asset-by-asset basis to maximize the value of each of our programs. For example, in April 2022, we entered into a Collaboration and License Agreement, or the Collaboration Agreement, with Jazz Pharmaceuticals Ireland Limited, or Jazz, pursuant to which we granted Jazz certain licenses to develop and commercialize products containing our Interferon alpha, ("or IFNα") INDUKINE™, INDUKINE molecule, JZP898, (formerly WTX-613), as well as products containing certain isolated recombinant polypeptides comprising IFNα that meet specified criteria. We may also enter into collaborations in connection with our platform technology in order to advance the development of programs beyond our initial focus in cytokines. Such collaborations may include the development and commercialization of any of our product candidates or the commercialization of any of our product candidates that are approved for marketing outside the United States. Our likely collaborators for any collaboration arrangements 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 our programs and platform technology. 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.

Existing and future collaborations involving our product candidates 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 drugs, 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;
- 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 our own development efforts, accurately forecast financial results or provide timely information to our stockholders regarding our out-licensed product candidates;
- if a collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our 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 in this Quarterly Report 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 our PREDATOR platform and other proprietary technologies we 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 our 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 our PREDATOR platform, our product candidates, 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 patent applications in the United States and abroad related to our PREDATOR platform and our product candidates 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. If we are unable to secure or maintain patent protection with respect to our PREDATOR platform, our product candidates 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 current and future 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 that 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 our PREDATOR platform or any of our product candidates 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 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 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 conditions, results of operations and prospects.

We rely on the Harpoon Agreement for patent rights with respect to our product candidates and may in the future acquire additional third-party intellectual property rights on which we may similarly rely. We face risks with respect to such reliance, including the risk that we could lose these rights that are important to our business if we fail to comply with our obligations under these licenses.

We rely on our Second Amended and Restated Assignment and License Agreement, or the Harpoon Agreement, with Harpoon, pursuant to which we have non-exclusive and exclusive rights to technology that is incorporated into our PREDATOR platform, development programs and product candidates. The Harpoon Agreement gives us non-exclusive, sublicensable, worldwide rights to develop, manufacture, and commercialize products containing certain of Harpoon's patented technology and exclusive, irrevocable rights to certain other Harpoon inventions that may be made during a limited collaboration period. The Harpoon Agreement imposes disclosure, royalty payment and other obligations on us.

Moreover, the growth of our business may depend in part on our ability to acquire, in-license or use additional third-party intellectual property rights. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies are also pursuing strategies to license or acquire third-party intellectual property rights that we may consider attractive. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. Licenses to additional third-party intellectual property, technology and materials that may be required for the development and commercialization of our product candidates or technology may not

be available at all or on commercially reasonable terms. In that event, we may be required to expend significant time and resources to redesign our product candidates or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize our future product candidates or technologies, which could materially harm our business, financial condition, results of operations and growth prospects.

Under the Harpoon Agreement, Harpoon is responsible for prosecution and maintenance of the licensed patents and any future third party from whom we may license patent rights may similarly be responsible for prosecution and maintenance of such patents. We have limited control over the activities that are the responsibility of Harpoon and would have limited control over the activities that are the responsibility of any future licensor, and it is possible that prosecution and maintenance of licensed patents by Harpoon or any future licensor may be less vigorous than had we conducted such activities ourselves. Furthermore, the Harpoon Agreement is subject to, and we expect our future license agreements may also be subject to, a reservation of rights by the licensor and/or one or more third parties. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

Disputes may arise regarding intellectual property subject to the Harpoon Agreement or any future license agreements of ours, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our or our licensor's ability to defend intellectual property and to enforce intellectual property rights against third parties;
- the extent to which our technology, product candidates and processes infringe, misappropriate or otherwise violate any intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under the license agreement;
- our diligence obligations under the license agreement and what activities satisfy those diligence obligations;
- the inventorship and ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and any partners of ours; and
- the priority of invention of patented technology.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. We are generally also subject to all of the same risks described in this Quarterly Report with respect to protection of intellectual property that we license as we are for intellectual property that we own. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

Harpoon and any potential future licensors might conclude that we have materially breached our license agreements and might therefore terminate the relevant license agreements, thereby removing our ability to develop and commercialize products and technology covered by such license agreements. If any of our current or future inbound license agreements are terminated, or if the underlying patents fail to provide the intended exclusivity, competitors would have the freedom to seek regulatory approval of, and to market, products that are covered by such license agreements and underlying patents, which might be identical to our products or product candidates. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and growth prospects. Our business also would suffer if any current or future licensors fail to abide by the terms of the license or fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights.

Any licensor of ours may have relied on third-party consultants or collaborators or on funds from third parties, such as the United States government, such that such licensor is not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations, and prospects.

In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

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. Our or our licensor's failure to comply with all such provisions during the patent process could result in abandonment or lapse of a patent or patent application that we own or license, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market and compete with us earlier than would otherwise have been the case.

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. 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 our PREDATOR platform and product candidates 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 our product candidates, PREDATOR platform and research programs 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 our clinical trials, 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 *inter partes* review, post-grant review 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 post-grant review 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 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 current product candidates will eventually become commercially available in biosimilar drug 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 have issued patents with certain composition of matter claims with respect to WTX-124 and IL-12 INDUKINE molecules and also have pending patent applications with other composition of matter claims with respect to our product candidates. We cannot be certain, however, 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, significant elements of our product candidates and PREDATOR platform, including aspects of sample preparation, methods of manufacturing, cell culturing conditions, computational-biological algorithms and related processes 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 policy 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 current or planned 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 to publicly or to competitors.

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 post-grant review 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 our product candidates 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 the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates 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 our fields, there may be a risk that third parties may allege they have patent rights encompassing our product candidates, technologies or methods.

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 WTX-124, WTX-330, JZP898, (formerly WTX-613), WTX-712, WTX-518 or another product candidate we develop in the future 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 current or future 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.

Presently we have certain intellectual property rights, under patents and patent applications that we own or will own and under the Harpoon Agreement, related to WTX-124, WTX-330, JZP898, (formerly WTX-613), WTX-712, WTX-518 and other product candidates we may develop in the future. Our development of additional product candidates may require the use of proprietary rights held by third parties, the growth of our business will

likely depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, while we have patent rights directed to certain INDUKINE constructs we may not be able to obtain intellectual property to broad INDUKINE polypeptides or engineered INDUKINE constructs.

Our product candidates may also require specific formulations to work effectively and efficiently, and rights to such formulation technology may be held by others. 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.

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 our product candidates or 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, *inter partes* review, post-grant review

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 involve 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.

We have obtained granted patents in the United States that we consider to be important for certain of our product candidates, however, we may have less robust intellectual property rights outside the United States, and, in particular, we may not be able to pursue generic coverage of our PREDATOR platform or of our INDUKINE molecules outside of the United States. 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 is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business 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 we do not obtain patent term extension and data exclusivity for any of our current or future product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any of our current or future product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, 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 be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed.

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 Our Product Candidates and Other Legal Compliance Matters

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

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

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

In addition, changes in 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 could delay, limit or prevent marketing approval of a product candidate. Any marketing approval we ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved product not commercially viable.

Further, under the Pediatric Research Equity Act, a BLA or supplement to a BLA for certain biological products must contain data to assess the safety and effectiveness of the biological product 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 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.

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

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

In order to market and sell our products in the European Union 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.

Additionally, we could face heightened risks with respect to seeking obtaining marketing approval authorization in the United Kingdom UK as a result of the withdrawal of the United Kingdom UK from the EU, commonly referred to as Brexit. The UK is no longer part of the European Single Market and EU Customs Union. As of January 1, 2021, the Medicines and Healthcare products Regulatory Agency, or the MHRA, became responsible for supervising medicines and medical devices in Great Britain, comprising England, Scotland and Wales under domestic law, whereas under the terms of the Northern Ireland will continue to be Protocol, Northern Ireland is currently subject to EU rules rules. The UK and EU have however agreed to the Windsor Framework which fundamentally changes the existing system under the Northern Ireland Protocol. The MHRA will rely on Protocol, including with respect to the Human Medicines Regulations 2012 (SI 2012/1916) (as amended), or the HMR, as the basis for regulating medicines. The HMR has incorporated into the domestic law regulation of the body of EU law instruments governing medicinal products that pre-existed prior to in the United Kingdom's withdrawal from UK. Once implemented, the EU. The MHRA may rely on a decision taken changes introduced by the European Commission on Windsor Framework will see the approval of a new marketing authorization via MHRA be responsible for approving all medicinal products destined for the centralized procedure until December 31, 2023. UK market (i.e., Great Britain and Northern Ireland), and the EMA will no longer have any role in approving medicinal products destined for Northern Ireland. Any delay in obtaining, or an inability to obtain, any marketing approvals, authorizations, as a result of Brexit or otherwise, may force us to restrict or delay efforts to seek regulatory approval in the United Kingdom UK for our product candidates, which could significantly and materially harm our business.

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 review process, in the context of the Pharmaceutical Strategy for Europe initiative, launched by the European Commission in November 2020. The European Commission's proposal for revision of several legislative instruments related to medicinal products (potentially reducing the duration of regulatory data protection, revising the eligibility for expedited pathways, etc.) was published on April 26, 2023. The proposed revisions remain to be agreed and adopted by the European Parliament and European Council and the proposals may therefore be substantially revised before adoption, which is not anticipated before early 2026. The revisions may however 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 our product candidates and, even if we do, that exclusivity may not prevent the FDA or the EMA 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 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. Generally, a product with orphan drug designation only becomes entitled to orphan drug exclusivity if it receives the first marketing approval for the indication for which it has such designation, in which case the FDA or the European Medicines Agency, or EMA 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 and

ten years in Europe. The European exclusivity period can be reduced to six years if a product no longer meets the criteria for orphan drug designation or if the product is sufficiently profitable so that market exclusivity is no longer justified.

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 to make a major contribution to patient care. Finally, orphan drug exclusivity may be lost if the FDA or the EMA determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

The FDA may further reevaluate re-evaluate the Orphan Drug Act and its regulations and policies. This may be particularly true in light of a decision from the Court of Appeals for the 11th Circuit in September 2021 finding that, for the purpose of determining the scope of exclusivity, the term "same disease or condition" means the designated "rare disease or condition" and could not be interpreted by the FDA to mean the "indication or use." Thus, the Court of Appeals concluded that orphan drug exclusivity applies to the entire designated disease or condition rather than the "indication or use." Although there have been legislative proposals to overrule this decision, they have not been enacted into law. On January 23, 2023, the FDA announced that, in matters beyond the scope of that court order, it will continue to apply its existing regulations tying orphan-drug exclusivity to the uses or indications for which the orphan drug was approved. We do not know if, when, or how the FDA or Congress may change the orphan drug regulations and policies in the future, and it is uncertain how any changes might affect our business. Depending on what changes the FDA may make to its orphan drug regulations and policies, our business could be adversely impacted.

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 of our product candidates are approved.

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

In addition, later discovery of previously unknown adverse events or more of our other problems with any product candidates, we will continue to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production, product surveillance and quality control. If we fail to comply with these requirements, we could have the marketing approvals for our products withdrawn by regulatory authorities and our ability to market any products could be limited, which could adversely affect our ability to achieve or sustain profitability.

We must also comply with requirements concerning advertising and promotion for any of our product candidates for which we may obtain marketing approval. Promotional communications with respect to prescription products are subject to a variety of legal approval and regulatory restrictions and must be consistent with the information in the product's approved labeling. Thus, we will not be able to promote any products we develop for indications its manufacturers or uses for which they are not approved. The FDA and other agencies, including the Department of Justice, manufacturing processes or the DOJ, closely regulate and monitor the post-approval marketing and promotion of products to ensure that they are marketed and distributed only for the approved indications and in accordance with the provisions of the approved labeling. In September 2021, the FDA published final regulations which describe the types of evidence that the FDA will consider in determining the intended use of a drug or biologic. Violations of the Federal Food, Drug, and Cosmetic Act and other statutes, including the False Claims Act, relating to the promotion and advertising of prescription products may lead to investigations and enforcement actions alleging violations of federal and state health care fraud and abuse laws, as well as state consumer protection laws.

Failure failure to comply with regulatory requirements, may yield various results, including:

- restrictions on such products, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on distribution or use of a product;
- requirements to conduct post-marketing studies or clinical trials;

- warning letters or untitled letters;
- withdrawal of the products from the market;
- refusal to approve pending applications or supplements to approved applications that we submit;
- recall of products;
- damage to relationships with collaborators;
- unfavorable press coverage and damage to our reputation;
- fines, restitution or disgorgement of profits or revenues;
- suspension or withdrawal of marketing approvals;
- refusal to permit the import or export of our products;
- product seizure;
- injunctions or the imposition of civil or criminal penalties; and
- litigation involving patients using our products.

Similar Finally, our ability to develop and market new drug products may be impacted by ongoing litigation challenging the FDA's approval of mifepristone. Specifically, on April 7, 2023, the U.S. District Court for the Northern District of Texas stayed the approval by the FDA of mifepristone, a drug product which was originally approved in 2000 and whose distribution is governed by various conditions adopted under a REMS. In reaching that decision, the district court made a number of findings that may negatively impact the development, approval and distribution of drug products in the U.S. Among other determinations, the district court held that plaintiffs were likely to prevail in their claim that FDA had acted arbitrarily and capriciously in approving mifepristone without sufficiently considering evidence bearing on whether the drug was safe to use under the conditions identified in its labeling. Further, the district court read the standing requirements governing litigation in federal court as permitting a plaintiff to bring a lawsuit against the FDA in connection with its decision to approve an NDA or establish requirements under a REMS based on a showing that the plaintiff or its members would be harmed to the extent that FDA's drug approval decision effectively compelled the plaintiffs to provide care for patients suffering adverse events caused by a given drug.

On April 12, 2023, the district court decision was stayed, in part, by the U.S. Court of Appeals for the Fifth Circuit. Thereafter, on April 21, 2023, the U.S. Supreme Court entered a stay of the district court's decision, in its entirety, pending disposition of the appeal of the district court decision in the Court of Appeals for the Fifth Circuit and the disposition of any petition for a writ of certiorari to the Supreme Court. The Court of Appeals for the Fifth Circuit held oral argument in the case on May 17, 2023 and, on August 16, 2023, issued its decision. The court declined to order the removal of mifepristone from the market, finding that a challenge to the FDA's initial approval in 2000 is barred by the statute of limitations. However, the Appeals Court did hold that plaintiffs were likely to prevail in their claim that changes allowing for expanded access of mifepristone that the FDA authorized in 2016 and 2021 were arbitrary and capricious. On September 8, 2023, the Justice Department and a manufacturer of mifepristone filed petitions for a writ of certiorari, requesting that the U.S. Supreme Court to review the Appeals Court decision. The Supreme Court granted these petitions for writ of certiorari for the appeals court decision, heard oral arguments in the first quarter of 2024 and a ruling is expected in mid-2024.

Post-approval restrictions 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 authorized drugs, which are strictly regulated in the EU and are also subject to EU Member State laws. 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 regulations restricting the promotion of our products for unapproved uses, we could be subject to criminal penalties, substantial fines or other sanctions and damage awards.

The regulations relating to the promotion of products for unapproved uses are complex and subject to substantial interpretation by the FDA, EMA, MHRA and other government agencies. In September 2021, the FDA published final regulations which describe the types of evidence that the agency will consider in determining the intended use of a drug 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 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 October 2023, the FDA published draft guidance outlining the agency's non-binding policies governing the distribution of scientific information on unapproved uses to healthcare providers. This draft guidance calls for such communications to be truthful, non-misleading, factual, and unbiased and include all information necessary for healthcare providers to interpret the strengths and weaknesses and validity and utility of the information about the unapproved use. 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 drug or unapproved uses of an approved drug. We may engage in these discussions and communicate with healthcare providers, payors and other constituencies in compliance with all applicable laws, regulatory guidance and industry best practices. We will need to carefully navigate the FDA's various regulations, guidance and policies, along with recently enacted legislation, to ensure compliance with restrictions governing promotion of our products.

In recent years, a significant number of pharmaceutical and biotechnology companies have been the target of inquiries and investigations by various federal and state regulatory, investigative, prosecutorial and administrative entities in connection with the promotion of products for unapproved uses and other sales practices, including the Department of Justice and various U.S. Attorneys' Offices, the Office of Inspector General of the Department of Health and Human Services, the FDA, the Federal Trade Commission, or the FTC, and various state Attorneys General offices. These investigations have alleged violations of various federal and state laws and regulations, including claims asserting antitrust violations, violations of the Federal Food, Drug, and Cosmetic Act, 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.

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 our product candidates, 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 offers major advances in treatment or provides a treatment where no adequate therapy exists, the FDA may designate the product candidate for priority review. A priority review designation means that the goal for the FDA to review an application is six months, rather than the standard review period of ten months.

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 of our product candidates, 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 CHMP rapporteur from the Committee for Human Medicinal Products 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 of our current or future product candidates, may not lead to a faster development or regulatory review or approval process and it does not increase the likelihood that our product candidates will receive marketing approval.

We may seek approval of any of our current and future 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. The FDA or other applicable regulatory agency makes the determination regarding whether a surrogate endpoint is reasonably likely to predict long-term clinical benefit.

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

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

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

With passage of the Food and Drug Omnibus Reform Act, or FDORA, in December 2022, Congress modified certain provisions governing accelerated approval of drug and biologic products. Specifically, the new legislation authorized the FDA to: require a sponsor to have its confirmatory clinical trial underway before accelerated approval is awarded, require a sponsor of a product granted accelerated approval to submit progress reports on its post-approval studies to the FDA every six months until the study is completed; and use expedited procedures to withdraw accelerated approval of an NDA or BLA after the confirmatory trial fails to verify the product's clinical benefit. Further, FDORA requires the agency to publish on its website "the rationale for why a post-approval study is not appropriate or necessary" whenever it decides not to require such a study upon granting accelerated approval.

More recently, in March 2023, the FDA issued draft guidance that outlines its current thinking and approach to accelerated approval. The FDA indicated that the accelerated approval pathway is commonly used for approval of oncology drugs due to the serious and life-threatening nature of cancer. Although single-arm trials have been commonly used to support accelerated approval, a randomized controlled trial is the preferred approach as it provides a more robust efficacy and safety assessment and allows for direct comparisons to an available therapy. To that end, the FDA outlined considerations for designing, conducting, and analyzing data for trials intended to support accelerated approvals of oncology therapeutics. While this guidance is currently only in draft form and will not be legally binding even when finalized, we will need to consider the FDA's guidance closely if we seek accelerated approval for any of our products. Accordingly, even if we do receive accelerated approval, we may not experience a faster development or regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate full FDA 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 pending studies are provided, a conditional marketing authorization can become a "standard" marketing authorization. However, if the conditions are not fulfilled within the timeframe set by the EMA, the marketing authorization will cease to be renewed.

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

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

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

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

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

We intend in the future to conduct clinical trials for certain of our 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 intend in the future to conduct one or more of our 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 good clinical practice. The FDA must be able to validate the data from the trial through an onsite inspection if necessary. The trial population must also have a similar profile to the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful, except to the extent the disease being studied does not typically occur in the United States. 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 our 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 our clinical trials;
- administrative burdens of conducting clinical trials under multiple non-U.S. regulatory authority schema;
- foreign exchange rate fluctuations; and
- diminished protection of intellectual property in some countries.

Inadequate funding for the FDA, the SEC and other government agencies, including from government shut downs, or other disruptions to these agencies' operations, including from the COVID-19 pandemic, could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. In addition, government funding of the U.S. Securities and Exchange Commission, or the SEC, and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA, EMA and other agencies may also slow the time necessary for new product candidates drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several in recent years, including in 2018 and 2019, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact In addition, disruptions may also be caused by events similar to the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Separately, in response to COVID-19 pandemic. During the COVID-19 pandemic, a number of companies announced receipt of complete response letters due to the FDA's inability to complete required inspections for their applications. As In the event of early 2022, a similar public health emergency in the FDA has resumed inspections of domestic and foreign facilities to ensure timely reviews of applications for medical products. However, future, the FDA may not be able to continue its current pace and review timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required. In response to the COVID-19 pandemic, the FDA issued numerous guidance documents and took other actions to facilitate research and development of new drug products. The public health emergency declarations related to COVID-19 ended on May 11, 2023. In connection therewith, the FDA ended 22 COVID-19-related policies on May 11, 2023 and allowed 22 to continue for 180 days. The FDA plans to retain 24 COVID-19-related policies with appropriate changes and four whose duration is not tied to the end of the public health

emergency. At this point, it is unclear how, if at all, these developments will impact our efforts to develop and commercialize our product candidates. extended. Regulatory authorities outside the U.S. have adopted or United States facing similar circumstances may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic a similar public health emergency and may also experience delays in their regulatory activities.

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

Current and future legislation may increase the difficulty and cost for us to obtain reimbursement for any of our 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 ACA substantially changed the way healthcare is financed by both governmental and private insurers and continues to significantly impact the U.S. pharmaceutical industry. Since enactment of the ACA, there have been numerous legal challenges and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the TCJA in 2017, Congress repealed the “individual mandate.” The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. Further, in December 2018, a U.S. District Court judge in the Northern District of Texas ruled that the individual mandate portion of the ACA is an essential and inseverable feature of the ACA, and therefore because the mandate was repealed as part of the TCJA, the remaining provisions of the ACA are invalid as well. In June 2021, the U.S. Supreme Court dismissed this a legal action after finding that the plaintiffs do not have standing to challenge the constitutionality of the ACA. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation’s automatic reduction to several government programs. These changes included aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2032 under the CARES Act. These Medicare sequester reductions were suspended and reduced through the end of June 2022, with the full 2% cut resuming thereafter. The American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any of our product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used. The Consolidated Appropriations Act, which was signed into law by President Biden in December 2022, made several changes to sequestration of the Medicare program. Section 1001 of the Consolidated Appropriations Act delays the 4% Statutory Pay-As-You-Go Act of 2010, or PAYGO, sequester for two years, through the end of calendar year 2024. Triggered by enactment of the American Rescue Plan Act of 2021, the 4% cut to the Medicare program would have taken effect in January 2023. The Consolidated Appropriations Act’s health care offset title includes Section 4163, which extends the 2% Budget Control Act of 2011 Medicare sequester for six months into fiscal year 2032 and lowers the payment reduction percentages in fiscal years 2030 and 2031.

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

This Executive Order also directs the U.S. Department of Health and Human Services, or HHS, to create a special enrollment period for the Health Insurance Marketplace in response to the COVID-19 pandemic.

In the EU, on December 13, 2021, Regulation No 2021/2282 on Health Technology Assessment, or HTA, amending Directive 2011/24/EU, was adopted. While the Regulation entered into force in January 2022, it will only begin to apply from January

2025 onwards, with preparatory and implementation-related steps to take place in the interim. Once applicable, it will have a phased implementation depending on the concerned products. 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 will permit EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas, including joint clinical assessment of the innovative health technologies with the highest potential impact for patients, joint scientific consultations whereby developers can seek advice from HTA authorities, identification of emerging health technologies to identify promising technologies early, and continuing voluntary cooperation in other areas. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technology, and making decisions on pricing and reimbursement.

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

In addition, in October 2020, HHS and the FDA published a final rule allowing states and other entities to develop a Section 804 Importation Program, or SIP, to import certain prescription drugs from Canada into the United States. That regulation was challenged in a lawsuit by the Pharmaceutical Research and Manufacturers of America, ("PhRMA") 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. As of March 2023, eight Nine states (Colorado, Florida, Maine, New Hampshire, New Mexico, North Dakota, Texas, Vermont and Wisconsin) have passed laws allowing for the importation of drugs from Canada. Six Certain of those these states have submitted Section 804 Importation Program proposals and are awaiting FDA approval. Further, on November 20, 2020 On January 5, 2024, HHS finalized the FDA approved Florida's plan for Canadian drug importation. The rule also creates a regulation that would eliminate the current new safe harbor Medicare drug rebates and create for price reductions reflected at the point-of-sale, as well as a new safe harbors harbor for beneficiary point-of-sale discounts certain fixed fee arrangements between pharmacy benefit managers and PBM service fees. It originally was set to go into effect on January 1, 2022, but manufacturers, the implementation of which has been delayed by Congress until January 1, 2032. by the Inflation Reduction Act, or IRA.

On July 9, 2021, President Biden signed Executive Order 14063, which focuses on, among other things, the price of pharmaceuticals. The Executive Order directs HHS to create a plan within 45 days to combat "excessive pricing of prescription pharmaceuticals and enhance domestic pharmaceutical supply chains, to reduce the prices paid by the federal government for such pharmaceuticals, and to address the recurrent problem of price gouging." On September 9, 2021, HHS released its plan to reduce pharmaceutical prices. The key features of that plan are to: (a) make pharmaceutical prices more affordable and equitable for all consumers and throughout the health care system by supporting pharmaceutical price negotiations with manufacturers; (b) improve and promote competition throughout the prescription pharmaceutical industry by supporting market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase transparency; and (c) foster scientific innovation to promote better healthcare and improve health by supporting public and private research and making sure that market incentives promote discovery of valuable and accessible new treatments.

More recently, on On August 16, 2022, the IRA was signed into law by President Biden. The new legislation has implications for Medicare Part D, which is a program available to individuals who are entitled to Medicare Part A or enrolled in Medicare Part B to give them the option of paying a monthly premium for outpatient prescription drug coverage. Among other things, the IRA requires manufacturers of certain drugs to engage in price negotiations with Medicare (beginning in 2026), with prices that can be negotiated subject to a cap, imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation (first due in 2023), and replaces the Part D coverage gap discount program with a

new discounting program (beginning in 2025). The IRA permits the Secretary of HHS to implement many of these provisions through guidance, as opposed to regulation, for the initial years.

Specifically, with respect to price negotiations, Congress authorized Medicare to negotiate lower prices for certain costly single-source drug and biologic products that do not have competing generics or biosimilars and are reimbursed under Medicare Part B and Part D. CMS may negotiate prices for ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. This provision applies to drug products that have been approved for at least nine years and biologics that have been licensed for 13 years, but it does not apply to drugs and biologics that have been approved for a single rare disease or condition. Nonetheless, since CMS may establish a maximum price for these products in price negotiations, we would be fully at risk of government action if our products are the subject of Medicare price negotiations. Moreover, given the risk that could be the case, these provisions of the IRA may also further heighten the risk that we would not be able to achieve the expected return on our drug products or full value of our patents protecting our products if prices are set after such products have been on the market for nine years.

Further, the legislation subjects drug manufacturers to civil monetary penalties and a potential excise tax for failing to comply with the legislation by offering a price that is not equal to or less than the negotiated “maximum fair price” under the law or for taking price increases that exceed inflation. The legislation also requires manufacturers to pay rebates for drugs in Medicare Part D whose price increases exceed inflation. The new law also caps Medicare out-of-pocket drug costs at an estimated $4,000 a year in 2024 and, thereafter beginning in 2025, at $2,000 a year. In addition, the IRA potentially raises legal risks with respect to individuals participating in a Medicare Part D prescription drug plan who may experience a gap in coverage if they required coverage above their initial annual coverage limit before they reached the higher threshold, or “catastrophic period” of the plan. Individuals requiring services exceeding the initial annual coverage limit and below the catastrophic period, must pay 100% of the cost of their prescriptions until they reach the catastrophic period. Among other things, the IRA contains many provisions aimed at reducing this financial burden on individuals by reducing the co-insurance and co-payment costs, expanding eligibility for lower income subsidy plans, and price caps on annual out-of-pocket expenses, each of which could have potential pricing and reporting implications.

Since mid-2023, several large pharmaceutical companies, as well as U.S. Chamber of Commerce and PhRMA, have On June 6, 2023, Merck & Co. filed lawsuits a lawsuit against the HHS and CMS asserting that, among other things, the IRA’s Drug Price Negotiation Program for Medicare constitutes an uncompensated taking in violation of the Fifth Amendment of the Constitution. Litigation Subsequently, a number of other parties, including the U.S. Chamber of Commerce, Bristol Myers Squibb Company, the PhRMA, Astellas, Novo Nordisk, Janssen Pharmaceuticals, Novartis, AstraZeneca and Boehringer Ingelheim, also filed lawsuits in various courts with similar constitutional claims against the HHS and CMS. We expect that litigation involving these and other provisions of the IRA will likely continue, for some time, with unpredictable and uncertain results.

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

At the 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. 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 drug 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.

Finally, outside the United States, in some nations, including those of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control and access. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we or our collaborators may be required to conduct a clinical trial that compares the cost-effectiveness of our product to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

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

Healthcare providers, third-party payors and others will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our current and future arrangements with healthcare providers and third-party payors will expose us to broadly applicable

fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research as well as market, sell and distribute any products for which we obtain marketing approval. Potentially applicable U.S. federal and state healthcare laws and regulations include the following:

Anti-Kickback Statute. The federal Anti-Kickback Statute prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or

reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid.

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

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

HIPAA and HITECH. 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 HHS information related to payments and other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists, and chiropractors) and teaching hospitals, as well as ownership and investment interests by physicians and their immediate family members. As of January 1, 2022, 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 laws and regulations, such as state anti-kickback and false claims laws, and transparency laws, may apply to sales or marketing arrangements, and claims involving healthcare items or services reimbursed by non-governmental third party payors, including private insurers, and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, in addition to requiring manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures. Many state laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Foreign laws also govern the privacy and security of health information in many circumstances.

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

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

physicians or other providers or entities with whom we expect to do business is found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

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 are 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, 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 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, and a wide range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns based on general consumer protection laws. The Federal Trade Commission, or FTC and state Attorneys General all are aggressive in reviewing privacy and data security protections for consumers. New laws also are being considered at both the state and federal levels. For example, the FTC has been particularly focused on the unpermitted processing of health and genetic data through its recent enforcement actions and is expanding the types of privacy violations that it interprets to be “unfair” under Section 5 of the FTC 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). The agency is also in the process of developing rules related to commercial surveillance and data security that may impact our business. 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 existing laws, a broad range of legislative measures have been introduced at both the federal and state levels. For example, the California Consumer Privacy Act, or CCPA, which went into effect on January 1, 2020, imposed 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 erasure of such personal information. Additionally, in November 2020, California voters approved a new privacy law, the California Privacy Rights Act, or CPRA, which expands the CCPA to incorporate additional provisions, including requiring that the use, retention, and sharing of personal information of California residents be reasonably necessary and proportionate to the purposes of collection or processing, granting additional protections for sensitive personal information, and requiring greater disclosures related to notice to residents regarding retention of information. Most CPRA provisions took effect on January 1, 2023, though the obligations apply to any personal information collected after January 1, 2022.

In addition to California, at least eleven other states including Virginia, Colorado, Utah, and Connecticut, already have passed state comprehensive privacy laws similar to the CCPA and other states CPRA. These laws are considering similar legislation. Certain state either in effect or will go into effect sometime before the end of 2026. Like the CCPA and CPRA, these laws may be more stringent or broader in scope, or offer greater individual rights, with respect create obligations related to confidential, sensitive and personal information than federal, international or other state laws, and such laws may differ from each other, which may complicate compliance efforts. Failure to comply with federal and state laws regarding privacy and security the processing of personal information, could expose us as well as special obligations for the processing of “sensitive” data (which includes health data in some cases). Some of the provisions of these laws may apply to fines our business activities. There are also states that are strongly considering or have already passed comprehensive privacy laws during the 2023 legislative sessions that will go into effect in 2024 and penalties under such laws. beyond, including New Hampshire and New Jersey. Other states will be considering these laws in the future, and Congress has also been debating passing a federal privacy law. There are also states that are specifically regulating health information that may affect our business. For example, Washington state recently passed a health privacy law that will regulate the collection and sharing of health information, and the law also has a private right of action, which further increases the relevant compliance risk. Connecticut and Nevada have also passed similar laws regulating consumer health data. These laws may impact our business activities, including our identification of research subjects, relationships with business partners and ultimately the marketing and distribution of our products.

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. For example, the Federal Trade Commission FTC and state Attorneys General are aggressive in reviewing privacy and data security protections for consumers. In addition to the risks associated with enforcement activities, there also is the threat of consumer class actions related to these laws and the overall protection of personal data. 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.

Similar to the laws in the United States, there are significant privacy and data security laws that apply in Europe and other countries. For example, the collection, use, disclosure, transfer, or other processing of personal data, including personal health data, regarding individuals who are located in the European Economic Area, or the EEA, is subject to the EU General Data Protection Regulation, or the GDPR, which took effect across all member states of the EEA in May 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including strict rules on the transfer of personal data to countries outside the European Union, 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 European Union member states may make their own further laws and regulations limiting the processing of personal data, 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 data from such sites to countries that are considered to lack an adequate level of data protection, such as the United States. There are also open questions about how personal data will be protected in the United Kingdom and whether personal information can transfer from the EU to the United Kingdom. Following

In October 2022, President Biden signed an executive order to implement the withdrawal of EU-U.S. Data Privacy Framework, which serves as a replacement to the United Kingdom EU-U.S. Privacy Shield. The European Commission adopted the adequacy decision on July 10, 2023. The adequacy decision permits U.S. companies who self-certify to the EU-U.S. Data Privacy Framework to rely on it as a valid data transfer mechanism for data transfers from the EU, the United Kingdom Data Protection Act of 2018 applies to the processing of personal data that takes place in the United Kingdom and includes parallel obligations to those set forth by GDPR. While the United Kingdom Data Protection Act of 2018 “implements” and complements the GDPR, and has achieved Royal Assent and is effective in the United Kingdom, it is unclear whether transfer of data from the EEA European Union to the United Kingdom States. However, some privacy advocacy groups have already suggested that they will remain lawful under GDPR. The United Kingdom government has already determined that it considers all European Union 27 be challenging the EU-U.S. Data Privacy Framework. If these challenges are successful, they may not only impact the EU-U.S. Data Privacy Framework, but also further limit the viability of the standard contractual clauses and EEA member states to be adequate for the purposes of data protection, ensuring that data flows from the United Kingdom to the European Union/EEA remain unaffected. In addition, a recent decision from the European Commission appears to deem the United Kingdom as being “essentially adequate” for purposes of other data transfer from mechanisms. The uncertainty around this issue has the EU potential to the United Kingdom, although this decision may be re-evaluated in the future. Beyond GDPR, there are privacy and data security laws in a growing number of countries around the world. While many loosely follow GDPR as a model, other laws contain different or conflicting provisions. These laws may impact our ability to conduct our business activities, including clinical trials and any eventual sale and distribution of commercial products. business.

These evolving compliance and operational requirements 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 data, 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 our clinical trials, 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 our clinical research activities abroad and/or to obtain necessary permits, licenses, and other regulatory approvals. We can be held liable for the corrupt or other illegal activities of these third-party intermediaries, our employees, representatives, contractors, partners and agents, even if we do not explicitly authorize or have actual knowledge of such activities.

Noncompliance with 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.

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 our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

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

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

Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with the FDA or other regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. Even with appropriate policies and procedures, it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent such activity may not be

effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations and prospects, including the imposition of significant fines or other sanctions.

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 our product candidates, sales and marketing personnel, is critical to our success. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, replacing executive officers and 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 our 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 also experience competition for the hiring of scientific and clinical personnel from universities and research institutions. In addition, we rely on consultants and advisors, including scientific and clinical advisors, to assist us in formulating our research and development strategy. Our consultants and advisors may be employed by employers other than us and may have commitments under consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited, and could harm our business, prospects, financial condition and results of operations.

We expect to grow our organization, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

As of September 30, 2023 March 31, 2024, we had 46 employees. We expect to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of clinical development, regulatory affairs, finance and, if any of our product candidates receive marketing approval, sales, marketing and distribution. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities to devote time to managing these growth activities. To manage these growth activities, we must continue to implement and improve our managerial, operational and financial systems, expand our facilities and continue to recruit and train additional qualified personnel. Due to our limited financial resources and the limited experience of our management team in managing a company with such anticipated growth, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. Our inability to effectively manage the expansion of our operations may result in weaknesses in our infrastructure, give rise to operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If our management is unable to effectively manage our expected growth, our expenses may increase more than expected, our potential ability to generate revenue could be reduced and we may not be able to implement our business strategy.

We depend on 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 technology systems, and any failure of these systems could harm our business. Security breaches, loss of theft, data inability to access systems, and other disruptions could compromise sensitive information related corruption, operational disruption, damage to our business reputation, or prevent us from accessing critical information and expose us to liability, which could adversely affect our business, results of operations and financial condition.

loss. We collect and maintain information in digital and other forms that is necessary to conduct our business, and we are increasingly dependent on information technology systems and infrastructure, including mobile technologies, to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential Our technologies, systems, networks, or other proprietary information, including intellectual property, proprietary business information and personal information. It is critical that we do so in a secure manner to maintain the privacy, security, confidentiality, availability and integrity of such confidential information. Our internal information technology systems and infrastructure, and those of our contractors, consultants, vendors, suppliers and other third parties on which we rely, are vulnerable to damage business partners, may become the target of cyberattacks or information security breaches that could result in the unauthorized access release, gathering, monitoring, misuse, loss, or

use resulting from computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the Internet, denial or degradation destruction of service attacks, ransomware, hacking, phishing proprietary and other social engineering attacks, attachments information, or could otherwise lead to emails, intentional or accidental actions or inactions by persons inside the disruption of our organization or by persons with access to systems inside our organization.

business operations. The risk of a security breach or disruption, or data loss, particularly through cyber-attacks cyberattacks or cyber intrusion, including by computer hackers, supply chain attacks 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. In addition, the prevalent use of mobile devices that access confidential information increases the risk of lost or stolen devices, security Moreover, certain cyber incidents, such as surveillance, may remain undetected for an extended period and data security breaches, which could lead to disruptions in critical systems or the unauthorized release of confidential or otherwise protected information. These events could lead to financial loss 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 internal computer systems, or those used by our third-party research institution collaborators, CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors, vendors, and consultants may be vulnerable to damage from cybersecurity risks, including attempts to gain unauthorized access to and to harm sensitive or confidential information or other intellectual property. As and networks, insider threats, and ransomware. These vulnerabilities may be heightened as a result of flexible work arrangements, including hybrid or remote work policies implemented by us and our third-party contractors, that were first adopted in response to the COVID-19 pandemic we and have experienced increases continued by many businesses in remote an effort to attract and hybrid working since March 2020 retain talent.

Investigations into and as a result, have increasingly relied upon teleconferencing remedial efforts in connection with any security incidents, even those with immaterial impact, can be costly and cloud-based means of communication time-consuming and data storage. In addition, many of our internal systems operate on cloud-based platforms. There have been numerous publicized attempts of bad actors attempting to intercept proprietary communications and cloud-based systems. We may be similarly susceptible to those kinds of threats.

The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be material, or cause significant and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service, negative publicity and other harm disruption, to our business and our competitive position. In addition, if a ransomware attack or other cybersecurity incident occurs, either internally or at our vendors or third-party technology service providers, we could be prevented from accessing our data or systems, which may cause interruptions or delays in our business operations, cause us to incur remediation costs, subject us to demands to pay a ransom, or damage our reputation, regardless of whether we pay the ransom amount. Any such event, or other loss of information, could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation, any of which could adversely affect our business.

In addition to the foregoing, any breach of privacy laws or data security laws, particularly resulting in a significant security incident or breach involving the misappropriation, loss or other unauthorized use or disclosure of sensitive or confidential patient or consumer information, could have a material adverse effect on our business, reputation and financial condition. As a data controller, we will be accountable for any third-party service providers we engage to process personal data on our behalf, including our CROs. There is no assurance that privacy and security-related safeguards we implement will protect us from all risks associated with the third-party processing, storage and transmission of such information.

Any security compromise affecting us, our partners or our industry, whether real or perceived, could harm our reputation, erode confidence in the effectiveness of our security measures and lead to regulatory scrutiny. If such an event were to occur and cause interruptions in our operations or result in the unauthorized acquisition of or access to personally identifiable information or individually identifiable health information (violating certain privacy laws, as applicable, such as HIPAA, CCPA, HITECH and GDPR), it could result in a material disruption of our discovery and development programs and our business operations, whether due to a loss of our trade secrets or other similar disruptions. Some of the federal, state and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships. Notifications and follow-up actions related to a security breach could impact our reputation, cause us to incur significant costs, including legal expenses and remediation costs. For example, the loss of clinical trial data from completed ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the lost data. Likewise, we rely on third parties for research and development, the manufacture and supply of drug product and drug substance and to conduct clinical trials. We would depend on these third parties to implement adequate controls and safeguards to protect against and report cybersecurity incidents. If they fail to do so, 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 the further development and commercialization of our 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. The techniques used by criminal elements 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 must also be exposed reported to a risk affected individuals and various government and/or regulatory agencies, and in some cases to the media, under provisions of loss, governmental investigations or enforcement, or litigation HIPAA, as amended by HITECH, other U.S. federal and potential liability, any state law, and requirements of which could materially adversely affect our business, results of operations non-U.S. jurisdictions, including the European Union Data Protection Directive, and financial condition. penalties may also apply.

Our insurance policies may not be adequate to compensate us for the potential losses arising from 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, contract manufacturers, and CROs, and other parties, 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 manmade man-made disasters or business interruptions, for which we are, and they may be, predominantly self-insured. Because we rely on third-party contract manufacturers to produce our product candidates, our ability to obtain clinical supplies of our 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 such as the COVID-19 pandemic (including variants of COVID-19) 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 current or 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 of our current service providers, manufacturers and other partners 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 our product candidates internationally, if approved, could materially adversely affect our business.

We plan to 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 geo-political 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 strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time, we may consider 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

An active trading market for our common stock may not continue to develop or be sustained and our stockholders may not be able to resell their shares of our common stock.

Our common stock began trading on the The Nasdaq Global Select Market, or Nasdaq, on April 30, 2021. Prior to April 30, 2021, there was no public market for our common stock. We cannot predict the extent to which an active market for our common stock will continue to develop or be sustained, or how the development of such a market might affect the market price for our common stock. As a result, it may be difficult for our stockholders to sell their shares of our common stock at an attractive price or at all.

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

Our stock price is likely be volatile. For example, from April 30, 2021 January 1, 2023, when our stock first began trading on Nasdaq until November 10, 2023 April 29, 2024, our stock price has ranged from $1.39 $1.57 to $23.99. $8.19. 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;
- developments with respect to the COVID-19 pandemic;
- general political and economic conditions; 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 with provide favorable coverage. Although we have obtained coverage, if one or more of the analysts covering us downgrades our stock or publishes unfavorable or inaccurate research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline.

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

Our executive officers, directors, holders of 5% or more of our common stock and their respective affiliates beneficially own a significant portion of our outstanding common stock.

As a result of their share ownership, these stockholders, if they act together, have the ability to influence our management and policies and are able to significantly affect the outcome of matters requiring stockholder approval such as elections of directors, amendments of our organizational documents or approvals of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that our stockholders may feel are in their best interest.

In addition, this concentration of ownership might adversely affect the market price of our common stock by:

- delaying, deferring or preventing a change of control of us;
- impeding a merger, consolidation, takeover or other business combination involving us; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of us.

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 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. In addition, the terms of the Loan Agreement and any future debt agreements may preclude us from paying dividends. Any return to stockholders will therefore be limited in the foreseeable future to the appreciation of their stock.

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 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.

We In the past, we have identified a material weakness weaknesses in our internal control over financial reporting, and that weakness has led if we are unable to a conclusion that 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 and disclosure controls and procedures were not effective reporting. All material weaknesses previously identified have been fully remediated as of September 30, 2023 March 31, 2024. Our inability to remediate

If, in the future, we have a material weakness in our discovery of additional weaknesses, internal controls over financial reporting, we may not detect errors on a timely basis and our inability consolidated financial statements may be materially misstated. We or our independent registered public accounting firm may not be able to achieve and maintain conclude on an ongoing basis that we have effective disclosure controls and procedures and internal control over financial reporting, which could adversely affect harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of operations, our stock price to fall. In addition, as a public company we are required to file accurate and investor confidence. 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 Global Select 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.

Section 404 requires that companies evaluate and report on the effectiveness If we fail to maintain an effective system of their internal control over financial reporting. 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. Failure Any failure to have effective internal control over financial implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting and disclosure controls and procedures can impair obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our ability to produce accurate financial statements on a timely basis and could lead to a restatement of our financial statements. If, as a result of the ineffectiveness of independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting and disclosure controls and procedures, we cannot provide reliable 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 business decision processes remediation of previous material weaknesses may be adversely affected, not prevent any future deficiency in our business and results of operations internal control over financial reporting. Inferior

internal controls could be harmed, also cause investors could to lose confidence in our reported financial information, which could harm our business and our ability to obtain additional financing, or additional financing have a negative effect on favorable terms, could be adversely affected.

We identified a material weakness in the second quarter of 2023 in our internal control over financial reporting. The material weakness that we identified related to design and operating deficiencies in our purchasing process, specifically related to the application of invoices to purchase orders and processes to estimate progress on open purchase orders and to identify inaccurate expense estimates within purchase orders. Due to the material weakness in our internal control over financial reporting, we have also concluded that our disclosure controls and procedures were not effective as of September 30, 2023. We have implemented, and are continuing to implement, measures designed to improve internal control over financial reporting to remediate the control deficiencies that led to the material weakness by, among other things, expanding managerial oversight of, and adding process controls to, our purchasing process, including approval and ongoing management of purchase orders and related invoices, and assessment of progress and estimated expenses. We have utilized and will continue to utilize financial consultants to assist with the evaluation and documentation of process controls. We expect to complete the remediation of the material weakness in the near future by hiring additional finance personnel and the continued adoption of incremental financial policies, procedures, and internal controls. We will incur additional costs to remediate these weaknesses, primarily personnel costs and external consulting fees. We cannot provide assurances that the measures we have taken to date, together with any measures we may take in the future, will be sufficient to remediate the control deficiencies that led to our material weakness in our internal control over financial reporting or to avoid potential future material weaknesses. If we are unable to successfully remediate our existing or any future material weaknesses in our internal control over financial reporting, or if we identify any additional material weaknesses, the accuracy and timing trading price of our financial reporting may be adversely affected, we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports in addition to applicable stock exchange listing requirements, investors may lose confidence in our financial reporting, and our stock price may decline as a result. We also could become subject to investigations by Nasdaq, the SEC or other regulatory authorities. 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 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 the 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 5. Other Information.

On May 2, 2024, we, as borrower, entered into a loan and security agreement, or the Loan Agreement, with K2 HealthVentures LLC, or K2HV (we refer to K2HV, together with any other lender from time to time, as the Lenders); K2HV, as administrative agent for the Lenders; and Ankara Trust Company, LLC, as collateral trustee for the Lenders. The Loan Agreement provides for 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 upon closing and $5.0 million from the second tranche commitment. A third tranche commitment of up to $10.0 million is available to be drawn at our option during certain availability periods, 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. A fourth tranche commitment of up to $20.0 million is available to be drawn down at our option through May 1, 2026 or if the third tranche is funded, May 1, 2027, subject to Lender's review of our clinical, financial and operating plan and subject to Lender's consent in its sole and absolute discretion.

The term loan matures on May 1, 2028, and we are obligated to make interest only payments for the first 24 months, or 36 months if the third tranche is funded, and then interest and equal principal payments for the next 24 or 12 months, as applicable. The term loan bears 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 may 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 are entitled and certain notice requirements. We were required to pay the Lenders' certain customary fees and expenses at closing and will be required to pay additional fees that may be due upon maturity or prepayment such as final payment fees and prepayment fees.

The Lenders may elect 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, at a conversion price of the lesser of $6.32 per share and the lowest effective price per share of our next equity financing, subject to customary adjustments and 9.99% and 19.99% beneficial ownership limitations. There will be no prepayment penalty for any principal amount converted into common stock. The Loan Agreement provides the Lenders with certain piggyback registration rights with respect to the shares of common stock issuable upon conversion of term loans under the Loan Agreement.

The Loan Agreement contains customary representations and warranties, events of default and affirmative and negative covenants, including covenants that limit or restrict 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. As security for its obligations under the 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.

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, subject to certain exceptions and conditions.

The foregoing description of the Loan Agreement is qualified in its entirety by reference to the full text thereof, which we intend to file as an exhibit to our Quarterly Report on Form 10-Q for the quarter ending June 30, 2024.

Item 6. Exhibits

Exhibit Number	Description
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	Second 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 27, 2023).
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.

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 14, 2023 May 3, 2024

By: /s/ Timothy W. Trost

Timothy W. Trost

Chief Financial Officer and Treasurer
(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 14, 2023 May 3, 2024

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, Timothy W. Trost, 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 14, 2023 May 3, 2024

By: /s/ Timothy W. Trost

Timothy W. Trost
Chief Financial Officer and Treasurer
(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, 2023 March 31, 2024 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 14, 2023 May 3, 2024 By: /s/ Daniel J. Hicklin

Daniel J. Hicklin, Ph.D.

President and Chief Executive Officer
(Principal Executive Officer)

Date: November 14, 2023 May 3, 2024 By: /s/ Timothy W. Trost

Timothy W. Trost

Chief Financial Officer and Treasurer
(Principal Financial and Accounting Officer)

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