

PROSPECTUS

7,500,000 Shares



Common Stock

We are offering 7,500,000 shares of common stock. This is our initial public offering of our common stock.

Prior to this offering, there has been no public market for our shares. The initial public offering price is \$16.00 per share. Our common stock has been approved for listing on The Nasdaq Global Select Market under the symbol "HOWL".

We are an "emerging growth company" under the federal securities laws and, as such, we have elected to comply with certain reduced public company reporting requirements for this prospectus and for future filings.

Investing in our common stock involves a high degree of risk. Before buying any shares, you should carefully read the discussion of the material risks of investing in our common stock under the heading "[Risk Factors](#)" starting on page 12 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission approved or disapproved of the securities that may be offered under this prospectus, nor have any of these organizations determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

	<u>PER SHARE</u>	<u>TOTAL</u>
Public offering price	\$ 16.00	\$120,000,000
Underwriting discount (1)	\$ 1.12	\$ 8,400,000
Proceeds, before expenses, to us	\$ 14.88	\$111,600,000

(1) We refer you to "Underwriting" beginning on page 171 of this prospectus for additional information regarding underwriting compensation.

Delivery of the shares of common stock is expected to be made on or about May 4, 2021.

We have granted the underwriters an option for a period of 30 days to purchase an additional 1,125,000 shares of our common stock. If the underwriters exercise the option in full, the total underwriting discounts and commissions payable by us will be \$9,660,000, and the total proceeds to us, before expenses, will be \$128,340,000.

Jefferies**SVB Leerink****Evercore ISI****H.C. Wainwright & Co.**

The date of this prospectus is April 29, 2021.

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Neither we nor the underwriters have authorized anyone to provide you with any information other than that contained in this prospectus, any amendment or supplement to this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The

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information contained in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of shares of our common stock. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: We have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

Through and including May 24, 2021 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

PROSPECTUS SUMMARY

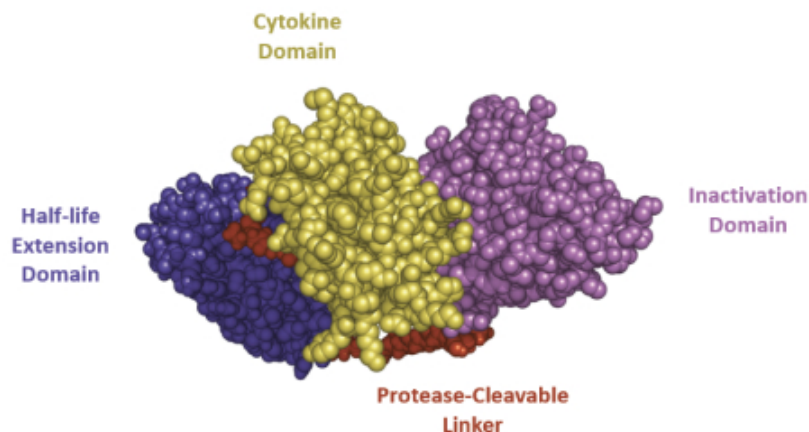
This summary highlights information contained elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, including our financial statements and the related notes appearing elsewhere in this prospectus and the information set forth in the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations," before making an investment decision. As used in this prospectus, unless the context otherwise requires, references to "we," "us," "our" and "Werewolf" refer to the consolidated operations of Werewolf Therapeutics, Inc., and its wholly owned subsidiary.

Company 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 INDUKINETM molecules, are intended to activate selectively in the tumor microenvironment, or TME. Our most advanced product candidates, WTX-124 and WTX-330, are systemically delivered, conditionally activated Interleukin-2, or IL-2, and Interleukin-12, or IL-12, respectively, INDUKINE molecules for the treatment of solid tumors. We plan to submit an investigational new drug application, or IND, to the U.S. Food and Drug Administration, or FDA, for each of WTX-124 and WTX-330 in the first half of 2022, and thereafter initiate a Phase 1/1b clinical trial for each candidate in multiple tumor types as a single agent and in combination with an immune checkpoint inhibitor.

We are building our PREDATOR platform to generate a pipeline of innovative therapeutics that cover a diversity of immune stimulating mechanisms with the potential to address significant unmet medical need in cancer.

Our PREDATOR platform consists of our protein engineering technologies and our know how, which we use to generate INDUKINE molecules with multiple functional domains rationally engineered into a single protein to achieve the desired pharmaceutical profile. Each of our lead INDUKINE molecules consists of four components: a cytokine, an inactivation domain, a half-life extension domain and a proprietary protease-cleavable linker. Our INDUKINE molecules contain cytokines that mediate pro-inflammatory, anti-cancer mechanisms within the TME, with full potency and functionality observed in preclinical studies. The inactivation domain physically blocks the cytokine portion of the INDUKINE molecule in non-tumor tissue throughout the body, or the periphery, preventing it from binding to its receptor until it is cleaved and thereby activated in the TME. We engineer the half-life extension domain to overcome the short half-lives of cytokines *in vivo*, which typically range from a few minutes to a few hours. The half-life extension domain enables high systemic and tumor tissue exposure for the INDUKINE molecule prior to its cleavage in the tumor. After cleavage in the tumor, the half-life extension domain is removed and the cytokine is released to activate immune cells. We select the proprietary protease-cleavable linker to enable conditional activation of the cytokine portion of the INDUKINE molecule within tumor tissue. This selection is based on our extensive screening in preclinical studies to identify protease-cleavable linkers that are efficiently cleaved by a broad array of human tumor tissues with minimal cleavage in non-tumor tissues.



We are leveraging our novel PREDATOR platform to engineer conditionally activated proinflammatory immunomodulators, or INDUKINE molecules, which are delivered systemically but activated only in the TME with the goal of generating potent anti-tumor response while minimizing toxicities. We have worldwide rights to our PREDATOR platform and our portfolio of INDUKINE product candidates, all of which we have developed internally. We believe our approach has the potential to overcome current limitations of systemic proinflammatory immunomodulatory therapies, such as cytokines, for the treatment of cancer.

Our Pipeline

Our current pipeline of INDUKINE molecules is summarized below:

Program	Indication(s)	Program Rights	Pre-IND	IND-Enabling	Phase 1	Phase 2	Phase 3	Upcoming Milestones	
WTX-124 IL-2 INDUKINE Molecule	Solid Tumors Monotherapy and in combination with checkpoint inhibitors								IND filing 1H2022
WTX-330 IL-12 INDUKINE Molecule	Solid Tumors and Lymphoma Monotherapy and in combination with checkpoint inhibitors								IND filing 1H2022
WTX-613 IFN-α INDUKINE Molecule	Solid Tumors and Hematologic Malignancies Monotherapy and in combination with standard of care								IND filing 1H2023

Using our PREDATOR platform, we have developed three initial product candidates: WTX-124, WTX-330 and WTX-613. In addition to these product candidates, we are pursuing additional immuno-oncology discovery programs in which we are applying our novel engineering approach to other targets.

WTX-124

Our lead product candidate, WTX-124, is designed to be a systemically delivered, conditionally activated IL-2 INDUKINE molecule for the treatment of advanced solid tumors. We believe that, unlike other next-generation IL-2 therapies in development, WTX-124 has the potential to be the only systemically delivered IL-2 therapy with full cytokine potency and function to drive robust antitumor effector responses. WTX-124 maintains binding to the high affinity receptor IL-2Ra/β/g once activated in tumors, which we believe is necessary for optimal anti-tumor activity by directing the generation of effective immune memory formation. We have designed WTX-124 to overcome IL-2 mediated toxicities by blocking its binding to IL-2 receptors in the periphery. In addition, we have engineered WTX-124 to include half-life extension for optimal exposure in tumors. We believe these design features of WTX-124's pharmacologic profile have the potential to make it a differentiated therapeutic, if approved. We plan to submit an IND to the FDA for WTX-124 in the first half of 2022 and thereafter initiate a Phase 1/1b clinical trial in relapsed or refractory advanced or metastatic solid tumors as monotherapy or in combination with an immune checkpoint inhibitor.

WTX-330

Our second product candidate, WTX-330, is designed to be a systemically delivered, conditionally activated IL-12 INDUKINE molecule for the treatment of relapsed or refractory advanced or metastatic solid tumors or lymphoma. We are developing WTX-330 to minimize the severe toxicities that have been observed with recombinant human IL-12, or rhIL-12, therapy and maximize clinical benefit when administered as monotherapy or in combination with immune checkpoint inhibitors. IL-12 is a potent inducer of innate and adaptive antitumor immunity, but there currently are no approved IL-12 therapies. We believe WTX-330 has the potential to be the only systemically delivered, conditionally activated IL-12 therapy with normal tissue IL-12 receptor, or IL-12R, blockade and with full IL-12 potency and function. Key features of WTX-330 include peripheral blockade of the IL-12 – IL-12R interaction to limit systemic toxicity, half-life extension for optimal exposure in tumors and conditional activation in the TME. We plan to submit an IND to the FDA for WTX-330 in the first half of 2022 and thereafter initiate a Phase 1/1b clinical trial in immunotherapy resistant advanced or metastatic solid tumors or lymphoma followed by expansion arms in tumors that are relapsed or refractory following treatment with checkpoint inhibitors or tumors for which checkpoint inhibitors are not approved.

WTX-613

Our third product candidate, WTX-613, is designed to be a systemically delivered, conditionally activated Interferon alpha, or IFN- α , INDUKINE molecule for the treatment of solid tumors and hematologic malignancies. We are developing WTX-613 to minimize the severe toxicities that have been observed with recombinant IFN- α , or rIFN- α , therapy and maximize clinical benefit when administered as monotherapy or in combination with a checkpoint inhibitor or other standard of care therapy. Recombinant human IFN- α , or rhIFN- α , is clinically active in multiple cancers but clinical use is limited by severe systemic toxicity. We believe WTX-613 has the potential to deliver higher intratumoral exposure than other IFN- α therapies to maximize efficacy and minimize systemic toxicity. Key features of WTX-613 include the high efficiency blockade of off tumor IFN- α – IFN receptor, or IFNR, interaction, half-life extension for optimal exposure in tumors and conditional activation in the TME. We plan to submit an IND to the FDA for WTX-613 in the first half of 2023 for a clinical trial of WTX-613, which we anticipate will evaluate safety and tolerability, pharmacokinetics, biomarker changes and preliminary anti-tumor activity.

Our Strategy

Our goal is to utilize our proprietary PREDATOR platform to redefine the cancer treatment landscape with therapies to transform the lives of cancer patients. Key elements of our strategy include:

- Advancing our lead product candidate, IL-2 INDUKINE molecule (WTX-124), into and through clinical development in selected solid tumor indications.
- Advancing our IL-12 INDUKINE molecule (WTX-330) into clinical development in selected solid tumors and lymphoma.
- Leveraging our proprietary PREDATOR platform to advance our IFN- α INDUKINE molecule (WTX-613) through preclinical development and expand our pipeline of product candidates.
- Establishing a leading position in protein engineering and developing optimized conditionally activated molecules.
- Selectively entering into strategic partnerships while retaining key rights to our programs and platform in major pharmaceutical markets.

Our Team and History

We have assembled an experienced management team, board of directors and scientific founders who bring extensive industry experience to our company. The members of our team have deep experience in discovering, developing and commercializing therapeutics with a particular focus on cancer and immunological disorders, having worked at companies such as Novartis, Schering-Plough, Merck, ImClone Systems (acquired by Bristol-Myers Squibb), Tizona Therapeutics (acquired by Gilead Sciences), CoStim Pharmaceuticals (acquired by Novartis), Potenza Therapeutics (acquired by Astellas Pharma) and others. We are backed by leading investors in the life science and biotechnology industry, including MPM Capital, which was our founding investor, RA Capital, Deerfield Management Partners, Longwood Fund, Arkin Holdings, Taiho Ventures, HBM Partners, Soleus Capital, Sphera Healthcare, Adage Capital and CaaS Capital.

We were founded in October 2017 by Daniel Hicklin, Ph.D., Luke Evin, Ph.D., and other advisors associated with MPM Capital, an early-stage life sciences venture investing firm and our founding investor. Dr. Evin, who has decades of experience in early stage and venture financing of oncology companies, served as our President and Chief Executive Officer from December 2017 until August 2019 and has served on our board of directors since October 2017 and as chairman of our board of directors since August 2019. Over the past eight years, as a component of his MPM activities, Dr. Evin has been a co-founder and served as chairman of the board for seven MPM portfolio companies, including Harpoon Therapeutics, Inc., with which we entered into a license agreement that is described below under “Business – Our License and Royalty Agreements” and “Certain Relationships and Related Persons Transactions.” Dr. Hicklin, who has served as our President and Chief Executive Officer since August 2019, has over thirty years’ experience in oncology drug discovery and development, including as founder and Chief Executive Officer of Potenza Therapeutics, President and Chief Scientific Officer of CoStim Pharmaceuticals and in several positions at Merck Research Laboratories (formerly

the Schering-Plough Research Institute prior to its acquisition by Merck), including leading its Biologics Strategy for Oncology and the Immuno-Modulation Discovery team.

Risks Associated with Our Business

You should consider carefully the risks described under the "Risk Factors" section beginning on page 12 and elsewhere in this prospectus. The risks that could materially and adversely affect our business, financial condition, operating results and prospects include 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 or become profitable or, if we achieve profitability, we may not be able to sustain it.
- Even if this offering is successful, we will need to obtain substantial additional funding to finance our operations and complete the development and any commercialization of our product candidates.
- We are very early in our development efforts. All of our product candidates are still in preclinical development and will require significant additional preclinical development before we can submit an IND to the FDA to commence clinical development.
- 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 clinical or 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 expect to develop 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 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.
- We identified material weaknesses in our internal control over financial reporting. If we are unable to remedy these material weaknesses, or if we fail to establish and maintain effective internal controls, we may be unable to produce timely and accurate financial statements, and we may determine that our internal control over financial reporting is not effective, which could adversely impact our investors' confidence and our stock price.

Corporate Information

We were incorporated under the laws of the state of Delaware on October 19, 2017 under the name Werewolf Therapeutics, Inc. Our principal executive offices are located at 1030 Massachusetts Avenue, Suite 210, Cambridge, MA 02138. Our website address is <http://www.werewolfTx.com>. The information contained on, or accessible through, our website does not constitute part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

Trademarks and Tradenames

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 PREDATOR™ and INDUKINE™. Other trademarks, service marks and trade names appearing in this prospectus are the property of their respective owners. Solely for convenience, some of the trademarks, service marks and trade names referred to in this prospectus 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.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act, or the JOBS Act, enacted in April 2012. As a result, we may take advantage of reduced reporting requirements that are otherwise applicable to public companies that are not emerging growth companies, including delaying auditor attestation of internal control over financial reporting, providing only two years of audited financial statements and related Management's Discussion and Analysis of Financial Condition and Results of Operations in this prospectus and reducing executive compensation disclosures.

We may remain an emerging growth company until December 31, 2026, which is the last day of the fiscal year ending after the fifth anniversary of this offering. However, if certain events occur prior to the end of 2026, including if we become a "large accelerated filer," our annual gross revenue exceeds \$1.07 billion, or we issue more than \$1 billion of non-convertible debt in any three-year period, we will cease to be an emerging growth company prior to the end of 2026.

We have elected to take advantage of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. In particular, in this prospectus, we have provided only two years of audited financial statements and have not included all of the executive compensation related information that would be required if we were not an emerging growth company. However, we have irrevocably elected not to avail ourselves of the extended transition period for complying with new or revised accounting standards, and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

We are also a "smaller reporting company," meaning that the market value of our stock held by non-affiliates is less than \$700.0 million and our annual revenue is less than \$100.0 million during the most recently

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completed fiscal year. We may continue to be a smaller reporting company after this offering if either (i) the market value of our stock held by non-affiliates is less than \$250.0 million or (ii) our annual revenue is less than \$100.0 million during the most recently completed fiscal year and the market value of our stock held by non-affiliates is less than \$700.0 million. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

THE OFFERING

Common stock offered by us	7,500,000 shares
Common stock to be outstanding immediately after this offering	27,539,359 shares (or 28,664,359 shares if the underwriters exercise their option to purchase additional shares in full).
Option to purchase additional shares	We have granted the underwriters an option for a period of 30 days from the date of this prospectus to purchase up to 1,125,000 additional shares of our common stock at the initial public offering price less underwriting discounts and commissions.
Use of proceeds	<p>We estimate that the net proceeds from this offering will be approximately \$108.9 million (or approximately \$125.6 million if the underwriters exercise their option to purchase additional shares in full), after deducting underwriting discounts and commission and estimated offering expenses payable by us.</p> <p>We intend to use the net proceeds to us from this offering for the development of WTX-124 through dose escalation and expansion trials as a monotherapy or in combination with an immune checkpoint inhibitor, the development of WTX-330 through dose escalation and expansion trials as a monotherapy or in combination with an immune checkpoint inhibitor, the preclinical development of WTX-613 and the advancement of our discovery programs and other general corporate purposes. See "Use of Proceeds" for more information.</p>
Risk Factors	You should read the "Risk Factors" section of this prospectus beginning on page 12 for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.
Nasdaq Global Select Market symbol	"HOWL"

The number of shares of our common stock to be outstanding after this offering is based on 20,039,359 shares of our common stock outstanding as of March 31, 2021, after giving effect to the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 18,279,712 shares of common stock upon the closing of this offering, but excludes:

- 2,401,085 shares of common stock issuable upon exercise of stock options outstanding as of March 31, 2021, under our 2017 Stock Incentive Plan, as amended, or the 2017 Plan, at a weighted-average exercise price of \$4.16 per share;
- 58,904 shares of common stock issuable upon exercise of warrants to purchase common stock outstanding as of March 31, 2021, at an exercise price \$0.09 per share;
- 28,983 shares of common stock available for future issuance as of March 31, 2021 under the 2017 Plan (which shares, to the extent that they remained available for future issuance immediately prior to the effectiveness of the registration statement of which this prospectus is a part, became available for issuance under our 2021 Stock Incentive Plan, or the 2021 Plan);

- 2,843,116 additional shares of common stock available for future issuance under the 2021 Plan, as well as any shares which may be reserved pursuant to provisions in the 2021 Plan that automatically increase the number of shares of common stock reserved for issuance under the 2021 Plan (which includes shares of common stock underlying stock option awards that our board of directors agreed to grant to certain of our non-employee directors and executive officers, upon this offering, as described below under "Executive Compensation—Narrative Disclosure to Summary Compensation Table—Equity Incentives" and "Executive Compensation—Employee Benefit and Equity Compensation Plans—2021 Stock Incentive Plan," which options will have an exercise price per share equal to the initial public offering price); and
- 244,000 additional shares of common stock available for future issuance under our 2021 Employee Stock Purchase Plan, or the 2021 ESPP, as well as any shares which may be reserved pursuant to provisions in the 2021 ESPP that automatically increase the number of shares of common stock reserved for issuance under the 2021 ESPP.

Unless otherwise indicated, all information in this prospectus reflects and assumes:

- a one-for-8.6691 reverse stock split of our common stock, and a proportionate adjustment in the ratio at which our preferred stock is convertible into our common stock, that became effective on April 23, 2021;
- the automatic conversion of all outstanding shares of our preferred stock into 18,279,712 shares of our common stock upon the closing of this offering;
- no exercise of the outstanding stock options described above;
- no exercise of the outstanding warrants to purchase common stock described above;
- no exercise by the underwriters of their option to purchase additional shares of our common stock; and
- the filing and effectiveness of our restated certificate of incorporation and the adoption of our amended and restated bylaws upon the closing of this offering.

SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables set forth a summary of our historical consolidated financial data as of, and for the periods ended on, the dates indicated. We have derived the following summary consolidated statement of operations data for the years ended December 31, 2019 and 2020 and the summary consolidated balance sheet data as of December 31, 2020 from our audited consolidated financial statements appearing elsewhere in this prospectus. This summary consolidated financial data should be read in conjunction with our consolidated financial statements and the related notes included elsewhere in this prospectus and the "Selected Consolidated Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future.

(in thousands, except share and per share data)	YEAR ENDED DECEMBER 31,	
	2019	2020
Consolidated Statement of Operations Data:		
Operating expenses:		
Research and development	\$ 6,340	\$ 16,641
General and administrative	3,596	5,763
Total operating expenses	<u>9,936</u>	<u>22,404</u>
Loss from operations	(9,936)	(22,404)
Other income (expense):		
Change in fair value of preferred stock tranche liability	487	7,301
Interest income (expense), net	(372)	101
Other expense, net	(57)	(38)
Change in fair value of warrant liabilities	(370)	—
Total other income (expense)	<u>(312)</u>	<u>7,364</u>
Net loss	<u>(10,248)</u>	<u>(15,040)</u>
Accretion of redeemable convertible preferred stock to redemption value	(7,981)	(13,177)
Net loss attributable to common stockholders	<u>\$ (18,229)</u>	<u>\$ (28,217)</u>
Net loss per share attributable to common stockholders, basic and diluted (1)	<u>\$ (28.49)</u>	<u>\$ (28.09)</u>
Weighted-average common shares outstanding, basic and diluted (1)	<u>639,888</u>	<u>1,004,691</u>
Pro forma net loss per share attributable to common stockholders—basic and diluted (unaudited) (2)		<u>\$ (1.68)</u>
Pro forma weighted-average common shares outstanding, basic and diluted (unaudited) (2)		<u>8,970,732</u>

(1) See Note 2 to our consolidated financial statements appearing elsewhere in this prospectus for an explanation of the method used to calculate the basic and diluted net loss per share attributable to common stockholders and the number of shares used in the computation of the per share amounts.

(2) The calculations for the unaudited pro forma net loss per share attributable to common stockholders, basic and diluted, and the unaudited pro forma weighted-average common shares outstanding, basic and diluted, assume the conversion of all our outstanding shares of preferred stock into shares of our common stock, as if the conversion had occurred at the beginning of the period presented, or the issuance date, if later, and the reclassification of the preferred stock tranche liability as of the date of issuance. See Note 14 to our consolidated financial statements appearing elsewhere in this prospectus for additional information on the method used to calculate unaudited pro forma net loss per share, basic and diluted, and unaudited pro forma weighted-average shares outstanding, basic and diluted.

(in thousands)	AS OF DECEMBER 31, 2020		
	ACTUAL	PRO FORMA (1)	PRO FORMA AS ADJUSTED (2)
Consolidated Balance Sheet Data:			
Cash and cash equivalents	\$ 92,570	\$ 92,570	\$ 201,459
Working capital (3)	87,630	87,630	196,519
Total assets	96,398	96,398	205,287
Redeemable convertible preferred stock	141,082	—	—
Accumulated deficit	(51,865)	(51,865)	(51,865)
Total stockholders' (deficit) equity	(51,863)	89,219	198,108

(1) The pro forma consolidated balance sheet data give effect to the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 18,279,712 shares of common stock upon the closing of this offering.

(2) The pro forma as adjusted consolidated balance sheet data give further effect to our issuance and sale of 7,500,000 shares of common stock in this offering at the initial public offering price of \$16.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

(3) We define working capital as total current assets less total current liabilities.

RISK FACTORS

Investing in our common stock is speculative and involves a high degree of risk. Before investing in our common stock, you should carefully consider the risks described below, as well as the other information in this prospectus, including our financial statements and the related notes and "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. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations. This prospectus 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. See "Cautionary Note Regarding Forward-Looking Statements and Industry Data."

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 you can evaluate our business and prospects. 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 and preclinical studies 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 three product candidates, WTX-124, WTX-330 and WTX-613, none of which have entered clinical development, and all of our other development programs are in discovery or preclinical stages. We have not yet demonstrated an ability to successfully submit an investigational new drug application, or IND, to the U.S. Food and Drug Administration, or the FDA, or successfully complete any Phase 1, Phase 2 or pivotal clinical trials, obtain regulatory approvals, manufacture a clinical- or 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 revenue. If our product candidates are not successfully developed and approved, we may never generate any revenue. Our net losses were \$10.2 million and \$15.0 million for the years ended December 31, 2019 and 2020, respectively. As of December 31, 2020, we had an accumulated deficit of \$51.9 million. We expect to continue to incur losses for the foreseeable future, and we anticipate these losses will increase substantially as WTX-124, WTX-330, WTX-613 and any future product candidates advance through preclinical studies and into 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;

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- successfully submit our INDs to the FDA for WTX-124, WTX-330, WTX-613 and any future product candidates;
- successfully initiate clinical trials for WTX-124, WTX-330, WTX-613 and any future product candidates;
- successfully enroll subjects in, and complete, our planned clinical trials and 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 you to lose all or part of your investment.

Even if this offering is successful, we will need to obtain substantial additional funding to finance our operations and complete the development and any commercialization of WTX-124, WTX-330, WTX-613 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, WTX-613 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 December 31, 2020, we had cash and cash equivalents of \$92.6 million. We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our operations for at least 24 months from the filing date of the registration statement of which this prospectus is a part. In particular, we expect that the net proceeds from this offering will allow us to complete the development of WTX-124 through dose escalation and expansion trials as a monotherapy or in combination with an immune checkpoint inhibitor, the development of WTX-330 through dose escalation and expansion trials as a monotherapy or in combination with an immune checkpoint inhibitor and the preclinical development of WTX-613.

The net proceeds of this offering, together with our existing cash and cash equivalents, will not be sufficient to complete development of WTX-124, WTX-330, WTX-613 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

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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 our planned clinical trials of WTX-124 and WTX-330;
- the costs associated with attracting, hiring and retaining skilled personnel and consultants as our preclinical and clinical activities increase;
- the cost of manufacturing WTX-124, WTX-330, WTX-613 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 planned combination clinical trials that are not covered by such third parties or other sources;
- the potential additional expenses attributable to adjusting our development plans (including any supply related matters) as a result of the COVID-19 pandemic;
- the timing of, and the cost involved in, obtaining marketing approval for WTX-124, WTX-330, WTX-613 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, WTX-613 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.

Other than our ability to draw down up to \$14.0 million under our term loan facility prior to November 2021, 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 resulting from the ongoing COVID-19 pandemic and any disruptions to, or volatility in, the credit and financial markets in the United States and worldwide that arise from the pandemic. 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, including purchasers of shares in this offering, 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, borrowings under our loan and security agreement with Pacific Western Bank, debt financings, collaborations and licensing arrangements or other sources. Our issuance of additional securities, whether equity or debt, or the possibility of such issuance, may cause the market price of our common stock to decline, and our stockholders may not agree with our financing plans or the terms of such financings. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a stockholder. To the extent that we incur indebtedness under our loan and security agreement, we would become obligated to make monthly payments to repay the loan balance with interest and pay an additional success fee. The incurrence of any other indebtedness would result in additional payment obligations. Under our loan and security agreement, we are required 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, and any agreements governing any other indebtedness that we may incur could require us to comply with additional covenants. 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.

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. As of December 31, 2020, we had federal and state net operating loss carryforwards of \$35.9 million and \$35.3 million, respectively. We do not anticipate generating revenue from sales of products for the foreseeable future, if ever, and we may never achieve profitability. Under Section 382 of the Internal Revenue Code of 1986, as amended, or 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 may have in the past experienced, and we may in the future experience as a result of this offering or otherwise, ownership changes, some of which are outside our control. 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 may be 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. Similar provisions of state tax law may also apply.

Under the Tax Cuts and Jobs Act, or TCJA, net operating loss carryforwards arising in tax years beginning after December 31, 2017 may be used to offset only 80% of taxable income and may not be carried back. However, the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, enacted in 2020, removes the 80% taxable income limitation for net operating loss deductions in tax years beginning prior to January 1, 2021. In addition, net operating losses generated in tax years beginning after December 31, 2017 and before January 1, 2021 can be carried back up to five taxable years.

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

We are very early in our development efforts. All of our product candidates are still in preclinical development and will require significant additional preclinical development before we can submit an IND to the FDA to commence clinical development.

We are very early in our development efforts and all of our product candidates are still in preclinical development. 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. We expect to submit an IND to the FDA with respect to each of WTX-124 and WTX-330 in the first half of 2022. Additionally, we have a portfolio of

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programs, including those described in the “Business—Our Programs” section of this prospectus, 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, each of which is in preclinical development.

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 our first clinical trials 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.

To date, we have not submitted an IND to the FDA and have only had limited interactions with the FDA regarding our clinical development plans. We may experience issues surrounding preliminary trial execution, such as delays in FDA acceptance of our planned 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, from the FDA. We have not previously submitted a BLA to the FDA, or similar marketing application to comparable foreign regulatory authorities. A BLA 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 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 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 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 of WTX-124, WTX-330, WTX-613 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;

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- receipt of marketing approvals from applicable regulatory authorities, including BLAs 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, WTX-613 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 WTX-124, WTX-330, WTX-613 and any future product candidates, which may never occur. However, 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, WTX-330 and WTX-613, each of which we are developing by leveraging our PREDATOR platform, 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.

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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 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 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. Before we can commence clinical trials for a product candidate, 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. As a result, we cannot be sure that we will be able to submit INDs or similar applications for WTX-124, WTX-330, WTX-613 or any future preclinical 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 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 candidate, WTX-124, for the treatment of advanced solid tumors. We plan to develop our second product candidate, WTX-330, for the treatment of relapsed or refractory advanced or metastatic tumors or lymphoma. 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.

All of our product candidates are still in the preclinical stage, and their risk of failure is high. Before we can commence clinical trials for a product candidate, we must complete extensive preclinical testing and studies that support our planned 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 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 product candidates will successfully complete preclinical studies or clinical trials evaluating their safety and effectiveness in humans or will ultimately receive regulatory approval. To obtain the requisite regulatory approvals to market and sell any 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. To date, we have never advanced a product candidate into a clinical trial. 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, WTX-330 and WTX-613, we do not know whether any of these product candidates will perform in our planned clinical trials as it has performed in these prior preclinical studies. Additionally, if we successfully commence clinical trials 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 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;

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- 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 the continuing COVID-19 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,

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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 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 assure you 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 the COVID-19 pandemic, that 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

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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. We have not yet initiated clinical trials for any of our product candidates and it is likely that, as is the case with many treatments for cancer, there may be side effects associated with their use. 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.

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The COVID-19 pandemic, 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 have implemented 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 impacts our operations, including our preclinical testing, 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, our planned 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 our planned 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, could have a material adverse effect on our business and our results of operation 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.

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We expect to develop WTX-124 and 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 intend to develop WTX-124 and WTX-330, and likely other future product candidates, in combination with third-party cancer drugs, which may be either approved or unapproved. For example, we plan to conduct clinical trials of WTX-124 and WTX-330 both as monotherapy and in combination with immune checkpoint inhibitors. 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 planned clinical trials for WTX-124 and WTX-330 in combination with an immune checkpoint inhibitor 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;

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- 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.

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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 commenced clinical trials of or 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 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 or low-dose IL-2 programs in development for the treatment of cancer, including Alkermes, BioNTech, Medicenna, Nektar Therapeutics (Bristol-Myers Squibb), Neoleukin Therapeutics, Roche, Synthorx (Sanofi) and Xilio Therapeutics.

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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 based cancer therapies that are in development, including modified IL-12 or intra-tumoral IL-12 delivery programs for the treatment of cancer in development by DragonFly Therapeutics, Juno Therapeutics (Bristol-Myers Squibb), Oncorus and Turnstone Biologics.

If approved, WTX-613 may face competition from other Interferon alpha, or IFN- α , cancer therapies. Intron-A, a recombinant IFN- α molecule marketed by Merck, has been approved by the FDA for the treatment of several forms of cancer, including specific types of leukemia and lymphoma, and we are aware of other IFN- α programs targeting the treatment of cancer in development by Immunomedics and Takeda.

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

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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;

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- 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 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 CROs, to conduct preclinical studies and our planned 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

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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 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 third-party contract manufacturers, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials, result in higher costs of drug product and adversely affect our business.

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We have entered into a contract manufacturing services agreement with Lonza Biologics, or Lonza, pursuant to which we agreed to retain their services for 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. We will consider engagement with Lonza for drug substance manufacturing for our third program, WTX-613, but we could contemplate others as the program advances. We have entered into a contract manufacturing services agreement with Patheon Manufacturing Services, or Patheon, pursuant to which we agreed to retain their services for drug product manufacturing process development and to manufacture clinical supply of WTX-124 and WTX-330 vialled drug product to cGMP specifications. To support the manufacture of clinical vialled drug product, Lonza will conduct substantial analytical testing of WTX-124 and WTX-330 vialled drug product. If Lonza or Patheon 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 third-party contract manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements or capacity could be limited at each of the qualified replacements. 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 planned combination clinical trials of WTX-124 or WTX-330 with immune checkpoint inhibitors, we will need to procure supply of the immune checkpoint inhibitors 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 manufacturers fail to comply with such requirements or to perform their obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third-party, which we may not be able to do on reasonable terms, if at all. The transfer of the manufacturing of biologic products to a new contract manufacturer and any additional process development that may be necessary can be lengthy and involve significant additional costs. If we are required to change manufacturers for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. The delays associated with the verification of a new manufacturer would negatively affect our ability to develop product candidates in a timely manner or within budget.

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

- inability to meet our drug specifications 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;

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- 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 third-party manufacturers and suppliers are subject to FDA inspection from time to time. Failure by our third-party manufacturers 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 third-party manufacturers and suppliers are subject to numerous environmental, health and safety laws and regulations, including those governing the handling, use, storage, treatment and disposal of waste products, and failure to comply with such laws and regulations could result in significant costs associated with civil or criminal fines and penalties for such third parties. Based on the severity of the regulatory action, our clinical or commercial supply of drug and packaging and other services could be interrupted or limited, which could harm our business.

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

We may 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. 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.

Collaborations involving our product candidates would 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;

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- 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 future 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 prospectus 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 assure you 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

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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.

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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. For more information regarding the Harpoon Agreement, see "Business—Our License and Royalty Agreements."

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 one or more third parties, including the licensor. 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

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product candidates. We are generally also subject to all of the same risks described in this prospectus 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

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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.

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

Composition of matter patents for biological and pharmaceutical products are generally considered to be the strongest form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of making or method of use. We cannot be certain, 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

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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, WTX-613 or another product candidate is approved by the FDA, a third party may then seek to enforce its patent by filing a patent infringement lawsuit against us. While we do not believe that any claims that could otherwise have a materially adverse effect on the commercialization of our product

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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, WTX-613 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

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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

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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;

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- 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.

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Finally, disruptions at the FDA and other agencies may prolong the time necessary for new drugs to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. The Trump Administration also took several executive actions that could impose significant burdens on, or otherwise materially delay, the FDA's ability to engage in routine regulatory and oversight activities.

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

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

In order to market and sell our products in the European Union and other foreign jurisdictions, we must obtain separate marketing approvals and comply with numerous and varying regulatory requirements. The approval procedure varies among countries and can involve additional testing. The time required to obtain approval may differ substantially from that required to obtain FDA approval. The marketing approval process outside the United States generally includes all of the risks associated with obtaining FDA approval. We 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 marketing approval in the United Kingdom as a result of the recent withdrawal of the United Kingdom from the European Union, commonly referred to as Brexit. The United Kingdom and European Union entered into a Trade and Cooperation Agreement in connection with Brexit that sets out certain procedures for approval and recognition of medical products in each jurisdiction. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of the Trade and Cooperation Agreement would prevent us from commercializing any product candidates in the United Kingdom and/or the European Union and restrict our ability to generate revenue and achieve and sustain profitability. If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the United Kingdom and/or European Union for any product candidates, which could significantly and materially harm our business.

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.

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

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

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;

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

Non-compliance with EU requirements regarding safety monitoring or pharmacovigilance, and with requirements related to the development of products for the pediatric population, can also result in significant financial penalties. Similarly, failure to comply with the European Union's requirements regarding the protection of personal information can also lead to significant penalties and sanctions.

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.

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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 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.

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, on December 14, 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 inseparable 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. On December 18, 2019, the Court of Appeals for the Fifth Circuit court affirmed the lower court's ruling that the individual mandate portion of the ACA is unconstitutional and it remanded the case to the district court for reconsideration of the severability question and additional analysis of the provisions of the ACA. Thereafter, the U.S. Supreme Court agreed to hear this case. Oral argument in the case took place on November 10, 2020, and a ruling by the Court is expected sometime

this year. On February 10, 2021, the DOJ withdrew the federal government's support for overturning 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 2030, with the exception of a temporary suspension from May 1, 2020, through March 31, 2021, unless additional Congressional action is taken. Legislation is currently pending in Congress that would further extend this suspension through December 31, 2021. 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 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 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.

Further, it is possible that additional governmental action will be taken in response to the COVID-19 pandemic.

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 costs of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. In recent years, there have been several U.S. congressional inquiries, executive orders and policy initiatives, as well as proposed and enacted state and federal legislation designed to, among other things, implement drug pricing reform, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. To those ends, the Trump Administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives, and several agencies, including the FDA, the Centers for Medicaid & Medicare Services and HHS, issued rulemaking related to drug pricing reform during the Trump Administration. It is unclear whether the Biden Administration will work to reverse these measures or pursue similar policy initiatives.

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

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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 ownership and investment interests by physicians and their immediate family members. Beginning in 2022, applicable manufacturers also will be 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

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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.

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. Globally, virtually every jurisdiction in which we operate or are likely to operate has established its own data security and privacy frameworks with which we must comply. For example, the collection, use, disclosure, transfer, or other processing of personal data regarding individuals in the European Union, including personal health data, is subject to the EU General Data Protection Regulation, or the GDPR, which took effect across all member states of the European Economic Area, or 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.

Brexit has complicated data protection regulation in the United Kingdom because, as of January 1, 2021, the GDPR has been converted into United Kingdom law and the United Kingdom is now a "third country" under the GDPR, subject to a transition period. Unless the European Commission makes an 'adequacy finding' in respect of the United Kingdom before the expiration of the transition period, the United Kingdom will become an 'inadequate third country' under the GDPR and transfers of data from the EEA to the United Kingdom will require a 'transfer mechanism,' such as the standard contractual clauses. Furthermore, following the expiration of the specified period, there will be increasing scope for divergence in application, interpretation and enforcement of the data protection law as between the United Kingdom and EEA.

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. 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 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

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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.

Actions are either in place or under way in the United States to enact similar legislation. There are a broad variety of data protection laws that are applicable to our 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 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 California Consumer Privacy Act, or CCPA, which went into effect on January 1, 2020, is creating similar risks and obligations as those created by GDPR, though the Act does exempt certain information collected as part of a clinical trial subject to the Federal Policy for the Protection of Human Subjects (the Common Rule). Many other states are considering similar legislation. A broad range of legislative measures also have been introduced at the federal level. Accordingly, failure to comply with federal and state laws (both those currently in effect and future legislation) regarding privacy and security of personal information could expose us to fines and penalties under such laws. 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 these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our reputation and our business.

Additionally, California voters approved a new privacy law, the California Privacy Rights Act, or CPRA, in the November 3, 2020 election. Effective starting on January 1, 2023, the CPRA will significantly modify the CCPA, including by expanding consumers' rights with respect to certain sensitive personal information. The CPRA also creates a new state agency that will be vested with authority to implement and enforce the CCPA and the CPRA.

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.

New legislation proposed or enacted in Illinois, Massachusetts, Nevada, New Jersey, New York, Rhode Island, Virginia, Washington and other states, and a proposed right to privacy amendment to the Vermont Constitution, imposes, or has the potential to impose, additional obligations on companies that collect, store, use, retain, disclose, transfer and otherwise process confidential, sensitive and personal information, and will continue to shape the data privacy environment nationally. State laws are changing rapidly and there is discussion in Congress of a new federal data protection and privacy law to which we would become subject if it is enacted. All of these evolving compliance and operational requirements impose significant costs that are likely to increase over time, may require us to modify our data processing practices and policies, divert resources from other initiatives and projects, and could restrict the way products and services involving data are offered, all of which could significantly harm our business, financial condition, results of operations and prospects. Further, certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect 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.

Given the breadth and depth of changes in data protection obligations, preparing for and complying with such requirements is rigorous and time intensive and 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. The GDPR and other changes in 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, may 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 and could have a material adverse effect on our business, financial condition or results of operations.

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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.

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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 Cambridge area of Boston, 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 March 31, 2021, we had 28 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

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

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 to operate our business. In the ordinary course of our business, we collect, store and transmit large amounts of confidential 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 and other third parties on which we rely, are vulnerable to damage or unauthorized access 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 of service attacks, ransomware, hacking, phishing and other social engineering attacks, attachments to emails, intentional or accidental actions or inactions by persons inside our organization or by persons with access to systems inside our organization.

The risk of a security breach or disruption or data loss, particularly through cyber-attacks 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 incidents and data security breaches, which could lead to the loss of confidential information or other intellectual property. As a result of the COVID-19 pandemic, we may face increased risks of a security breach or disruption due to our reliance on internet technology and the number of our employees who are working remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. The costs to us to mitigate network security problems, bugs, viruses, worms, malicious software programs and security vulnerabilities could be significant, and while we have implemented security measures to protect our data security and information technology systems, our efforts to address these problems may not be successful, and these problems could result in unexpected interruptions, delays, cessation of service, negative publicity and other harm to our business and our competitive position. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs.

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

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from completed 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. We would also be exposed to a risk of loss, governmental investigations or enforcement, or litigation and potential liability, any of which could materially adversely affect our business, results of operations and financial condition.

Business disruptions could seriously harm our future revenue and financial condition and 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, terrorist attacks, and other natural or manmade 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.

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

We plan to 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 this Offering, Ownership of Our Common Stock and Our Status as a Public Company

An active trading market for our common stock may not develop and you may not be able to resell your shares of our common stock at or above the initial offering price, if at all.

Prior to this offering, there has been no public market for our common stock. We cannot predict the extent to which an active market for our common stock will develop or be sustained after this offering, or how the development of such a market might affect the market price for our common stock. The initial public offering price for our common stock was determined through negotiations with the underwriters and may not be indicative of the price at which our common stock will trade after the closing of this offering. Although our common stock has been approved for listing on The Nasdaq Global Select Market, or Nasdaq, an active trading market for our shares may never develop or be sustained following this offering. If an active market for our common stock does not develop or is not sustained, it may be difficult for you to sell shares you purchased in this offering at an attractive price or at all.

The price of our common stock could be subject to volatility related or unrelated to our operations and your investment in us could suffer a decline in value.

Our stock price is likely to be volatile. 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 or above the initial public offering price. 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 future 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;

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- 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 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 will depend in part on the research and reports that securities or industry analysts publish about us or our business. We do not currently have research coverage by securities and industry analysts, and if no significant coverage is initiated or maintained following this offering, the market price for our common stock may be adversely affected. If no securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who cover 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.

Upon the completion of this offering, based on shares outstanding as of March 31, 2021, our executive officers, directors, holders of 5% or more of our common stock and their respective affiliates will beneficially own in the aggregate approximately 62.7% of our outstanding common stock, assuming no purchases of shares by these persons in this offering, assuming no exercise of the underwriters' option to purchase additional shares in this offering and assuming we issue the number of shares of common stock as set forth on the cover page of this prospectus.

As a result of their share ownership, these stockholders, if they act together, will have the ability to influence our management and policies and will be 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.

Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the price at which shares are being sold in this

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offering and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders. 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.

See “Principal Stockholders” in this prospectus for more information regarding the ownership of our outstanding common stock by our executive officers, directors, principal stockholders and their affiliates.

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

Our management will have broad discretion in the application of our existing cash and cash equivalents and the net proceeds from this offering, including for any of the purposes described in the section of this prospectus entitled “Use of Proceeds,” and you will not have the opportunity as part of your investment decision to assess whether such proceeds are being used appropriately. We could utilize the net proceeds in ways our stockholders may not agree with or that do not yield a favorable return, if any. Because of the number and variability of factors that will determine our use of our existing cash and cash equivalents and the net proceeds from this offering, their ultimate use may vary substantially from their currently intended use. Our management might not apply our existing cash and cash equivalents and the net proceeds from this offering in ways that ultimately increase the value of your investment. The failure by our management to apply these funds effectively could harm our business. Pending their use, we may invest the net proceeds from this offering in short-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

Purchasers in this offering will experience immediate and substantial dilution in the book value of their investment.

The initial public offering price of our common stock is substantially higher than the pro forma as adjusted net tangible book value per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our pro forma as adjusted net tangible book value per share after this offering. Based on the initial public offering price of \$16.00 per share, you will experience immediate dilution of \$8.89 per share, representing the difference between our pro forma as adjusted net tangible book value per share after this offering and the initial public offering price. In addition, to the extent outstanding stock options are exercised, there will be further dilution to investors in this offering. Further, if the underwriters exercise their option to purchase additional shares, you will experience additional dilution. See “Dilution” for a more detailed description of the dilution to new investors in the offering.

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

Sales of a substantial number of shares of our common stock in the public market, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. After this offering, we will have 27,539,359 shares of common stock outstanding based on the number of shares outstanding as of March 31, 2021 after giving effect to the automatic conversion of our convertible preferred stock. This includes the shares that we are selling in this offering, which may be resold in the public market immediately without restriction, unless purchased by our affiliates. The remaining 20,039,359 shares are currently restricted as a result of securities laws or lock-up agreements but will become eligible to be sold at various times after the offering as described in the section of this prospectus titled “Shares Eligible for Future Sale.” Jefferies LLC, SVB Leerink LLC and Evercore Group L.L.C., in their sole discretion, may release some or all of the securities subject to lock-up agreements at any time and without notice, which would allow for earlier sales of shares in the public market.

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In addition, promptly following the closing of this offering, we intend to file one or more registration statements on Form S-8 under the Securities Act of 1933, as amended, or the Securities Act, registering the issuance of approximately 5,993,906 shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under these registration statements on Form S-8 will be available for sale in the public market subject to vesting arrangements and exercise of options, the lock-up agreements described above and the restrictions of Rule 144 in the case of our affiliates.

Moreover, beginning 180 days after the completion of this offering, holders of an aggregate of 18,279,712 shares of our common stock will have rights, subject to specified conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described in the "Underwriting" section of this prospectus.

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

As a public company, we will incur significant legal, accounting and other expenses that we did not 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 will need 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. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified members of our board of directors.

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, in our second annual report due to be filed with the Securities and Exchange Commission, or SEC, after becoming a public company, we will be 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 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 will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, including through hiring additional financial and accounting personnel, potentially engage outside consultants and adopt a detailed work plan

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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 identified material weaknesses in our internal control over financial reporting. If we are unable to remedy these material weaknesses, or if we fail to establish and maintain effective internal controls, we may be unable to produce timely and accurate financial statements, and we may determine that our internal control over financial reporting is not effective, which could adversely impact our investors' confidence and our stock price.

We have identified material weaknesses in our internal control over financial reporting. A material weakness is defined as 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 our financial statements will not be prevented or detected on a timely basis. The material weaknesses that we identified related to the lack of maintaining a sufficient complement of personnel commensurate with the accounting and financial reporting requirements in order to have adequate segregation of key duties and responsibilities.

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 our material weaknesses by, among other things, hiring qualified personnel with appropriate expertise to perform specific functions, and designing and implementing improved processes and internal controls, including ongoing senior management review and audit committee oversight. We commenced measures to remediate the identified material weaknesses by hiring a full-time chief financial officer in early February 2021, by hiring additional finance personnel, as well as by engaging financial consultants to assist with the evaluation and documentation of technical accounting matters. We have hired additional senior accounting staff, including those with expertise in SEC reporting and internal controls, and we expect to complete the remediation of the material weaknesses in the near future. We will incur additional costs to remediate these weaknesses, primarily personnel costs and external consulting fees. We cannot assure you 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 weaknesses in our internal control over financial reporting or to avoid potential future material weaknesses. In addition, neither our management nor an independent registered public accounting firm has ever performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act because no such evaluation has been required. Had we or our independent registered public accounting firm performed an evaluation of our internal control over financial reporting in accordance with the provisions of the Sarbanes-Oxley Act, additional material weaknesses may have been identified. 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 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.

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

Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is designed to prevent fraud. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could harm our business and have a negative effect on the trading price of our stock.

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We will be required to disclose changes made in our internal controls and procedures on a quarterly basis and our management will be 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 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.

Upon completion of this offering, we will become subject to certain reporting requirements of the Securities Exchange Act of 1934, as amended, or 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 and our amended and restated bylaws that will become effective upon the closing of this offering 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 you might otherwise receive a premium for your 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 that will become effective upon the closing of this offering.

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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 that will become effective upon the closing of this offering 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 that will become effective upon the closing of this offering 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 that will become effective upon the closing of this offering 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.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS AND INDUSTRY DATA

This prospectus contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this prospectus, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "might," "plan," "potential," "predict," "project," "should," "target," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this prospectus include, among other things, statements about:

- the initiation, timing, progress and results of our research and development programs and preclinical studies and planned clinical trials;
- the anticipated timing of the submission of investigational new drug applications to the U.S. Food and Drug Administration for WTX-124, WTX-330 and WTX-613;
- our estimates regarding expenses, capital requirements, need for additional financing and the period over which we believe that the net proceeds from this offering, together with 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 for, 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;
- our expectations related to the use of proceeds from this offering;
- 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;
- developments and expectations regarding developments and projections relating to our competitors and our industry; and
- the COVID-19 pandemic, which could adversely impact our business, including our preclinical studies and clinical trials.

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 prospectus, particularly in the "Risk Factors" section of this prospectus, 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 may make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, collaborations, joint ventures or investments we may make or enter into.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement of which this prospectus is a part completely and with the understanding that our actual

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future results may be materially different from what we expect. The forward-looking statements contained in this prospectus are made as of the date of this prospectus, 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 prospectus, 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 investors are cautioned not to unduly rely on these statements.

This prospectus includes statistical and other industry and market data that we obtained from independent industry publications and research, surveys and studies conducted by independent third parties as well as our own estimates of the prevalence of certain diseases and conditions. The market data used in this prospectus involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such data. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information.

USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of 7,500,000 shares of our common stock in this offering will be approximately \$108.9 million (or approximately \$125.6 million if the underwriters exercise their option to purchase additional shares in full), after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

As of December 31, 2020, we had cash and cash equivalents of \$92.6 million. We currently anticipate that we will use the net proceeds from this offering, together with our cash and cash equivalents, as follows:

- approximately \$54.2 million for the development of WTX-124 through dose escalation and expansion trials as a monotherapy or in combination with an immune checkpoint inhibitor.
- approximately \$57.7 million for the development of WTX-330 through dose escalation and expansion trials as a monotherapy or in combination with an immune checkpoint inhibitor;
- approximately \$12.1 million for the preclinical development of WTX-613;
- the remaining proceeds for the advancement of our discovery programs and other general corporate purposes.

We may also use a portion of the net proceeds from this offering to in-license, acquire, or invest in complementary businesses, technologies, products or assets. However, we have no current plans, commitments or obligations to do so.

Based on our current plans, we believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our operations for at least 24 months from the filing date of the registration statement of which this prospectus is a part. The net proceeds of this offering, together with our existing cash and cash equivalents, will not be sufficient to complete development of WTX-124, WTX-330, WTX-613 or any other product candidate, and we will need to raise substantial additional capital to complete the development and commercialization of any product candidate.

Our expected use of the net proceeds from this offering represents our intentions based on our current plans and prevailing business conditions. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering, or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual use of the net proceeds will vary depending on numerous factors, including the progress, cost and results of our preclinical programs, our ability to obtain additional financing and other factors described in the "Risk Factors" section of this prospectus, as well as the amount of cash used in our operations and any unforeseen cash needs. We may find it necessary or advisable to use the net proceeds for other purposes. Our management will have broad discretion in the application of the net proceeds, and investors will be relying on our judgment regarding the application of the net proceeds from this offering.

Pending our use of the net proceeds from this offering, we intend to invest the net proceeds in a variety of capital preservation investments, including short-term, investment-grade, interest-bearing instruments and U.S. government securities.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain all available funds and any future earnings to support our operations and finance the growth and development of our business. We do not anticipate paying any cash dividends in the foreseeable future. In addition, our ability to pay cash dividends is currently restricted by the terms of our loan and security agreement with Pacific Western Bank, and future debt or other financing arrangements may contain terms prohibiting or limiting the amount of dividends that may be declared or paid on our common stock.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and our capitalization as of December 31, 2020:

- on an actual basis;
- on a pro forma basis to reflect (i) the filing and effectiveness of our restated certificate of incorporation in connection with the closing of this offering, and (ii) the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 18,279,712 shares of our common stock upon the closing of the this offering; and
- on a pro forma as adjusted basis to give further effect to our issuance and sale of 7,500,000 shares of common stock in this offering at the initial public offering price of \$16.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this information in conjunction with our financial statements and the related notes included elsewhere in this prospectus and the “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Selected Consolidated Financial Data” sections of this prospectus.

	AS OF DECEMBER 31, 2020		
	ACTUAL	PRO FORMA	PRO FORMA AS ADJUSTED ⁽¹⁾
	(in thousands, except share and per share data)		
Cash and cash equivalents	\$ 92,570	\$ 92,570	\$ 201,459
Series A and Series B redeemable convertible preferred stock, \$0.0001 par value per share; 158,468,738 shares authorized, 158,468,738 shares issued and outstanding, actual; no shares authorized, issued and outstanding, pro forma and pro forma as adjusted	\$ 141,082	\$ —	\$ —
Stockholders’ (deficit) equity:			
Preferred stock, \$0.0001 par value per share; no shares authorized, issued and outstanding, actual; 5,000,000 shares authorized, no shares issued and outstanding, pro forma and pro forma as adjusted	—	—	—
Common stock, \$0.0001 par value per share; 193,500,000 shares authorized, 1,746,231 shares issued and outstanding, actual; 200,000,000 shares authorized, pro forma and pro forma as adjusted; 20,025,943 shares issued and outstanding, pro forma; 27,525,943 shares issued and outstanding, pro forma as adjusted	2	2	3
Additional paid-in capital	—	141,082	249,970
Accumulated deficit	(51,865)	(51,865)	(51,865)
Total stockholders’ (deficit) equity	(51,863)	89,219	198,108
Total capitalization	\$ 89,219	\$ 89,219	\$ 198,108

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The number of shares of our common stock outstanding in the table above excludes, as of December 31, 2020:

- 2,058,964 shares of common stock issuable upon exercise of stock options outstanding as of December 31, 2020, under our 2017 Stock Incentive Plan, as amended, or the 2017 Plan, at a weighted-average exercise price of \$3.79 per share;
- 58,904 shares of common stock issuable upon exercise of warrants to purchase common stock outstanding as of December 31, 2020, at an exercise price \$0.09 per share;
- 136,711 shares of common stock available for future issuance as of December 31, 2020 under the 2017 Plan (which shares, to the extent that they remained available for future issuance immediately prior to the effectiveness of the registration statement of which this prospectus is a part, became available for issuance under our 2021 Stock Incentive Plan, or the 2021 Plan);
- 2,843,116 additional shares of common stock available for future issuance under the 2021 Plan, as well as any shares which may be reserved pursuant to provisions in the 2021 Plan that automatically increase the number of shares of common stock reserved for issuance under the 2021 Plan (which includes shares of common stock underlying stock option awards that our board of directors agreed to grant to certain of our non-employee directors and executive officers, upon this offering, as described below under “Executive Compensation—Employee Benefit and Equity Compensation Plans—2021 Stock Incentive Plan”, which options will have an exercise price per share equal to the initial public offering price); and
- 244,000 additional shares of common stock available for future issuance under our 2021 Employee Stock Purchase Plan, or the 2021 ESPP, as well as any shares which may be reserved pursuant to provisions in the 2021 ESPP that automatically increase the number of shares of common stock reserved for issuance under the 2021 ESPP.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

Our historical net tangible book deficit as of December 31, 2020 was \$(54.3) million, or \$(31.12) per share of our common stock. Our historical net tangible book deficit is the amount of our total tangible assets less our total liabilities and preferred stock, which is not included within stockholders' deficit. Historical net tangible book deficit per share represents historical net tangible book deficit divided by the number of shares of our common stock outstanding as of December 31, 2020.

Our pro forma net tangible book value as of December 31, 2020 was \$86.8 million, or \$4.33 per share of our common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities, after giving effect to the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 18,279,712 shares of common stock upon the closing of this offering. Pro forma net tangible book value per share represents pro forma net tangible book value divided by the total number of shares of our common stock outstanding as of December 31, 2020, after giving effect to such conversion.

After giving further effect to our issuance and sale of 7,500,000 shares of our common stock in this offering at the initial public offering price of \$16.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2020 would have been \$195.6 million, or \$7.11 per share. This represents an immediate increase in pro forma as adjusted net tangible book value per share of \$2.78 to existing stockholders and an immediate dilution in pro forma as adjusted net tangible book value per share of \$8.89 to new investors purchasing common stock in this offering. Dilution per share to new investors is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the initial public offering price per share paid by new investors.

The following table illustrates this dilution on a per share basis:

Initial public offering price per share		\$16.00
Historical net tangible book deficit per share as of December 31, 2020	\$(31.12)	
Increase per share attributable to the conversion of preferred stock	35.45	
Pro forma net tangible book value per share as of December 31, 2020	4.33	
Increase in pro forma as adjusted net tangible book value per share attributable to new investors purchasing common stock in this offering	2.78	
Pro forma as adjusted net tangible book value per share after this offering		7.11
Dilution per share to new investors purchasing common stock in this offering		<u>\$ 8.89</u>

If the underwriters exercise their option to purchase 1,125,000 additional shares of common stock in full, at the initial public offering price of \$16.00 per share, after deducting underwriting discounts and commissions and estimated offering expenses payable by us, the pro forma as adjusted net tangible book value per share of common stock after this offering would be \$7.41 per share, and the dilution in pro forma as adjusted net tangible book value per share to new investors purchasing shares of common stock in this offering would be \$8.59 per share.

The following table summarizes, as of December 31, 2020, on the pro forma as adjusted basis described above, the total number of shares of common stock purchased from us on an as converted to common stock basis, the total consideration paid or to be paid, and the weighted-average price per share paid or to be paid by existing stockholders and by new investors in this offering at the initial public offering price of \$16.00 per share, before deducting underwriting discounts and commissions and estimated offering expenses payable by us. As the table shows, new investors purchasing common stock in this offering will pay an average price per share substantially higher than our existing stockholders paid.

	SHARES PURCHASED		TOTAL CONSIDERATION		AVERAGE PRICE PER SHARE
	NUMBER	PERCENT	AMOUNT	PERCENT	
Existing stockholders	20,025,943	72.8%	\$128,270,296	51.7%	\$ 6.41
New investors	7,500,000	27.2	120,000,000	48.3	\$ 16.00
Total	<u>27,525,943</u>	<u>100.0%</u>	<u>\$248,270,296</u>	<u>100.0%</u>	

The table above assumes no exercise of the underwriters' option to purchase 1,125,000 additional shares in this offering. If the underwriters' option to purchase additional shares is exercised in full, the number of shares of our common stock held by existing stockholders would be reduced to approximately 69.9% of the total number of shares of our common stock outstanding after this offering, and the number of shares of common stock held by new investors purchasing shares of common stock in this offering would be increased to approximately 30.1% of the total number of shares of our common stock outstanding after this offering.

The number of shares of our common stock to be outstanding after this offering is based on 20,025,943 shares of our common stock outstanding as of December 31, 2020 (including an aggregate of 18,279,712 shares of common stock issuable upon conversion of our outstanding preferred stock as of December 31, 2020), but excludes:

- 2,058,964 shares of common stock issuable upon exercise of stock options outstanding as of December 31, 2020, under our 2017 Stock Incentive Plan, as amended, or the 2017 Plan, at a weighted-average exercise price of \$3.79 per share;
- 58,904 shares of common stock issuable upon exercise of warrants to purchase common stock outstanding as of December 31, 2020, at a weighted-average exercise price \$0.09 per share;
- 136,711 shares of common stock available for future issuance as of December 31, 2020 under the 2017 Plan (which shares, to the extent that they remained available for future issuance immediately prior to the effectiveness of the registration statement of which this prospectus is a part, became available for issuance under our 2021 Stock Incentive Plan, or the 2021 Plan);
- 2,843,116 additional shares of common stock available for future issuance under the 2021 Plan, as well as any shares which may be reserved pursuant to provisions in the 2021 Plan that automatically increase the number of shares of common stock reserved for issuance under the 2021 Plan (which includes shares of common stock underlying stock option awards that our board of directors agreed to grant to certain of our non-employee directors and executive officers, upon this offering, as described below under "Executive Compensation—Employee Benefit and Equity Compensation Plans—2021 Stock Incentive Plan", which options will have an exercise price per share equal to the initial public offering price); and
- 244,000 additional shares of common stock available for future issuance under our 2021 Employee Stock Purchase Plan, or the 2021 ESPP, as well as any shares which may be reserved pursuant to provisions in the 2021 ESPP that automatically increase the number of shares of common stock reserved for issuance under the 2021 ESPP.

To the extent that any outstanding stock options or warrants are exercised, new stock options are issued, or we issue additional shares of common stock in the future at per share prices below the price per share to the public in this offering, there will be further dilution to new investors. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

SELECTED CONSOLIDATED FINANCIAL DATA

The following tables set forth a summary of our historical consolidated financial data as of, and for the periods ended on, the dates indicated. We have derived the consolidated statement of operations data for the years ended December 31, 2019 and 2020 and the consolidated balance sheet data as of December 31, 2019 and 2020 from our audited consolidated financial statements appearing elsewhere in this prospectus. This selected consolidated financial data should be read in conjunction with our financial statements and the related notes included elsewhere in this prospectus and the "Management's Discussion and Analysis of Financial Condition and Results of Operations" section of this prospectus. Our historical results are not necessarily indicative of the results that may be expected in the future.

(in thousands, except share and per share data)	YEAR ENDED	
	DECEMBER 31,	
	2019	2020
Consolidated Statement of Operations Data:		
Operating expenses:		
Research and development	\$ 6,340	\$ 16,641
General and administrative	3,596	5,763
Total operating expenses	<u>9,936</u>	<u>22,404</u>
Loss from operations	(9,936)	(22,404)
Other income (expense):		
Change in fair value of preferred stock tranche liability	487	7,301
Interest income (expense), net	(372)	101
Other expense, net	(57)	(38)
Change in fair value of warrant liabilities	(370)	—
Total other income (expense)	<u>(312)</u>	<u>7,364</u>
Net loss	<u>(10,248)</u>	<u>(15,040)</u>
Accretion of redeemable convertible preferred stock to redemption value	(7,981)	(13,177)
Net loss attributable to common stockholders	<u>\$ (18,229)</u>	<u>\$ (28,217)</u>
Net loss per share attributable to common stockholders, basic and diluted (1)	<u>\$ (28.49)</u>	<u>\$ (28.09)</u>
Weighted-average common shares outstanding, basic and diluted (1)	<u>639,888</u>	<u>1,004,691</u>
Pro forma net loss per share attributable to common stockholders—basic and diluted (unaudited) (2)		<u>\$ (1.68)</u>
Pro forma weighted-average common shares outstanding, basic and diluted (unaudited) (2)		<u>8,970,732</u>

(1) See Note 2 to our consolidated financial statements included elsewhere in this prospectus for an explanation of the method used to calculate the basic and diluted net loss per share attributable to common stockholders and the number of shares used in the computation of the per share amounts.

(2) The calculations for the unaudited pro forma net loss per share attributable to common stockholders, basic and diluted, and the unaudited pro forma weighted-average common shares outstanding, basic and diluted, assume the conversion of all our outstanding shares of preferred stock into shares of our common stock, as if the conversion had occurred at the beginning of the period presented, or the issuance date, if later, and the reclassification of the preferred stock tranche liability as of the date of issuance.

(in thousands)	AS OF DECEMBER 31,	
	2019	2020
Consolidated Balance Sheet Data:		
Cash and cash equivalents	\$ 17,896	\$ 92,570
Working capital (1)	16,019	87,630
Total assets	21,679	96,398
Preferred stock tranche liability	7,301	—
Redeemable convertible preferred stock	34,073	141,082
Accumulated deficit	(24,408)	(51,865)
Total stockholders' deficit	(24,304)	(51,863)

(1) We define working capital as total current assets less total current liabilities. See our audited consolidated financial statements included elsewhere in this prospectus and related notes for further details regarding our total current assets and total current liabilities.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with the section entitled "Summary Consolidated Financial Data" and our financial statements and related notes appearing elsewhere in this prospectus. Some of the information contained in this discussion and analysis or set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the section entitled "Risk Factors," our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. You should carefully read the section entitled "Risk Factors" to gain an understanding of the important factors that could cause actual results to differ materially from our forward-looking statements. Please also see the section entitled "Cautionary Note Regarding Forward-Looking Statements and Industry Data."

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, or TME. 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 solid tumors. We plan to submit an investigational new drug application, or IND, to the U.S. Food and Drug Administration for each of WTX-124 and WTX-330 in the first half of 2022, and thereafter initiate a Phase 1/1b clinical trial for each candidate in multiple tumor types as a single agent and in combination with an immune checkpoint inhibitor.

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 promissory notes and preferred stock. 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. In addition, in May 2020, we entered into a loan and security agreement, or the Loan Agreement, under which we have the ability to borrow up to \$14.0 million until November 2021. As of March 31, 2020, we had no outstanding borrowings under the Loan Agreement.

We have incurred significant net losses since inception, including \$10.2 million and \$15.0 million for the years ended December 31, 2019 and 2020, respectively. As of December 31, 2020, we had an accumulated deficit of \$51.9 million. We expect to continue to incur significant and increasing expenses and net losses for the foreseeable future, as we 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.

We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for our product candidates. In addition, if we obtain regulatory approval for our product candidates and do not enter into a third-party commercialization partnership, we expect to incur significant expenses related to developing our commercialization capability to support product sales, marketing, manufacturing and distribution activities.

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

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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.

As of December 31, 2020, we had cash and cash equivalents of \$92.6 million. We believe that the net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our operations for at least 24 months from the filing date of the registration statement of which this prospectus is a part.

Impact of COVID-19 on Our Business

The worldwide COVID-19 pandemic may affect our ability to initiate and complete preclinical studies, delay the initiation of our future clinical trials, disrupt regulatory activities or have other adverse effects on our business, results of operations, financial condition and prospects. In addition, the pandemic has adversely impacted economies worldwide and may cause substantial disruption in the financial markets, both of which could adversely affect our business, operations and ability to raise funds to support our operations.

To date, we have not experienced a material financial statement impact or business disruptions, including with our vendors, or impairments of any of our assets as a result of the pandemic. We are following, and plan to continue to follow, recommendations from federal, state and local governments regarding workplace policies, practices and procedures. We have taken temporary precautionary measures intended to help minimize the risk of the virus to our employees, including temporarily requiring certain of our employees to work remotely, suspending all non-essential travel worldwide for our employees and discouraging employee attendance at industry events and in-person work-related meetings, which could negatively affect our business. We expect to continue to take actions as may be required or recommended by government authorities or as we determine are in the best interests of our employees and other business partners. We are continuing to monitor the potential impact of the pandemic, but we cannot be certain what the overall impact will be on our business, financial condition, results of operations and prospects.

Components of Our Results of Operations

Revenue

To date, we have not generated any revenue from any sources, including from product sales, and we do not expect to generate any revenue from the sale of products in the foreseeable future.

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 and preclinical activities on our behalf;
- costs of outside consultants, including their fees, stock-based compensation and related travel expenses;
- the costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and future 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.

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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 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 outsourced development costs by product candidate or development program, but we do not allocate personnel costs, license payments made under our licensing arrangements or other internal costs to specific development programs or product candidates.

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 initiate clinical trials of WTX-124 and WTX-330, continue preclinical studies of WTX-613 and continue to discover and develop additional product candidates.

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 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, business development and administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters; professional fees for accounting, auditing, 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 our continued research and development activities, manufacturing activities and expansion of our operations in connection with our anticipated commencement of clinical trials. We also anticipate increased expenses associated with being a public company, including costs for audit, legal, regulatory and tax-related services related to compliance with the rules and regulations of the Securities and Exchange Commission and listing standards applicable to companies listed on a national securities exchange, director and officer insurance premiums and investor relations costs.

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Other Income (Expense)

Change in fair value of preferred stock tranche liability

Change in fair value of our preferred stock tranche liability consists primarily of remeasurement gains or losses attributable to changes in the fair value of the tranche rights associated with our Series A preferred stock. The tranche liability was settled in June 2020 upon the closing of the second tranche of our Series A preferred stock financing. All obligations have been met by December 31, 2020 and therefore there will be no further remeasurement.

Interest income (expense), net

Interest expense, net primarily consists of interest expense from our convertible notes, partially offset by interest income from interest-bearing cash equivalents.

Change in fair value of warrant liabilities

Change in fair value of warrant liabilities consist primarily of remeasurement gains or losses attributable to changes in the fair value of the liabilities associated with warrants to purchase common stock issued in connection with our convertible notes. In 2019, the warrant liabilities were modified and reclassified from liability to equity. The warrants were marked-to-market immediately before and after the modification. As a result of this reclassification from liability to equity, there will be no further remeasurement.

Results of Operations

Comparison of the Years Ended December 31, 2019 and 2020

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

	YEAR ENDED DECEMBER 31,		CHANGE
	2019	2020	
Operating expenses:			
Research and development	\$ 6,340	\$ 16,641	\$ 10,301
General and administrative	3,596	5,763	2,167
Total operating expenses	9,936	22,404	12,468
Loss from operations	(9,936)	(22,404)	(12,468)
Other income (expense):			
Change in fair value of preferred stock tranche liability	487	7,301	6,814
Interest income (expense), net	(372)	101	473
Other expense, net	(57)	(38)	19
Change in fair value of warrant liabilities	(370)	—	370
Total other (expense) income	(312)	7,364	7,676
Net loss	<u>\$(10,248)</u>	<u>\$(15,040)</u>	<u>\$ (4,792)</u>

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Research and Development Expenses

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

	YEAR ENDED		CHANGE
	DECEMBER 31,		
	2019	2020	
Manufacturing	\$ 87	\$ 6,528	\$ 6,441
Personnel	2,540	4,289	1,749
Contract research organization expense	2,200	3,452	1,252
Protein production, lab supplies and consumables	1,478	2,154	676
Other	35	218	183
	<u>\$6,340</u>	<u>\$16,641</u>	<u>\$10,301</u>

Research and development expenses for the year ended December 31, 2019 were \$6.3 million, compared to \$16.6 million for the year ended December 31, 2020. The increase of \$10.3 million was primarily due to the following:

- An increase of \$6.4 million in manufacturing expense related to costs incurred with contract manufacturing organizations for production of pre-clinical and future clinical trial materials associated with our most advanced product candidates WTX-124 and WTX-330.
- An increase of \$1.7 million in personnel costs due to increased salaries and bonus expense and increased headcount associated with expanded research and development activities.
- An increase of \$1.3 million in contract research organization expenses driven by an increase in preclinical studies related to IND-enabling activities.
- An increase of \$0.7 million in protein production, lab supplies and consumables costs primarily due to significant increase in research activities for WTX-124, WTX-330 and WTX-613.

General and Administrative Expenses

General and administrative expenses were \$3.6 million for the year ended December 31, 2019, compared to \$5.8 million for the year ended December 31, 2020. The increase of \$2.2 million was primarily due to the following:

- An increase of \$0.8 million in compensation expense associated with increased headcount to develop our general and administrative staff.
- An increase of \$0.6 million in professional fees driven by increased audit, tax, valuation and legal services.
- An increase of \$0.3 million associated with human resource and recruiting initiatives to augment our administrative staff.

Other Income (Expense)

Change in Fair Value of Preferred Stock Tranche Liability

Changes in the fair value of preferred stock tranche liability resulted in a gain of \$0.5 million for the year ended December 31, 2019, compared to a gain of \$7.3 million for the year ended December 31, 2020. The increase of \$6.8 million was primarily due to an increase in the value of our preferred stock by the time of the re-measurement and subsequent settlement of the tranche liability upon achievement the second closing of our Series A preferred stock financing.

Interest Income (Expense), Net

Interest expense, net was \$0.4 million for the year ended December 31, 2019 compared to interest income, net of \$0.1 million for the year ended December 31, 2020. The change of \$0.5 million in interest income, net was the result of interest income generated on our higher average cash balance for the year ended December 31, 2020 compared to the year ended December 31, 2019, due to the receipt of \$94.1 million in proceeds from our Series A and Series B preferred stock financings in 2020.

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Change in Fair Value of Warrant Liabilities

Changes in the fair value of warrant liabilities resulted in an expense of \$0.4 million for the year ended December 31, 2019, which was due primarily to remeasurement of our warrants upon reclassification from liability to equity.

Liquidity and Capital Resources

Sources of Liquidity

We have incurred significant net losses since inception. We expect to continue to incur significant and increasing expenses and net losses for the foreseeable future, as we 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 December 31, 2020, we had cash and cash equivalents of \$92.6 million and an accumulated deficit of \$51.9 million. We have financed our operations primarily through issuances of our convertible promissory notes and preferred stock. 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. In addition, in May 2020, we entered into the Loan Agreement under which we have the ability to borrow up to \$14.0 million until November 2021. As of March 31, 2020, we had no outstanding borrowings under the Loan Agreement.

Cash Flows

The following table summarizes our cash flows for the periods indicated (in thousands):

	YEAR ENDED DECEMBER 31,	
	2019	2020
Cash flows used in operating activities	\$ (9,542)	\$ (18,624)
Cash flows used in investing activities	(266)	(560)
Cash flows provided by financing activities	21,909	93,857
Net increase in cash and cash equivalents	<u>\$ 12,101</u>	<u>\$ 74,673</u>

Operating Activities

Net cash used in operating activities for the year ended December 31, 2019 was \$9.5 million, which consisted primarily of our net loss of \$10.2 million decreased by net non-cash charges of \$1.4 million and increased by a net increase of \$0.7 million in our operating assets. The non-cash charges primarily consisted of stock-based compensation of \$0.6 million, non-cash interest expense of \$0.5 million on converted notes payable, non-cash lease expense of \$0.4 million and change in warrant liabilities of \$0.4 million, which were partially offset by a change in the fair value of preferred stock tranche liability of \$0.5 million. The net increase in our net operating assets was primarily due to a net increase in right of use assets and operating lease liability of \$0.5 million, a decrease in accrued expenses of \$0.3 million and an increase in prepaid and other assets of \$0.1 million, which were partially offset by an increase in accounts payable of \$0.1 million.

Net cash used in operating activities for the year ended December 31, 2020 was \$18.6 million, which consisted primarily of our net loss of \$15.0 million increased by net non-cash gains of \$5.9 million and decreased by a net decrease of \$2.3 million in our net operating assets. The non-cash gains were attributable to a \$7.3 million gain related to change in fair value of preferred stock tranche liability, which was partially offset by non-cash charges of \$0.6 million in stock-based compensation, \$0.6 million in non-cash lease expense and \$0.2 million in depreciation. The net decrease in our net operating assets was attributable to a \$2.6 million increase in accrued expenses and a \$0.4 million increase in accounts payable, which were partially offset by a net decrease in right of use assets and operating lease liability of \$0.5 million and a \$0.2 million increase in prepaid expenses and other assets.

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Investing Activities

During the years ended December 31, 2019 and 2020, we used \$0.3 million and \$0.6 million of cash, respectively, for investing activities related to purchases of property and equipment.

Financing Activities

Net cash provided by financing activities was \$21.9 million for the year ended December 31, 2019, representing proceeds from the issuance of Series A preferred stock partially offset by equity issuance costs of \$0.2 million.

Net cash provided by financing activities was \$93.9 million for the year ended December 31, 2020, representing proceeds from the issuance of Series A and Series B preferred stock partially offset by equity issuance costs and deferred financing costs of \$0.3 million.

Term Loan Agreement

In May 2020, we entered into the Loan Agreement with Pacific Western Bank, or PWB, under which we have the ability to borrow up to \$14.0 million in the form of a term loan on or prior to November 29, 2021. Borrowings under the Loan Agreement would be collateralized by substantially all of our assets, excluding intellectual property. As of March 31, 2020, we had no outstanding borrowings under the Loan Agreement.

Interest on any loan balances accrue at a variable annual rate equal to the greater of (i) PWB's prime rate plus 1.75% and (ii) 5.00%. Interest-only payments on any loan balances are required to be paid on a monthly basis through May 29, 2021 or, at our election, November 29, 2021. Subsequent to the interest-only period, any loan balances are required to be repaid in equal monthly payments of principal plus interest until the loan matures in May 2024. We have the option to prepay any amount borrowed under the Loan Agreement in full without a fee. In the event of a specified liquidation event, including this offering, we will be required to pay the bank a success fee of 5.00% of the total amount borrowed under the term loan, if any. The Loan Agreement contains customary representations, warranties and covenants and also includes customary events of default, including payment defaults, breaches of covenants, change of control and occurrence of a material adverse effect. We are required to maintain unrestricted cash balances of at least 2.5 times our monthly cash burn, and we have covenanted not to make any capital expenditures in excess of \$2.0 million in the aggregate in 2021 and \$0.5 million in the aggregate in any fiscal year thereafter without the prior written consent of PWB.

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 development and move into 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.

Due to our significant research and development expenditures, we have generated substantial net losses in each period since inception. We have incurred an accumulated deficit of \$51.9 million through December 31, 2020. We expect to incur substantial additional losses in the future as we expand our research and development activities. Based on our research and development plans, we expect that the net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our operations for at least 24 months from the filing date of the registration statement of which this prospectus is a part. 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.

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 planned clinical trials of WTX-124 and WTX-330;

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- the costs associated with attracting, hiring and retaining skilled personnel and consultants as our preclinical and clinical activities increase;
- the cost of manufacturing WTX-124, WTX-330, WTX-613 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 planned combination clinical trials that are not covered by such third parties or other sources;
- the potential additional expenses attributable to adjusting our development plans (including any supply related matters) as a result of the COVID-19 pandemic;
- the timing of, and the cost involved in, obtaining marketing approval for WTX-124, WTX-330, WTX-613 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, WTX-613 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.

The net proceeds of this offering, together with our existing cash and cash equivalents, will not be sufficient to complete development of WTX-124, WTX-330, WTX-613 or any other product candidate. 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 and prospects.

Off-Balance Sheet Arrangements

We have not entered into any off-balance sheet arrangements.

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Contractual Obligations

The following table summarizes our contractual obligations as of December 31, 2020 (in thousands):

	LESS THAN 1 YEAR	1 TO 3 YEARS	3 TO 5 YEARS	MORE THAN 5 YEARS	TOTAL
Operating lease obligations	\$ 870	\$2,051	\$ —	\$ —	\$2,921
Total	\$ 870	\$2,051	\$ —	\$ —	\$2,921

We have entered into an operating lease for rental space in Cambridge, Massachusetts. The amounts reflected in the table above consist of the future minimum lease payments under the non-cancelable lease arrangement. In March 2021, we entered into a lease for approximately 7,500 square feet of office and laboratory space in Watertown, Massachusetts pursuant to a lease that expires in May 2022. Under this lease, we are obligated to pay rent of approximately \$46,000 per month, which amount is not included in the table above.

We enter into contracts in the normal course of business with contract research organizations and other vendors to assist in the performance of our research and development and other services and products for operating purposes. These contracts typically do not contain minimum purchase commitments and generally provide for termination on notice, and therefore are cancelable contracts and not included in the table of contractual obligations.

In addition, we have entered into license and royalty agreements for intellectual property with certain parties, such as our license agreement with Harpoon and our royalty transfer agreement with MPM Oncology Charitable Foundation, Inc. and UBS Optimus Foundation. For further information regarding these agreements and amounts that could become payable in the future under these agreements, please see the section of this prospectus titled "Business—License and Royalty Agreements." Such arrangements may require additional payments, including payments upon achieving certain development, regulatory and commercial milestones, as well as royalties on commercial sales. Payments under these arrangements are expensed as incurred and are recorded as research and development expenses. We have not paid any milestone payments or royalties under these agreements to date. We have not included potential royalties or milestone obligations in the table above because they are contingent upon the occurrence of future events and the timing and likelihood of such potential obligations are not known with certainty. Based on our current development plans, in the next 12 months we do not expect to have any material potential milestone and royalty payments due to third parties. These payments become due and payable upon achievement of specified milestones or sales, none of which are considered probable as of December 31, 2020. If we commercialize and sell any licensed products covered by the Harpoon license agreement in the future, we will be obligated to pay a low single digit percentage royalty on net sales of such products by us or any of our affiliates, subject to an obligation to make a minimum annual royalty payment at an amount in the low hundreds of thousands of dollars beginning with the first commercial sale of any such product by us. We have agreed to pay a royalty of 0.5% of net sales of our products to each of MPM Oncology Charitable Foundation, Inc. and UBS Optimus Foundation.

Critical Accounting Policies and Use of Estimates

This management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States, or U.S. GAAP. The preparation of our 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. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our financial statements appearing within this prospectus, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our financial statements.

Research and Development Costs, Accrued Research and Development Costs and Related Prepaid Expenses

Research and development costs are expensed as incurred. Research and development expenses consist principally of personnel costs, including salaries, stock-based compensation, and benefits for employees, third-party license fees and other operational costs related to our research and development activities, including allocated facility-related expenses and external costs of outside vendors, and other direct and indirect costs. Non-refundable research and development advance payments are deferred and capitalized. The capitalized amounts are expensed as the related goods are delivered or services are performed. Costs for external development activities are recognized based on an evaluation of the progress to completion of specific tasks. Costs for certain research and development activities are recognized based on the pattern of performance of the individual arrangements, which may differ from the pattern of billings incurred, and are reflected in the consolidated financial statements as prepaid expenses or as accrued research and development expenses.

Stock-Based Compensation

We measure all stock options and other stock-based awards granted to our employees, directors, consultants and other non-employee service providers based on the fair value on the date of the grant. Compensation expense related to awards to employees and directors with service-based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is typically the vesting term. Compensation expense related to awards to employees with performance-based vesting conditions is recognized based on grant date fair value over the requisite service period using the accelerated attribution method to the extent achievement of the performance condition is probable. Non-employee option awards are measured at the earlier of the commitment date for performance by the counterparty or the date when the performance is complete, and compensation expense is recognized in the same manner as if we had paid cash for goods or services. We recognize forfeitures as they occur for our stock-based compensation awards.

We classify stock-based compensation expense in our consolidated statement of operations in the same way the award recipient's payroll costs are classified or in which the award recipients' service payments are classified.

We use the Black-Scholes option pricing model to estimate the fair value of stock options on the date of grant and we use the fair value of our common stock to determine the fair value of restricted common stock awards. Using the Black-Scholes option pricing model requires management to make significant assumptions and judgments. We determined these assumptions for the Black-Scholes option-pricing model as discussed below.

- *Expected Term*—The expected term represents the period that the stock-based awards are expected to be outstanding. As we do not have sufficient historical experience for determining the expected term of the stock option awards granted, we based our expected term for awards issued to employees and non-employees using the simplified method which is presumed to be the midpoint between the vesting date and the end of the contracted term.
- *Contractual Term*—The contractual term represents the nominal period that the stock-based awards are outstanding. Due to the nature of specific terms of our nonemployee share option arrangements, we determined the contractual term is the appropriate expected term to be used in estimating the fair value of the nonemployee share options.
- *Risk-Free Interest Rate*—The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the date of grant for zero-coupon U.S. Treasury constant maturity notes with terms approximately equal to the stock-based awards' expected term.
- *Expected Volatility*—Since we do not have a trading history of common stock, the expected volatility was derived from the average historical stock volatilities of the common stock of several public companies within the industry that we consider to be comparable to our business over a period equivalent to the expected term of the stock-based awards.
- *Dividend Rate*—The expected dividend rate is zero as we have not paid and do not anticipate paying any dividends in the foreseeable future.
- *Fair Value of Common Stock*—Prior to this offering, the fair value of the shares of common stock underlying the stock-based awards has been determined by our board of directors with input from management. Because there has been no public market for our common stock, our board of directors has determined the fair value of our common stock at the time of grant of the stock-based award by considering a number of

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objective and subjective factors, including having valuations of the common stock performed by a third-party valuation specialist, as further described below.

As of December 31, 2020, the total unrecognized compensation expense related to unvested employee and non-employee options was \$5.2 million, which we expect to recognize over an estimated weighted-average period of 3.8 years. Based upon the initial public offering price of \$16.00 per share, the aggregate intrinsic value of options outstanding as of December 31, 2020 was \$25.2 million, of which \$0.5 million related to vested options and \$24.7 million related to unvested options.

Common Stock Valuations

The fair value of the shares of common stock underlying our stock-based awards has historically been determined by our board of directors with input from management and contemporaneous third-party valuations. We believe that our board of directors has the relevant experience and expertise to determine the fair value of our common stock. Given the absence of a public trading market of our common stock, and in accordance with the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation, our board of directors exercised reasonable judgment and considered numerous and subjective factors to determine the best estimate of the fair value of our common stock at each grant date. These factors include:

- contemporaneous valuations of our common stock performed by independent third-party specialists;
- the prices, rights, preferences, and privileges of our preferred stock relative to those of our common stock;
- the prices of common or preferred stock sold to third-party investors by us;
- lack of marketability of our common stock;
- our actual operating and financial performance;
- current business conditions and projections;
- hiring of key personnel and the experience of our management;
- the history of our company;
- our stage of development;
- likelihood of achieving a liquidity event, such as an initial public offering or a merger or acquisition of our company given prevailing market conditions;
- the market performance of comparable publicly traded companies; and
- U.S. and global capital market conditions.

In valuing our common stock, our board of directors determined the equity value of our business using the hybrid method with input from management. The hybrid method is based upon the probability-weighted value across two scenarios, being (i) successfully consummating an initial public offering and (ii) alternative scenarios in which an initial public offering is not consummated. The hybrid method can be a useful alternative to explicitly modeling all probability-weighted expected return scenarios in situations when the company has transparency into one or more near term exits but is unsure about what will occur if current plans do not materialize.

Application of these approaches involves the use of estimates, judgment and assumptions that are highly complex and subjective, such as those regarding the time to the liquidation event and volatility. Changes in these estimates and assumptions or the relationships between these assumptions impact our valuations as of each valuation date and may have a material impact on the valuation of common stock.

For valuations after the completion of this offering, our board of directors will determine the fair value of each share of underlying common stock based on the closing price of our common stock as reported by Nasdaq on the date of grant. Future expense amounts for any particular period could be affected by changes in our assumptions or market conditions.

Fair Value Measurements

Warrant Liabilities

We have determined that warrants to purchase common stock issued in connection with our convertible notes represented a freestanding instrument. The resulting warrant liabilities were initially recorded at fair value, with

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gains and losses arising from changes in fair value recognized in other income (expense) in the consolidated statement of operations. The warrant liabilities were remeasured at each reporting period. In 2019, the warrant liabilities were modified and reclassified from liability to equity. The warrants were marked-to-market immediately before and after the modification. Due to their reclassification from liability to equity in 2019, there will be no further remeasurement.

Preferred Stock Tranche Rights

We have determined that our obligation to issue, and our investors' obligation to purchase, additional shares of Series A preferred stock upon the second closing represented a freestanding instrument. The resulting preferred stock tranche liability was initially recorded at fair value, with gains and losses arising from changes in fair value recognized in other income (expense) in the consolidated statement of operations. The preferred stock tranche liability was remeasured at each reporting period and upon the exercise or expiration of the obligation. The preferred stock tranche liability was valued using an option pricing model that utilized the fair value of the Series A preferred stock, expected volatility and the expected term. As of December 31, 2020, all Series A preferred stock closings have occurred and all associated tranche liabilities have been remeasured and reclassified to preferred stock.

Recent Accounting Pronouncements

For a description of recent accounting pronouncements, see Note 2 of the notes to our consolidated financial statements for the year ended December 31, 2020 appearing elsewhere in this prospectus.

Internal Control Over Financial Reporting

Internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with U.S. GAAP. Under standards established by the Public Company Accounting Oversight Board, or PCAOB, a deficiency in internal control over financial reporting exists when the design or operation of a control does not allow management or personnel, in the normal course of performing their assigned functions, to prevent or detect misstatements on a timely basis. The PCAOB defines a material weakness as a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of annual or interim financial statements will not be prevented, or detected and corrected, on a timely basis.

We identified material weaknesses in our internal control over financial reporting related to the lack of maintaining a sufficient complement of personnel commensurate with the accounting and financial reporting requirements in order to have adequate segregation of key duties and responsibilities.

We are in the process of implementing measures designed to improve our internal control over financial reporting to remediate these material weaknesses. For example, we have hired a full time Chief Financial Officer, have hired additional financial personnel and have engaged financial consultants to assist with the evaluation and documentation of technical accounting matters. See "Risk Factors—Risks Related to this Offering, Ownership of Our Common Stock and Our Status as a Public Company—We identified material weaknesses in our internal control over financial reporting. If we are unable to remedy these material weaknesses, or if we fail to establish and maintain effective internal controls, we may be unable to produce timely and accurate financial statements, and we may determine that our internal control over financial reporting is not effective, which could adversely impact our investors' confidence and our stock price."

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.

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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 million in annual revenue.

Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risk related to changes in interest rates. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our cash equivalents are held in money market savings accounts and FDIC insured interest-bearing checking accounts. However, because of the short-term nature of the investments in our portfolio, an immediate one percentage point change in market interest rates would not have a material impact on the fair market value of our investment portfolio or on our financial position or results of operations.

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates; however, we may be subject to market risk related to foreign currency exchange rates if we continue contracting with foreign vendors that are located outside the United States in the future.

BUSINESS

Company 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, or TME. Our most advanced product candidates, WTX-124 and WTX-330, are systemically delivered, conditionally activated Interleukin-2, or IL-2, and Interleukin-12, or IL-12, respectively, INDUKINE molecules for the treatment of solid tumors. We plan to submit an investigational new drug application, or IND, to the U.S. Food and Drug Administration, or FDA, for each of WTX-124 and WTX-330 in the first half of 2022, and thereafter initiate a Phase 1/1b clinical trial for each candidate in multiple tumor types as a single agent and in combination with an immune checkpoint inhibitor.

We are building our PREDATOR platform to generate a pipeline of innovative therapeutics that cover a diversity of immune stimulating mechanisms with the potential to address significant unmet medical need in cancer. Our PREDATOR platform consists of our protein engineering technologies and our know how, which we use to generate INDUKINE molecules with multiple functional domains rationally engineered into a single protein to achieve the desired pharmaceutical profile. Each of our lead INDUKINE molecules consists of four components: a cytokine, an inactivation domain, a half-life extension domain and a proprietary protease-cleavable linker. Our INDUKINE molecules contain cytokines that mediate pro-inflammatory, anti-cancer mechanisms within the TME, with full potency and functionality observed in preclinical studies. The inactivation domain physically blocks the cytokine portion of the INDUKINE molecule in non-tumor tissue throughout the body, or the periphery, preventing it from binding to its receptor until it is cleaved and thereby activated in the TME. We engineer the half-life extension domain to overcome the short half-lives of cytokines *in vivo*, which typically range from a few minutes to a few hours. The half-life extension domain enables high systemic and tumor tissue exposure for the INDUKINE molecule prior to its cleavage in the tumor. After cleavage in the tumor, the half-life extension domain is removed and the cytokine is released to activate immune cells. We select the proprietary protease-cleavable linker to enable conditional activation of the cytokine portion of the INDUKINE molecule within tumor tissue. This selection is based on our extensive screening in preclinical studies to identify protease-cleavable linkers that are efficiently cleaved by a broad array of human tumor tissues with minimal cleavage in non-tumor tissues.

We have assembled an experienced management team, board of directors and scientific founders who bring extensive industry experience to our company. The members of our team have deep experience in discovering, developing and commercializing therapeutics with a particular focus on cancer and immunological disorders, having worked at companies such as Novartis, Schering-Plough, Merck, ImClone Systems (acquired by Bristol-Myers Squibb), Tizona Therapeutics (acquired by Gilead Sciences), CoStim Pharmaceuticals (acquired by Novartis), Potenza Therapeutics (acquired by Astellas Pharma) and others. We are backed by leading investors in the life science and biotechnology industry, including MPM Capital, which was our founding investor, RA Capital, Deerfield Management Partners, Longwood Fund, Arkin Holdings, Taiho Ventures, HBM Partners, Soleus Capital, Sphera Healthcare, Adage Capital and CaaS Capital.

We were founded in October 2017 by Daniel Hicklin, Ph.D., Luke Evnin, Ph.D., and other advisors associated with MPM Capital, an early-stage life sciences venture investing firm and our founding investor. Dr. Evnin, who has decades of experience in early stage and venture financing of oncology companies, served as our President and Chief Executive Officer from December 2017 until August 2019 and has served on our board of directors since October 2017 and as chairman of our board of directors since August 2019. Over the past eight years, as a component of his MPM activities, Dr. Evnin has been a co-founder and served as chairman of the board for seven MPM portfolio companies, including Harpoon Therapeutics, Inc., with which we entered into a license agreement that is described below under "Business—Our License and Royalty Agreements" and "Certain Relationships and Related Persons Transactions." Dr. Hicklin, who has served as our President and Chief Executive Officer since August 2019, has over thirty years' experience in oncology drug discovery and development, including as founder and Chief Executive Officer of Potenza Therapeutics, President and Chief Scientific Officer of CoStim Pharmaceuticals and in several positions at Merck Research Laboratories (formerly the Schering-Plough Research Institute prior to its acquisition by Merck), including leading its Biologics Strategy for Oncology and the Immuno-Modulation Discovery team.

Our Pipeline

We are leveraging our novel PREDATOR platform to engineer conditionally activated proinflammatory immunomodulators, or INDUKINE molecules, which are delivered systemically but activated only in the TME with the goal of generating potent anti-tumor response while minimizing toxicities. We have worldwide rights to our PREDATOR platform and our portfolio of INDUKINE product candidates, all of which we have developed internally. We believe our approach has the potential to overcome current limitations of systemic proinflammatory immunomodulatory therapies, such as cytokines, for the treatment of cancer. Our current pipeline is summarized below:

Program	Indication(s)	Program Rights	Pre-IND	IND-Enabling	Phase 1	Phase 2	Phase 3	Upcoming Milestones
WTX-124 IL-2 INDUKINE Molecule	Solid Tumors Monotherapy and in combination with checkpoint inhibitors							IND filing 1H2022
WTX-330 IL-12 INDUKINE Molecule	Solid Tumors and Lymphoma Monotherapy and in combination with checkpoint inhibitors							IND filing 1H2022
WTX-613 IFN-α INDUKINE Molecule	Solid Tumors and Hematologic Malignancies Monotherapy and in combination with standard of care							IND filing 1H2023

Using our PREDATOR platform, we have developed three initial product candidates: WTX-124, WTX-330 and WTX-613. In addition to these product candidates, we are pursuing additional immuno-oncology discovery programs in which we are applying our novel engineering approach to other targets.

WTX-124

Our lead product candidate, WTX-124, is designed to be a systemically delivered, conditionally activated IL-2 INDUKINE molecule for the treatment of advanced solid tumors. We believe that, unlike other next-generation IL-2 therapies in development, WTX-124 has the potential to be the only systemically delivered IL-2 therapy with full cytokine potency and function to drive robust antitumor effector responses. WTX-124 maintains binding to the high affinity receptor IL-2Ra/β/g once activated in tumors, which we believe is necessary for optimal anti-tumor activity by directing the generation of effective immune memory formation. We have designed WTX-124 to overcome IL-2 mediated toxicities by blocking its binding to IL-2 receptors in the periphery. In addition, we have engineered WTX-124 to include half-life extension for optimal exposure in tumors. We believe these design features of WTX-124's pharmacologic profile have the potential to make it a differentiated therapeutic, if approved. We plan to submit an IND to the FDA for WTX-124 in the first half of 2022 and thereafter initiate a Phase 1/1b clinical trial in relapsed or refractory advanced or metastatic solid tumors as monotherapy or in combination with an immune checkpoint inhibitor.

WTX-330

Our second product candidate, WTX-330, is designed to be a systemically delivered, conditionally activated IL-12 INDUKINE molecule for the treatment of relapsed or refractory advanced or metastatic solid tumors or lymphoma. We are developing WTX-330 to minimize the severe toxicities that have been observed with recombinant human IL-12, or rhIL-12, therapy and maximize clinical benefit when administered as monotherapy or in combination with immune checkpoint inhibitors. IL-12 is a potent inducer of innate and adaptive antitumor immunity, but there currently are no approved IL-12 therapies. We believe WTX-330 has the potential to be the only systemically delivered, conditionally activated IL-12 therapy with normal tissue IL-12 receptor, or IL-12R, blockade and with full IL-12 potency and function. Key features of WTX-330 include peripheral blockade of the IL-12 – IL-12R interaction to limit systemic toxicity, half-life extension for optimal exposure in tumors and conditional activation in the TME.

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We plan to submit an IND to the FDA for WTX-330 in the first half of 2022 and thereafter initiate a Phase 1/1b clinical trial in immunotherapy resistant advanced or metastatic solid tumors or lymphoma followed by expansion arms in tumors that are relapsed or refractory tumors following treatment with checkpoint inhibitors or tumors for which checkpoint inhibitors are not approved.

WTX-613

Our third product candidate, WTX-613, is designed to be a systemically delivered, conditionally activated Interferon alpha, or IFN- α , INDUKINE molecule for the treatment of solid tumors and hematologic malignancies. We are developing WTX-613 to minimize the severe toxicities that have been observed with recombinant IFN- α , or rIFN- α , therapy and maximize clinical benefit when administered as monotherapy or in combination with a checkpoint inhibitor or other standard of care therapy. Recombinant human IFN- α , or rhIFN- α , is clinically active in multiple cancers but clinical use is limited by severe systemic toxicity. We believe WTX-613 has the potential to deliver higher intratumoral exposure than other IFN- α therapies to maximize efficacy and minimize systemic toxicity. Key features of WTX-613 include the high efficiency blockade of off tumor IFN- α – IFN receptor, or IFNR, interaction, half-life extension for optimal exposure in tumors and conditional activation in the TME. We plan to submit an IND to the FDA for WTX-613 in the first half of 2023 for a clinical trial of WTX-613, which we anticipate will evaluate safety and tolerability, pharmacokinetics, biomarker changes and preliminary anti-tumor activity.

Our Strategy

Our goal is to utilize our proprietary PREDATOR platform to redefine the cancer treatment landscape with therapies to transform the lives of cancer patients. Key elements of our strategy include:

- **Advancing our lead product candidate, IL-2 INDUKINE molecule (WTX-124), into and through clinical development in selected solid tumor indications.** We plan to submit an IND to the FDA in the first half of 2022 and thereafter initiate a Phase 1/1b clinical trial of WTX-124 in historically immunotherapy-sensitive relapsed or refractory advanced or metastatic solid tumors, including melanoma and renal cell carcinoma, or RCC, as both monotherapy and in combination with an immune checkpoint inhibitor. In this trial, we will evaluate safety and tolerability, pharmacokinetics, biomarker changes and preliminary anti-tumor activity. We believe the administration of WTX-124 as monotherapy in relapsed or refractory solid tumors that have progressed on or following treatment with checkpoint inhibitors could generate clinical benefit, with the potential for us to pursue an expedited clinical development and regulatory strategy if we are able to show positive single arm efficacy data in a relapsed or refractory tumor type with high unmet medical need.
- **Advancing our IL-12 INDUKINE molecule (WTX-330) into clinical development in selected solid tumors and lymphoma.** We plan to submit an IND to the FDA in the first half of 2022 to initiate a Phase 1/1b clinical trial of WTX-330 in immunotherapy resistant advanced or metastatic solid tumors or lymphoma followed by expansion arms in tumors that are relapsed or refractory following treatment with checkpoint inhibitors or tumors for which checkpoint inhibitors are not approved. We believe the administration of WTX-330 as monotherapy in relapsed or refractory solid tumors and lymphoma, including those that are resistant to checkpoint inhibitors or for which checkpoint inhibitors are not indicated, could generate clinical benefit, with the potential for us to pursue an expedited clinical development and regulatory strategy if we are able to show positive single arm efficacy data in a relapsed or refractory tumor type with high unmet medical need.
- **Leveraging our proprietary PREDATOR platform to advance our IFN- α INDUKINE molecule (WTX-613) through preclinical development and expand our pipeline of product candidates.** We plan to advance WTX-613 into preclinical pharmacology and safety studies, as well as cell line development. In addition, while we have initially focused on developing INDUKINE molecules incorporating well known and clinically validated cytokines, we plan to leverage our PREDATOR platform to identify and advance additional product candidates in multiple indications, including novel pro-inflammatory or anti-inflammatory cytokines.
- **Establishing a leading position in protein engineering and developing optimized conditionally activated molecules.** We have built considerable expertise engineering conditionally activated proteins and believe our PREDATOR platform has broad applicability beyond our initial focus. We plan to invest in our know-how and PREDATOR platform with the goal of establishing ourselves as the leader in developing next-generation proinflammatory immune therapies.
- **Selectively entering into strategic partnerships while retaining key rights to our programs and platform in major pharmaceutical markets.** We plan to explore potential partnerships on an asset-by-asset basis to maximize the

value of each program while ensuring we maintain significant rights to our programs in major pharmaceutical markets. We also plan to strategically enter into collaborations to advance the development of our programs or in connection with our platform technology.

Traditional Cancer Therapy, Immunotherapy and the Need for New Treatment Options

The treatment of certain cancers has improved markedly over the past decade. Whereas many cancer treatments were historically limited to surgical removal, chemotherapy and radiation, recent advances target specific genetic changes in individual tumors or redirect the patient's immune system to eliminate tumors and improve patient outcomes.

The latter approach, referred to as immunotherapy, represents one of the fastest growing segments in cancer treatment. The goal of immunotherapy is to harness an individual's immune system to better enable it to identify, attack and kill tumor cells and to form long-term immunologic memory against tumors. The immune system is generally divided into the innate and adaptive arms, which are responsible for driving immediate and lasting anti-tumor responses, respectively. The innate immune system involves a diverse set of cells, including natural killer, or NK, cells, mast cells, eosinophils, basophils, neutrophils, macrophages and dendritic cells, or DCs, all of which generate a rapid local response to a foreign body, pathogen or tumor cell and release signals to activate and recruit cells, specifically lymphocytes, from the adaptive immune system. The adaptive immune system is the line of defense that is specific to a pathogen or tumor antigen and is composed of T cells and B cells, which work in concert to kill cells directly, produce antibodies and form immunologic memory. The latter is critical for the body's immune response upon re-exposure to the initial antigen or pathogen. Many of the recent advances in immuno-oncology, such as immune checkpoint inhibitors, have focused on improving the function of T cells.

Over the past decade, the development of immune checkpoint inhibitors, in particular programmed cell death protein 1, or PD-1, and programmed death-ligand 1, or PD-L1, inhibitors, has revolutionized the treatment of many cancers. The efficacy of these T cell targeted immunomodulators, both as single agents or in combination with standard of care therapies, including chemotherapy, has resulted in many of these regimens moving up the treatment paradigm to become first- or second-line treatment options in numerous cancer types, and the landscape for immunotherapy continues to rapidly evolve. However, features of the tumor cells or the TME play a role in the efficacy of immune checkpoint inhibitors, leaving many patients with advanced or metastatic disease either ineligible for or unresponsive to treatment with immune checkpoint inhibitors. The majority of patients who do respond to these therapies ultimately develop resistance and experience disease progression. As a result, many patients are still underserved and could benefit from novel approaches to immunotherapy that complement and/or enhance checkpoint inhibition, whether as monotherapy or in combination. We believe that the best way to improve outcomes for cancer patients is to stimulate additional or *de novo* immune cell responses within the innate and adaptive arms of the immune system to complement immune checkpoint inhibitor therapy.

Leveraging our PREDATOR platform and drug development capabilities, we are creating a portfolio of conditionally activated proinflammatory immunomodulators, including cytokines, designed to be optimized for the treatment of cancer. Cytokines are small biologically active proteins that play an essential role in immune cell function of both the innate and adaptive arms of the immune system. These proteins regulate immune responses by acting as chemical messengers for the body's immune cells through receptor site binding. Interleukins, such as IL-2 and IL-12, and IFN- α are specific types of cytokines, produced primarily by cells of the immune system to signal and organize the immune response. In cancer, cytokines facilitate the ability of the immune system to recognize tumor cells as abnormal and harmful to the host. Cytokines further increase the proliferation of, enhance the survival of and direct a variety of immune cell types to infiltrate the TME and promote potent anti-tumor immune responses resulting in tumor cell killing and tumor clearance. Two cytokine therapies have received FDA approval for cancer treatment: aldesleukin for the treatment of metastatic RCC and melanoma and interferon- α 2b for the treatment of several malignancies, including advanced melanoma.

However, despite promising anti-tumor activity, the clinical utility of approved cytokine therapies is limited due to toxicity and poor pharmaceutical properties, such as short half-life, reduced exposure of active drug in the tumor and the requirement for frequent administration. The efficacy observed is often accompanied by side effects that can be severe and can make treatment difficult for many patients to tolerate, limiting the ability of patients to remain on therapy long-term.

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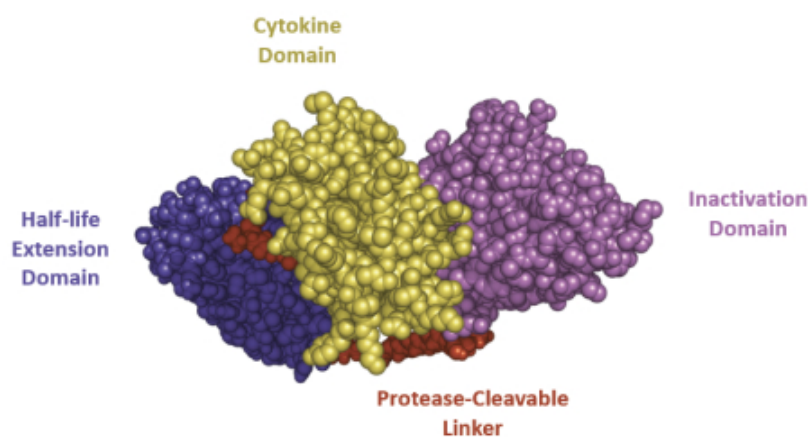
The need to improve the pharmaceutical properties of cytokines to achieve increased therapeutic indexes provides an opportunity to address a large unmet need for safer, and potentially more efficacious, cytokine therapeutics for the treatment of cancer. Our PREDATOR platform allows us to engineer cytokines that can be delivered systemically and have activity only upon reaching the TME, thus potentially limiting systemic toxicity. We believe this unique profile will help overcome the liabilities seen with other cytokine approaches.

Our Solution

Our PREDATOR Platform

We designed our PREDATOR platform to overcome the current limitations of systemic proinflammatory therapies. We use our PREDATOR platform to design molecules with superior tolerability and optimal pharmaceutical properties when administered systemically as inactive pro-drugs. They then undergo transformation to an active state only upon reaching the TME, thereby delivering the full biological potency of antitumor immune modulation for maximum therapeutic potential.

Our PREDATOR platform is based on protein engineering to combine four critical components into a single INDUKINE molecule, as shown in the figure below.



- **Cytokine Domain:** An immunostimulatory molecule with no mutations or sequence alteration. Upon tumor specific conditional activation, the released cytokine works as a fully potent agonist, displaying the expected pro-inflammatory mechanism and pharmacology.
- **Inactivation Domain:** A domain that blocks the activity of the immunostimulatory molecule outside of the tumor, for which we have identified and optimized multiple formats with high affinity blockade to achieve minimal off-tumor toxicity and low peripheral target receptor-mediated clearance.
- **Half-Life Extension Domain:** A domain that imparts a longer half-life to the INDUKINE molecule until cleavage within the tumor, when the immunostimulatory cytokine is released. We have selected multiple domain formats to enable our INDUKINE product candidates to maintain high systemic and tumor tissue exposure.
- **Protease-Cleavable Linker:** A novel, proprietary protease-cleavable linker substrate with optimal tumor selectivity that is used to impart conditional activation of the INDUKINE molecule through its cleavage, which releases the active cytokine. We have observed high stability of these proprietary protease-cleavable linker substrates in rodents and non-human primates, or NHPs, with minimal non-tumor tissue cleavage.

Linker Selection

A key challenge in the design of tumor-selective conditionally activated immunomodulators is the heterogeneity of tumor protease profiles. There is no single protease that is uniquely dysregulated in human tumors. Therefore, the identification of a linker substrate with the optimal profile cannot be achieved by biasing the linker sequence towards any single protease or protease family.

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To ensure INDUKINE molecules are broadly activated across multiple tumor types, the linker substrate must be efficiently cleaved in the TME of many different tumors while remaining stable in circulation and in normal non-tumor tissues. We achieve this by utilizing a differentiated approach for linker identification and let the tumors select the substrate, rather than screening for linkers sensitive to cleavage by a single protease. Our process begins with a novel proprietary library of peptide sequences designed to target the universe of protease families known to be dysregulated in tumors. We initially screen these libraries for a high efficiency of cleavage and, based on the result, generate additional libraries to optimize the sequence motifs. We then screen the prioritized linker sequences that we have identified from the initial novel proprietary library of peptide sequences for cleavage by a panel of primary human tumor specimens and for stability when incubated with human serum or normal tissues. This step allows us to eliminate linkers that are not efficiently cleaved by human tumor samples and identify proprietary linkers that are efficiently cleaved by human tumor specimens. Leveraging this screening process, we initially screened several thousand linker sequences for optimal biochemical properties, and then screened the lead sequences for cleavage by a panel of primary human tumor specimens and normal non-tumor tissues. Linker sequences that were not efficiently cleaved by human tumor samples (for example, the linker shown as Linker 1 in the diagram below) were eliminated in the screening and those that were efficiently cleaved by human tumors but not cleaved by normal serum or tissues (for example, the linker shown as Linker 3 in the diagram below) were selected for incorporation into our INDUKINE molecules to confirm their activity *in vitro* and *in vivo*. We have selected linkers for our INDUKINE molecules with characteristics similar to those of Linker 3 in the table below.

Human Tissue Screening for Selection of Optimized Linker Candidates

		Bioactive cytokine released from INDUKINE upon incubation with human dissociated tissue			
Cleavage (% of positive control)		Linker 1	Linker 2	Linker 3	
-	Not cleaved	-	+/-	+	Tumors
+/-	<20%	-	+	+	
+	~ 20-40%	+/-	++	+++	
++	~ 40-60%	+/-	+	+++	
+++	~60-80%	+/-	++	++++	
++++	>80%	-	+	++	
		-	+/-	+	
		-	-	+/-	Healthy Tissue
		-	-	+/-	

We seek to protect aspects of our PREDATOR platform technology by obtaining patent protection in the United States and internationally. Currently, our patent portfolio for our PREDATOR platform technology includes two families of pending patent applications, which disclose and claim protease cleavable linkers and libraries of protease cleavable linkers, as well as polypeptides that contain such linkers, methods of making libraries and methods of screening libraries to identify linkers with desired properties. These patent families were recently filed and no patents have granted. For more information see "Intellectual Property."

INDUKINE Molecules

We have rationally engineered INDUKINE molecules to have four key characteristics that we believe provide our product candidates with a unique profile and potential advantages in clinical settings when compared to other cytokines currently approved or in development:

- Optimized Anti-tumor Activity:** The active portion of our INDUKINE molecules consists of a wild-type cytokine. We believe that delivery of a fully potent and functional cytokine molecule, as opposed to a mutein or cytokine with sequence alterations, into the TME will enable our product candidates to capture the full proinflammatory and immunomodulatory potential of cytokines and potentially result in optimal anti-tumor activity.

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- **Enhanced Tolerability:** In order to improve tolerability, our INDUKINE molecules are designed to be administered as inactive pro-drugs that employ a tailored, high affinity blockade to minimize off-target toxicity. We aim to prevent peripheral pathway activation, as well as target-mediated disposition in normal tissues, with the goal of minimizing potential toxicity.
- **Optimized Pharmaceutical Properties:** We design INDUKINE molecules to be stable in the bloodstream and periphery and to have a long serum half-life in order to achieve efficacy without requiring the frequent dosing that is a limiting requirement of approved recombinant cytokines, such as aldesleukin. Our design allows us to achieve high, biologically relevant tumor tissue exposure with our INDUKINE molecules. Once our molecules are cleaved within the tumor, the cytokine is released for either intratumoral target binding or rapid systemic clearance.
- **Conditional Activation:** Upon reaching the TME, INDUKINE molecules are activated via cleavage of our proprietary linkers by tumor-specific proteases which results in release of the cytokines in the tumor. We select our linkers to be specifically cleaved in the tumor and be stable in circulation and normal non-tumor tissues, with the goal enhancing the tolerability profile of our INDUKINE molecules.

Our Programs

WTX-124: Our IL-2 INDUKINE Molecule

Overview

Our lead product candidate, WTX-124, is a systemically delivered, conditionally activated IL-2 INDUKINE molecule that we are developing to minimize the severe toxicities observed with recombinant human IL-2, or rhIL-2, therapy and maximize clinical benefit when administered as monotherapy or in combination with immune checkpoint inhibitors in advanced or metastatic tumors. We believe that these properties will also allow WTX-124 to have potential applicability in indications beyond those for which rhIL-2 therapy is currently approved. Key features of WTX-124 include preservation of full IL-2 potency and function as observed in preclinical trials, high affinity blockade of IL2—IL2R interaction in systemic circulation and non-tumor tissues, half-life extension for optimal tumor exposure and conditional protease activation within the TME due to our proprietary linker.

IL-2 is a critical cytokine for immune-mediated killing of cancer cells whose mechanism of action includes stimulation of both innate and adaptive immune cells. IL-2 increases the proliferation and activation of T cells and NK cells, and induces the differentiation of CD8+ T cells into effector and memory cells. The IL-2 receptor, or IL-2R, is composed of three subunits named IL-2Ra (CD25), IL-2R β (CD122), and IL-2R γ (CD132). Binding to monomeric IL-2Ra does not induce signaling, while binding to the medium affinity dimeric receptor comprised of a complex of the β and γ subunits will induce signaling. The trimeric receptor composed of all three subunits is a high affinity receptor for IL-2, with binding affinity approximately 10 to 100-fold higher than the medium affinity receptor. Binding to the medium affinity dimeric IL-2R or the high affinity trimeric IL-2R activates the JAK/STAT, MAPK, and PI3K signaling pathways in target immune cells resulting in immune cell activation and proliferation.

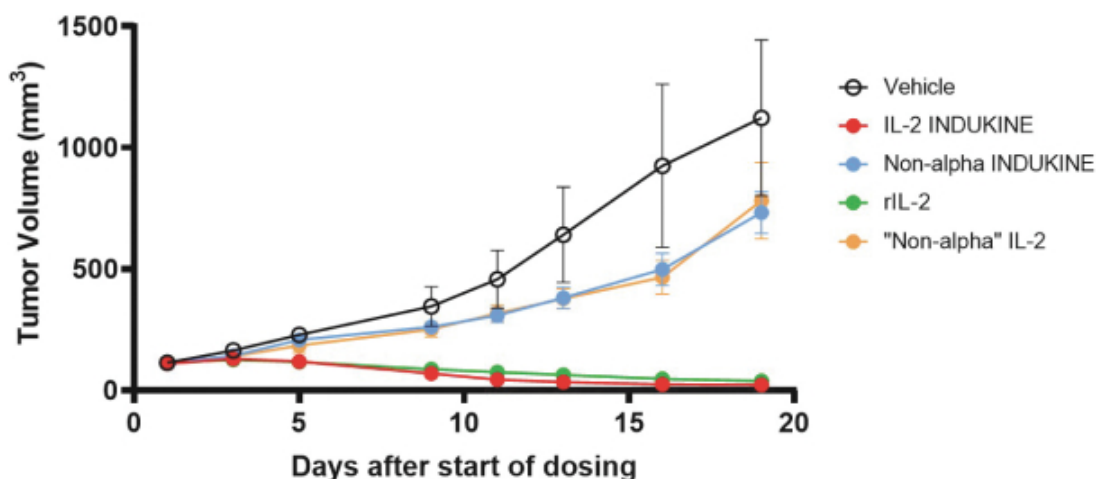
The medium affinity IL-2R β / γ is expressed on NK cells, monocytes, macrophages and resting CD4+ and CD8+ T cells, while the high affinity IL-2Ra/ β / γ is transiently induced on activated T and NK cells but is constitutively expressed on CD4+FoxP3+ regulatory T cells, or Tregs. Basal levels of IL-2 bind predominantly to high affinity IL-2Ra/ β / γ on Tregs to maintain immune homeostasis, but increased IL-2 production during an immune response results in levels of IL-2 that can activate both the medium and high affinity receptors, increasing the activation and proliferation of effector lymphocyte populations.

Numerous preclinical studies conducted by others have demonstrated that administration of IL-2 can be effective in eradicating tumors in mouse models. This concept was clinically validated with the approval of a rhIL-2 therapy (aldesleukin) for the treatment of RCC in 1992 and for the treatment of metastatic melanoma in 1998. Aldesleukin has demonstrated objective anti-tumor responses in about 15% of patients treated for RCC and metastatic melanoma. Unfortunately, high-dose rhIL-2 administration results in severe hypotension and vascular leak syndrome. These side effects limit the number of patients who can tolerate the recommended therapeutic regimen and achieve full clinical benefit from rhIL-2 therapy. It has been postulated that the observed toxicity of IL-2 is the result of IL-2 binding to the high affinity IL-2Ra/ β / γ on endothelial cells inducing vascular leak syndrome, and that the therapeutic efficacy of IL-2 is limited by activation of the high-affinity IL-2Ra/ β / γ on Tregs to induce the expansion of immunosuppressive

cells, which counteract anti-tumor immune responses. There are several companies developing next-generation IL-2 therapies designed to address these limitations by engineering molecules that bind only to the medium affinity receptor IL-2R β /g and with reduced binding to the high affinity receptor IL-2R α / β /g, in the hope of alleviating toxicities and reducing activation of Tregs. However, many of these molecules activate IL-2 β /g receptors in the periphery (due to lack of an IL-2R β /g blockade element) and do not minimize the IL-2 mediated toxicity resulting from IL-2R activation. The activity of these 'non-alpha' molecules is also attenuated in inducing newly primed T cell proliferation in the TME due to their reduced IL-2R α binding, which may limit their therapeutic window.

We believe that binding to the high affinity receptor IL-2R α / β /g in the TME may be necessary for stimulating optimal anti-tumor activity by directing the generation of effective immune memory and secondary responses, and that these immune responses are not hampered by the activity of full-agonist IL-2 on Tregs in the tumor. To test our hypothesis that a non-alpha IL-2 mutein would not provide anti-tumor activity equivalent to native IL-2, we constructed a non-alpha binding IL-2 mutein and furthermore incorporated that mutein into a non-alpha IL-2 INDUKINE molecule. This permitted us to compare directly, in the MC38 mouse tumor model, the anti-tumor activity of the non-alpha IL-2 mutein with that of rIL-2 and the anti-tumor activity of the non-alpha IL-2 INDUKINE molecule with that of a full-agonist IL-2 INDUKINE molecule. As shown in the figure below, neither the non-alpha IL-2 mutein nor the non-alpha IL-2 INDUKINE molecule produced any significant tumor reductions when administered at doses equal to doses of rIL-2 or a full agonist IL-2 INDUKINE, each of which resulted in almost complete regression of tumor issue over the treatment period.

"Non-Alpha" Hypothesis Not Supported in MC38 Tumor Model



We designed WTX-124 to address the limitations of next generation IL-2 therapies in development by blocking the binding of IL-2 to the IL-2R in the periphery, thereby inhibiting IL-2 signaling and potentially minimizing toxicities, while maintaining binding to the high affinity IL-2R α / β /g in tumors to ensure the full pharmacology of IL-2.

WTX-124 consists of wild-type human IL-2, an IL-2R β /g blockade element that eliminates binding to both high and medium affinity IL-2Rs expressed in normal tissues to neutralize IL-2 activity in the periphery, an antibody fragment that extends the circulation half-life and a proprietary linker for cleavage in the TME. As a prodrug, WTX-124 is conditionally activated in the TME to release an IL-2 cytokine to stimulate an anti-tumor immune response but with reduced peripheral toxicities. In preclinical studies, WTX-124 has exhibited favorable pharmacokinetic and tolerability profile with robust anti-tumor activity driven by the differentiation, activation and expansion of T effector and memory lymphocyte immune responses.

Market Opportunity

We are initially developing WTX-124 in tumor types known to be responsive to IL-2 and PD-1 targeting therapies including melanoma, RCC and non-small cell lung cancer. These are aggressive tumor types and many patients will eventually progress following treatment with standard of care. As a result, we believe there is a need for new

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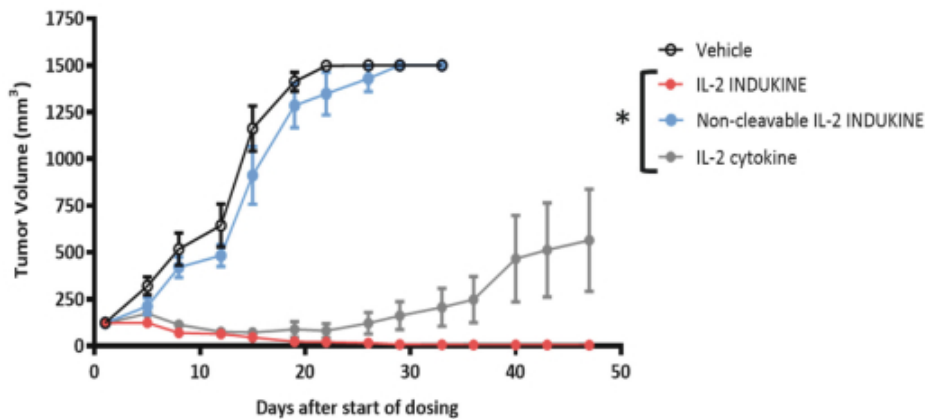
therapies to improve response and durability. If successfully developed and approved, we believe WTX-124 represents a promising therapeutic option for patients with life-threatening diseases with high unmet medical need, either as monotherapy or in combination with immune checkpoint inhibitors or current or potential future standard of care agents. PD-1 checkpoint inhibitors had nearly \$19.4 billion in worldwide sales in 2019 and are projected to have over \$36.0 billion in worldwide sales by 2024. We intend to develop WTX-124 as monotherapy and in combination with immune checkpoint inhibitors, and eventually in combination with other standard of care therapeutics across different lines of therapy.

WTX-124 Preclinical Results

We have conducted multiple preclinical studies to assess the pharmacological activity of WTX-124.

To test whether treatment with an IL-2 INDUKINE molecule could inhibit tumor growth, mice were implanted with MC38 tumors, and randomized into treatment groups when the tumors were between 100-150 mm³. Mice were then treated twice a week with titrated amounts of either a phosphate buffered solution, or PBS (acting as a vehicle), an IL-2 INDUKINE molecule tool compound, which is a test molecule that essentially replicates the activity of the study INDUKINE molecule and is used to investigate a biological hypothesis, or an IL-2 INDUKINE molecule engineered without the protease-cleavable linkers (uncleavable control). A total of four doses were administered. Treatment with the INDUKINE molecule was well tolerated by the mice, with no signs of body weight loss. As shown in the figure below, all animals treated with the IL-2 INDUKINE molecule had complete tumor regressions, while the mice treated with the non-cleavable control had no anti-tumor activity at any of the tested doses, demonstrating that the anti-tumor activity of the IL-2 INDUKINE molecule is dependent on enzymatic cleavage of its linkers. In addition, a cumulative equimolar dose of rhIL-2 cytokine was administered to a fourth group of mice twice per day, for 5 days on, 2 days' rest, 5 days on for a total of 20 doses. As shown in the figure below, we observed anti-tumor activity in these mice during the dosing period. However, in contrast to the INDUKINE molecule, many tumors regrew after dosing of the rhIL-2 cytokine ceased on day 12.

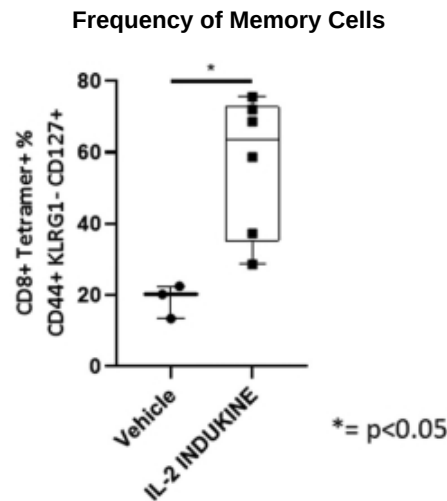
Anti-tumor Activity in MC38 Model



(*) Equivalent cumulative molar dose delivered over treatment period:
INDUKINE, two times per week for two weeks
rIL-2, two times per day for 10 days

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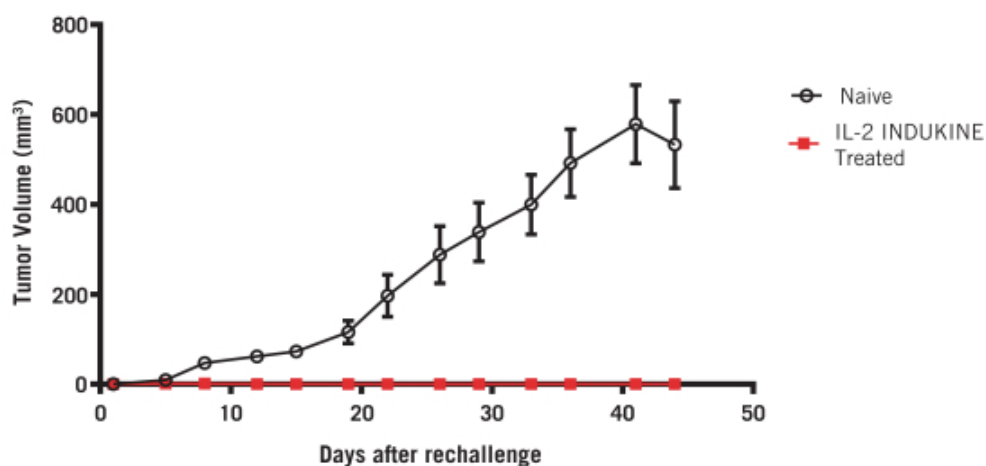
One hallmark of immunological rejection of a tumor is the development of protective memory against subsequent tumor rechallenge. To examine whether tumor rejection in animals treated with an IL-2 INDUKINE molecule resulted in immunological memory, the spleens from these animals were examined for the presence of tumor specific memory CD8+ T cells 40 days after the initial MC38 implantation. Tetramer staining was used to identify tumor specific CD8+ T cells, and those cells were examined for memory markers. As shown in the figure below, approximately 60% of the tetramer positive cells from the protected animals expressed the memory cell phenotype CD44+ KLRG1- CD127+, compared with only 20% of tetramer positive cells from control animals. This is consistent with our belief that treatment with an IL-2 INDUKINE molecule results in immune mediated tumor rejection that then translates into immunological memory.



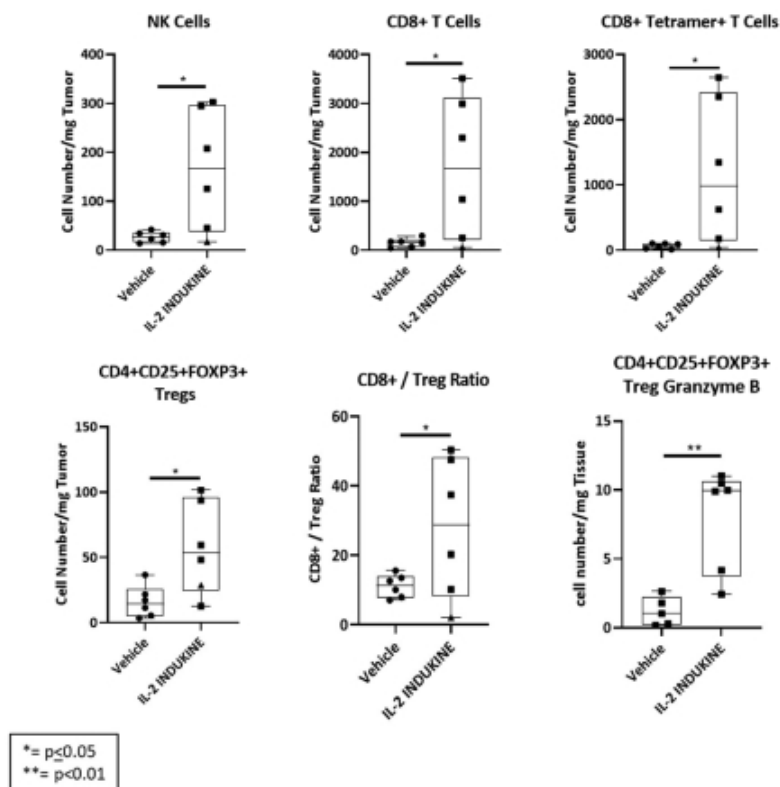
These results were statistically significant, with a p-value of less than 0.05. P-value is a conventional statistical method for measuring the statistical significance of study results. A p-value of 0.05 or less represents statistical significance, meaning there is a 1-in-20 or less statistical probability that the observed results occurred by chance.

While the phenotype of these splenocytes suggests the generation of tumor specific memory, the ultimate test of a memory response is protection against rechallenge. Therefore, mice that previously had complete MC38 tumor regressions following treatment with an IL-2 INDUKINE molecule were rechallenged by implanting more MC38 tumor cells 60 days after the initial implantation. Importantly, no treatment was administered during the rechallenge. As shown in the figure below, unlike naïve control animals who were also implanted with MC38 tumor cells, none of the animals previously treated with the IL-2 INDUKINE molecule developed tumors, suggesting that tumor rejection following prior IL-2 INDUKINE molecule treatment resulted in immunological memory and protection against subsequent tumor rechallenge.

Tumor Growth After Rechallenge

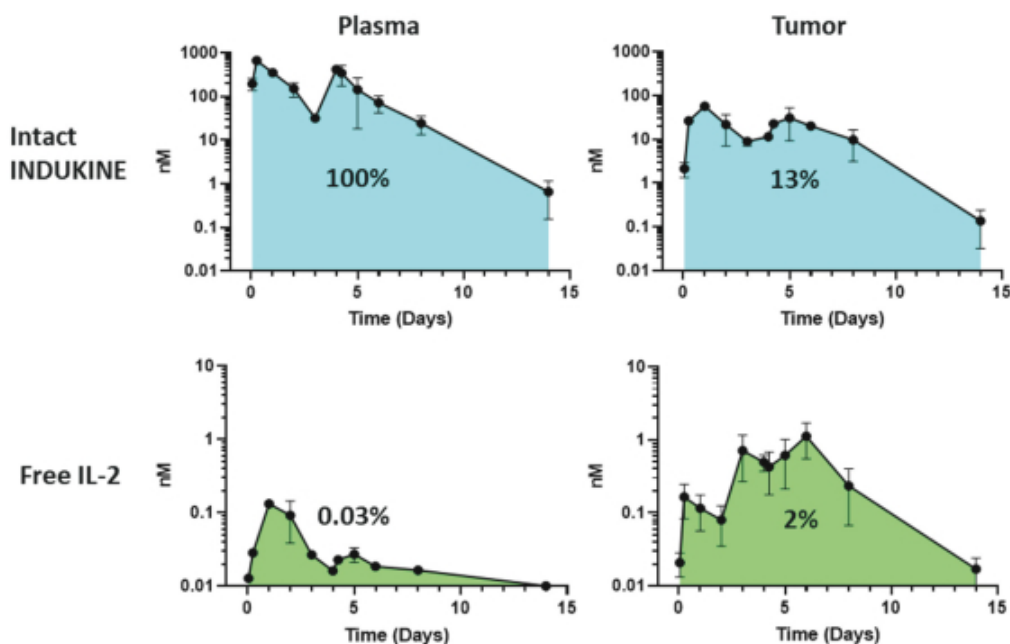


To better understand the mechanism by which the IL-2 INDUKINE molecule induces tumor regression, MC38 tumors from the mice treated with either PBS or the IL-2 INDUKINE molecule were harvested 24 hours after their second dose in the first week to collect tumor infiltrating lymphocytes that were subsequently analyzed by flow cytometry. Five days after the initial dose, we observed that treatment with the IL-2 INDUKINE molecule resulted in a large influx of immune cells, including NK cells, CD8+ T effector cells and tumor specific tetramer+ CD8+ T effector cells. While there was an increase in the number of Tregs (defined as CD4+CD25+FOXP3+ cells), the increase in CD8+ T cells far exceeded the increase in Tregs, resulting in a significant increase in the CD8+/Treg ratio. Additionally, treatment with the IL-2 INDUKINE molecule resulted in a subset of Tregs producing inflammatory cytokines such as Granzyme B, indicating that the Tregs that are expanded in tumors do not have a suppressive phenotype. Together, these data show that treatment with an IL-2 INDUKINE molecule increased immune cell tumor infiltration and activation in this model, thereby driving anti-tumor immunity.



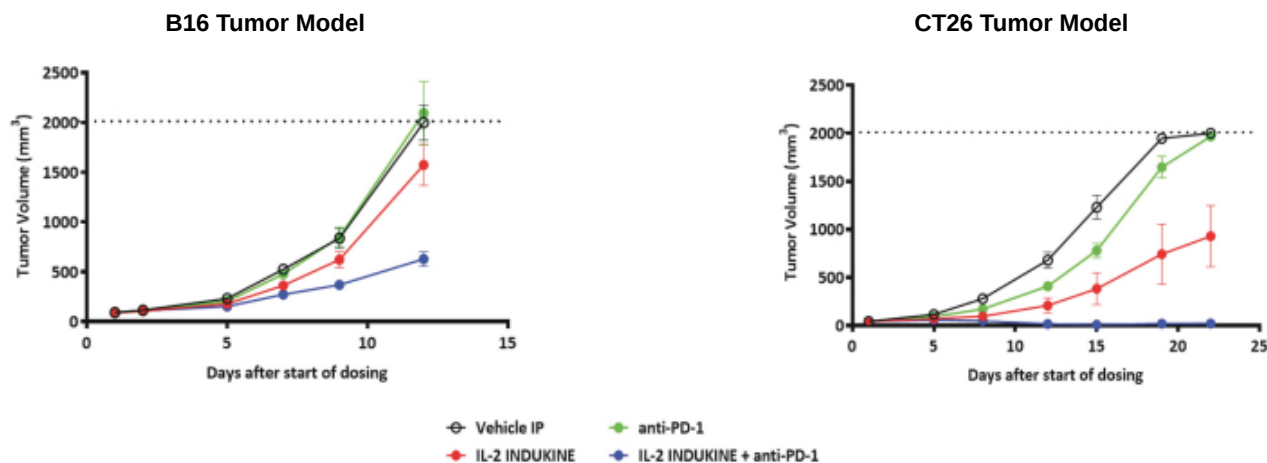
We use a conditionally activated, protease-cleavable linker in the IL-2 INDUKINE molecule to restrict the systemic activity of IL-2 while delivering IL-2 locally to the tumor. To test whether systemic dosing could result in localized delivery of IL-2 into the tumor, plasma and tumor samples were collected at various timepoints after dosing mice bearing MC38 tumors and analyzed for the presence of total, or intact, INDUKINE molecule as well as free IL-2 released due to activation of the INDUKINE molecule. As shown in the figure below, the exposure for the total INDUKINE molecule in plasma was approximately eight-fold higher than the exposure in the tumor, thus demonstrating favorable tumor tissue penetrance for the prodrug in this model. Low levels of free IL-2 were detected in the plasma, with 0.03% of the intact INDUKINE molecules in plasma processed to release free IL-2. In contrast, 2% of the total intact INDUKINE molecules in the tumor was processed to release IL-2. Furthermore, while the free IL-2 in the plasma reached maximum concentration, or C_{max}, at 24 hours post dosing, this exposure was transient. In contrast, the level of free IL-2 exposure in the tumor had a higher C_{max} and was sustained over time. This preferential activation of the INDUKINE molecule in the tumor results in an approximately 11-fold exposure of free IL-2 in tumors compared to the plasma. This suggests that tumor dependent processing drives the accumulation of IL-2 in the tumor following the systemic delivery of the IL-2 INDUKINE molecule.

INDUKINE Molecule is Preferentially Processed in Tumors



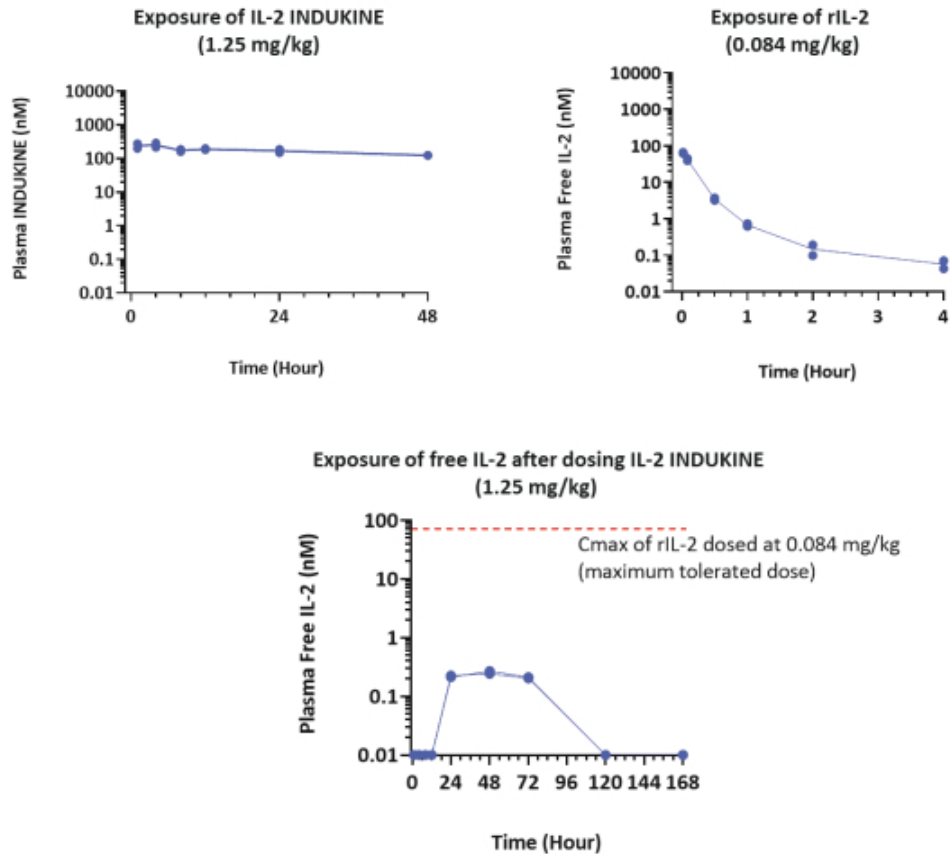
We have also tested our lead product candidate, WTX-124, in the MC38 mouse tumor model and observed, through dose-response studies, that antitumor activity of WTX-124 in this model is at least as potent as that of the IL-2 INDUKINE molecule tool compound described above.

We tested the activity of the IL-2 INDUKINE molecule in two additional mouse tumor models, B16 and CT26, both as a monotherapy and in combination with an anti-PD-1 therapy. In this study, the IL-2 INDUKINE molecule and the anti-PD-1 therapy were administered on the same schedule, with dosing twice per week for two weeks. Both models are refractory to anti-PD-1, and as expected resulted in no evidence of tumor control with anti-PD-1 alone, as shown in both panels of the figure below. In the B16 model, illustrated in the left panel of the figure below, there was little single-agent activity observed with either therapeutic agent alone, while tumor growth control was observed with the combination. In the CT26 model, shown on the right, the IL-2 INDUKINE molecule had modest anti-tumor activity; however the combination of the IL-2 INDUKINE molecule and anti-PD-1 therapy resulted in complete tumor regressions.



We have also administered our lead molecule, WTX-124, to NHPs in exploratory studies to determine the tolerability of WTX-124 and to measure the pharmacokinetic properties of both WTX-124 and IL-2 released from WTX-124. In the first study, we dosed animals with increasing amounts of WTX-124 from 0.05 mg/kg to 1.25mg/kg once per week for two weeks. Plasma exposure of WTX-124 (measured as area-under-the-curve, or AUC) at a dose of 1.25 mg/kg was more than 500 fold higher than plasma exposure of recombinant IL-2, or rIL-2, at a dose of 0.084 mg/kg, its maximum tolerated dose, confirming the INDUKINE molecule design achieved high systemic exposure of IL-2, as shown in the top panels of the figure below (left and right respectively). The mean half-life for WTX-124 after the first dose was approximately 57 hours, which was consistent across multiple dose levels. The plasma levels of free IL-2 released from WTX-124 were very low, with less than 0.01% of the plasma WTX-124 processed to release free IL-2, as shown in the bottom panel of the figure below. This confirms the stability of the molecule in circulation in the NHPs. Importantly, the C_{max} of circulating, free IL-2 that could be measured following WTX-124 treatment of NHPs was significantly lower than the C_{max} of rIL-2 at its maximum tolerated dose. In a subsequent study, doses of up to 2 mg/kg of WTX-124 were well tolerated by the animals.

Low Levels of Free IL-2 are Released in Non-Human Primates Following Systemic Administration of WTX-124



In addition to these studies completed to date, we plan to conduct additional *in vivo* and *in vitro* pharmacology and toxicology studies to support our planned submission to the FDA of an IND for WTX-124.

Clinical Development Plan for WTX-124

We have designed our clinical development strategy for WTX-124 with the goal of achieving rapid proof-of-concept in historically immunotherapy-sensitive tumor types, including melanoma and RCC, indications for which aldesleukin is approved. First, we intend to initiate a Phase 1/1b clinical trial of WTX-124 for the treatment of relapsed or refractory advanced or metastatic solid tumors as monotherapy or in combination with an immune checkpoint inhibitor. During the dose escalation phase of the trial, we expect to identify safe and pharmacodynamically active doses of WTX-124 for the respective dose escalation arms, following which we will open expansion arms for both monotherapy and in combination with checkpoint inhibitors or other standard of care therapy in advanced renal cell cancer and advanced cutaneous malignant melanoma.

The rationale for our clinical development strategy is as follows:

- **IL-2 has been shown to have single agent activity in some cancers.** Aldesleukin is approved for the treatment of metastatic RCC and melanoma. However, due to the toxicity associated with aldesleukin, which is noted in a black box warning, the drug is used infrequently. We believe, based on the mechanism of action of WTX-124, that it may be able to achieve higher intratumoral exposures of IL-2 than aldesleukin without systemic toxicity, leading to monotherapy anti-tumor immune responses in patients with historically immunotherapy-sensitive tumor types who have progressed on or subsequent to immune checkpoint

inhibitor therapy. Our preclinical data with WTX-124 show that it has single agent anti-tumor activity in mouse tumor models and was well-tolerated. WTX-124 was also well-tolerated in NHPs at doses greater than predicted to be required for anti-tumor activity based on modeling the mouse tumor data. Single agent activity with competitor IL-2 compounds has been limited, potentially affording an opportunity for us to pursue an expedited clinical development and regulatory strategy for WTX-124 if we can show positive single arm efficacy data in a relapsed or refractory tumor type with high unmet medical need.

- **IL-2 agonists and immune checkpoint inhibitors may act synergistically to enhance anti-tumor immune response.** Clinical results have shown that aldesleukin induces responses as a single agent in patients who progressed on immune checkpoint inhibitors. Our preclinical data with WTX-124 highlight the potential benefit of WTX-124 when combined with an anti-PD-1 antibody. These results suggest that combining novel IL-2 therapies with checkpoint inhibitors merits further evaluation as a regimen for treating cancer.

WTX-330: Our IL-12 INDUKINE Molecule

Overview

Our second product candidate, WTX-330, is a systemically delivered, conditionally activated IL-12 INDUKINE molecule that we are developing to minimize the severe toxicities observed with rhIL-12 therapy and maximize clinical benefit when administered as monotherapy or in combination with immune checkpoint inhibitors in relapsed or refractory advanced or metastatic solid tumors or lymphoma.

IL-12 is a potent, pleiotropic cytokine for immune-mediated killing of cancer cells, whose mechanism of action includes stimulation of both innate and adaptive immune responses. IL-12 is a heterodimeric cytokine (p70) containing two subunits (p35 and p40). A subset of antigen-presenting cells, such as DCs, produce IL-12 upon activation, during the antigen presentation process. Binding of IL-12 to the IL-12R expressed on multiple immune cell populations activates the JAK/STAT signaling pathway resulting in helper T cell differentiation, activation of cytotoxic NK and T cells, and inhibition or reprogramming of immunosuppressive cells such as tumor-associated macrophages or myeloid-derived suppressor cells. IL-12 also increases the expression of antigen-presentation machinery, which is necessary to initiate an immune response in tumors that have not naturally stimulated an anti-tumor immune response, also referred to as “cold” tumors. IL-12 induces the production of IFN γ , a potent proinflammatory mediator of the downstream activities of IL-12 signaling. IFN γ , in turn, increases the production of IL-12 by mature DCs aiding in their antigen presentation capacity and driving activation of effector T cells. Numerous studies conducted by others have demonstrated that IL-12 treatment has significant anti-tumor activity in a range of preclinical models, with the induction of a long-lasting anti-tumor immune memory.

Due to the robust anti-tumor activity seen in preclinical studies, there has been significant interest in developing rhIL-12 therapy for advanced solid tumors. In early clinical trials conducted by a third party, the use of systemically administered rhIL-12 produced evidence of clinical activity in several tumor types, including RCC, melanoma and non-Hodgkin's lymphoma. However, the systemic administration of rhIL-12 was shown to be toxic, resulting in the death of two patients in one Phase 2 trial and multiple hospitalizations. Additional trials at tolerated doses yielded modest clinical activity, potentially due to a lack of sufficient and durable exposure of rhIL-12 in the TME at lower doses.

Preclinical studies conducted by others support the hypothesis that localized delivery of IL-12 retains anti-tumor activity. The target cells for IL-12 are immune cells found within the TME and not lymphocytes in circulation. Intratumoral delivery of recombinant IL-12, or rIL-12, should increase exposure in the TME, activate tumor-specific immune cells, and induce a localized anti-tumor immune response which may ultimately result in systemic anti-tumor immunity while minimizing systemic toxicity. Therefore, methods for localized delivery of rhIL-12 may increase the clinical benefit in patients.

There are several companies developing next-generation IL-12 therapies designed to address the limitations of systemic rhIL-12 delivery using either intratumoral delivery approaches, such as plasmid, viral or mRNA based IL-12 gene delivery, or immunocytokines engineered with tumor targeting domains to increase exposure within the TME. While these approaches are promising in theory, IL-12 gene therapy approaches are hampered by technical limitations associated with low gene transfer efficiency and the challenge of intratumoral injections in a clinical setting. Meanwhile, the immunocytokine approach is limited by the selection of the appropriate tumor targeting domain to achieve selective accumulation of the molecule in the TME following systemic delivery. Additionally, the

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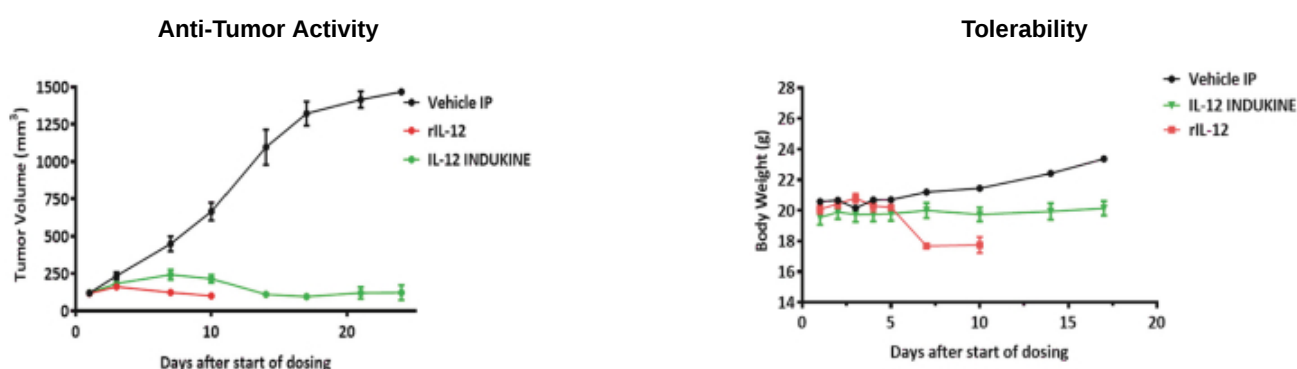
immunocytokines remain active while in circulation following systemic delivery, which may result in toxicity similar to wild-type IL-12 cytokine.

WTX-330 is designed to improve the pharmacological properties of IL-12 and require less frequent systemic administration. The prodrug is inactive while circulating in the periphery and is activated preferentially in the TME to release an IL-12 cytokine. We believe activation of WTX-330 in the TME has the potential to stimulate a robust anti-tumor immune response but without the peripheral toxicities that have been associated with systemic administration of rIL-12 therapy. Key features of WTX-330 include high affinity blockade of IL-12 – IL-12R interaction in systemic circulation and non-tumor tissues, half-life extension for optimal tumor exposure and conditional protease activation due to our proprietary linker. In preclinical studies, we have observed high anti-tumor activity of an IL-12 INDUKINE surrogate molecule across a broad range of preclinical tumor models and that it has a favorable pharmacokinetic and tolerability profile.

WTX-330 Preclinical Results

We have conducted multiple preclinical studies to assess the pharmacological activity of WTX-330.

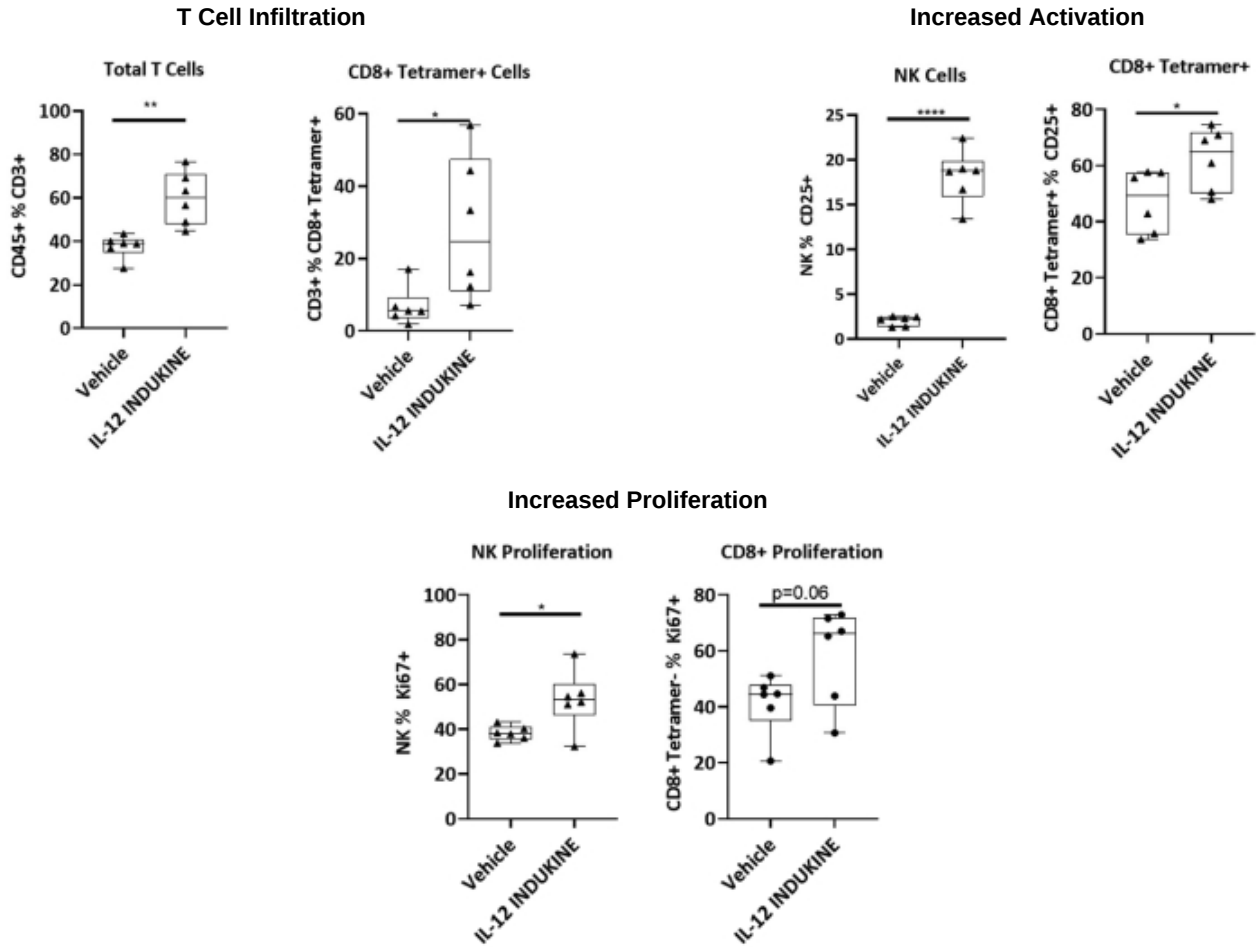
Since human IL-12 does not bind to mouse IL-12R, we tested a surrogate IL-12 INDUKINE molecule (consisting of a chimeric IL-12 molecule composed of mouse p35 and human p40) which is otherwise identical to WTX-330 for anti-tumor activity in the MC38 mouse tumor model at various doses ranging from 10 μ g to 172 μ g, administered twice per week for 2 weeks, and compared with equivalent molar doses of mouse rIL-12 administered twice daily for 10 days. The tolerability of the treatment in the mice was assessed by animal weight loss or death. As shown in the left panel of the figure below, we observed that the INDUKINE molecule exhibited significant anti-tumor activity, with complete tumor regressions observed in many of the animals treated with the high dose of IL-12 INDUKINE. Mice dosed with molar equivalent IL-12 delivered as free cytokine (rIL-12) also showed early signs of anti-tumor activity; however, this treatment was not tolerated. As shown in the right panel of the figure below, the mice treated with the molar equivalent dose of IL-12 experienced weight loss or died, while those receiving the INDUKINE molecule showed no evidence of weight loss or death. As of day 10, we discontinued dosing of rIL-12 due to lack of tolerability. These data suggest that the INDUKINE molecule design allows systemic delivery of IL-12 with minimal systemic toxicities while retaining the anti-tumor activity once the molecule is activated in the TME.



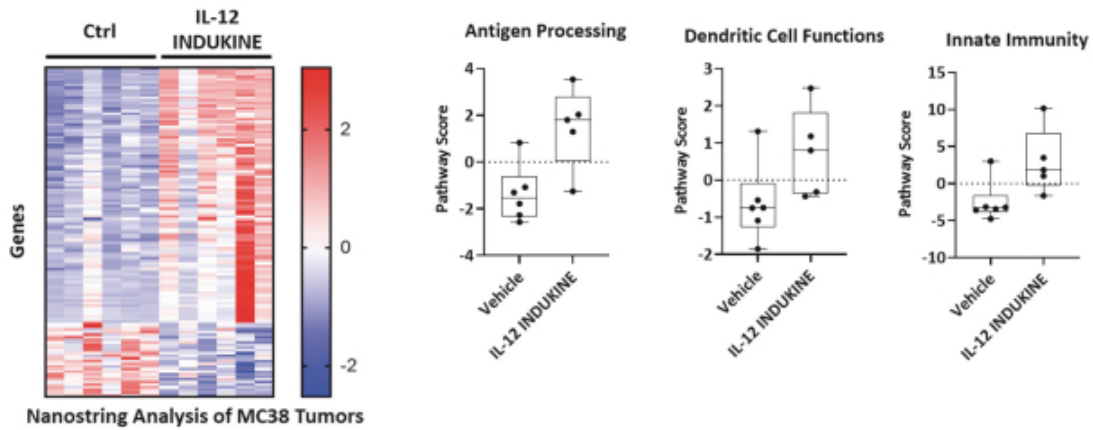
Equivalent cumulative molar dose delivered over treatment period:
INDUKINE, two times per week for two weeks
RIL-12, two times per day for 10 days

To assess the extent of immune activation in the TME, we harvested MC38 tumors from vehicle-treated mice or mice treated with the IL-12 INDUKINE molecule. Tissues were collected 24 hours after the second dose, and lymphocytes were collected and profiled by flow cytometry. Evidence for IL-12 induced T cell infiltration in tumors was assayed by measuring the total number of lymphocytes in the tumor, activation of immune cells was determined by measuring the number of effector lymphocytes expressing the activation marker CD25+, and lymphocyte proliferation was determined by assaying for the number of cells expressing the proliferation marker Ki67. As shown in the figure below, the IL-12 INDUKINE molecule showed statistically significant increases in T cell infiltration and activation

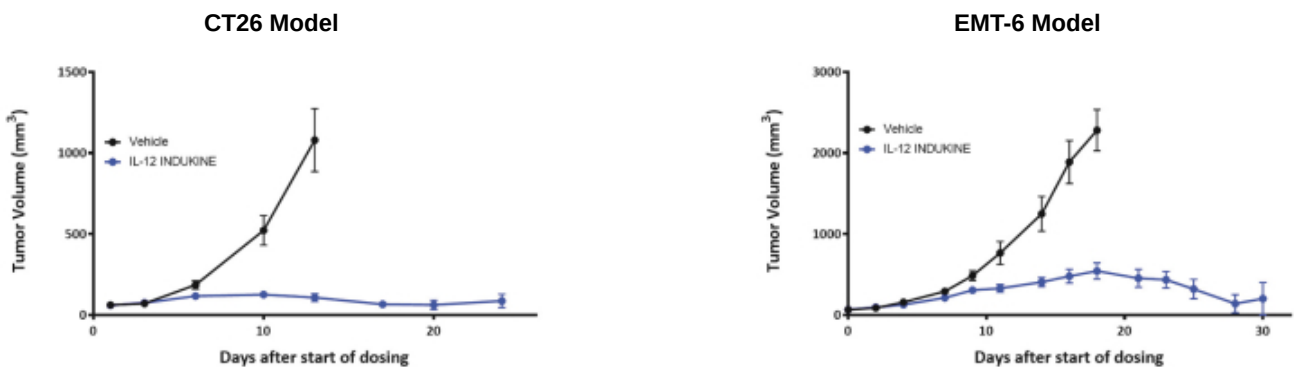
and proliferation of NK cells and T cells. These preclinical data showed that the INDUKINE molecule design was able to deliver IL-12 in the TME to drive anti-tumor immune responses in this model.



To determine changes in gene expression following treatment with the INDUKINE molecule, we subjected the same tumor material to Nanostring analysis using mRNA extracted from MC38 tumors from animals treated with either the vehicle or IL-12 INDUKINE molecule. Nanostring analysis allows for the rapid detection of up or down regulated genes and uses this information to assign a score to the activity of relevant signaling pathways. A comparison of the gene expression changes in tumors isolated from mice treated with the INDUKINE molecule or vehicle control is shown in the heat-map in the figure below. The analysis demonstrated that genes involved in antigen processing and DC functions, as well as genes in the innate immune response pathway, were strongly upregulated in tumors from the animals treated with IL-12 INDUKINE molecule. Together, these data show that treatment with an IL-12 INDUKINE molecule increased immune cell tumor infiltration and activation, innate immune responses and antigen presentation, thereby driving anti-tumor immunity in this model.



We also tested the IL-12 INDUKINE molecule in two additional syngeneic models, CT26 and EMT6. Both of these models are less immunogenic and are refractory to checkpoint inhibitors. As shown in the figures below, treatment with the IL-12 INDUKINE molecule resulted in tumor regressions in both of these models, suggesting that delivery of IL-12 has the potential to stimulate activity in cold tumors. In addition, immune profiling of tumor infiltrating lymphocytes, or TILs, from animals treated with the IL-12 INDUKINE in the CT26 model also showed antigen-presenting cell activation, TIL infiltration/activation and increased expression of peptide processing and antigen presentation genes.



We have also administered WTX-330 to NHPs in an exploratory study to determine the tolerability of WTX-330 and to measure the pharmacokinetic properties of both WTX-330 and IL-12 released from WTX-330. We dosed animals with increasing amounts of WTX-330 from 0.01 mg/kg to 10 mg/kg once per week for two weeks. The mean half-life for WTX-330 after the first dose was approximately 50 hours, across multiple dose levels. The plasma levels of free IL-12 released from WTX-330 were very low, with less than 0.1% of the plasma WTX-330 processed to release free IL-12. This confirmed the stability of the molecule in circulation in the NHPs.

WTX-330 was well tolerated in monkeys at exposures greater than predicted exposure required for anti-tumor activity based on modeling from mouse studies.

In addition to these studies completed to date, we plan to conduct additional *in vivo* and *in vitro* pharmacology and toxicology studies to support our planned submission to the FDA of an IND for WTX-330.

Clinical Development Plan for WTX-330

We plan to submit an IND with the FDA in the first half of 2022 to initiate a Phase 1/1b clinical trial of WTX-330 for the treatment of immunotherapy resistant advanced or metastatic solid tumors or lymphoma, followed by

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expansion arms in tumors that are relapsed or refractory tumors following treatment with checkpoint inhibitors or tumors for which checkpoint inhibitors are not approved. In this Phase 1/1b trial, we plan to evaluate safety and tolerability, pharmacokinetics, biomarker changes and preliminary signs of anti-tumor activity. We believe the administration of WTX-330 to patients with relapsed or refractory advanced or metastatic solid tumors or lymphoma, in particular those who are resistant to checkpoint inhibitors or for whom checkpoint inhibitors are not indicated, could demonstrate clinical benefit as monotherapy, with the potential for us to pursue an expedited clinical development and regulatory strategy if we are able to show positive single arm efficacy data in a relapsed or refractory tumor type with high unmet medical need.

WTX-613: Our IFN- α INDUKINE Molecule

Overview

WTX-613 is a systemically delivered, conditionally activated IFN- α INDUKINE molecule that we are developing to minimize the severe toxicities that have been observed with rhIFN- α therapy and maximize clinical benefit when administered as monotherapy or in combination with checkpoint inhibitors or other standard of care therapy.

IFN- α is a member of the type-I IFN family and a proinflammatory cytokine that exerts dual mechanisms of inhibiting tumor cell growth through both cytotoxic effects directly on tumor cells as well as driving anti-tumor immune responses. IFN- α binds and signals through a heterodimeric receptor formed by the subunits IFNAR1 and IFNAR2, resulting in the phosphorylation and activation of the JAK/STATs pathway, as well as activation of the PI3K, NF κ B and MAPK pathways. While IFN- α can inhibit proliferation and induce direct cell apoptosis of some cancer cell types, this mechanism by itself is unlikely to be sufficient to fully control tumor growth. The additional ability of IFN- α to activate and engage different cells of the immune system makes IFN- α a potentially effective anti-tumor agent. IFN- α activation of the immune response can occur directly by engagement of IFNARs on immune cells or indirectly by the induction of chemokines that attract immune cells to the tumor site. IFN- α can activate NK cells, enhance their ability to kill and increase their production of IFN- γ . Furthermore, it can increase macrophage activation and support differentiation and activation of DCs. Lastly, IFN- α can have a direct effect on B lymphocytes as well as T lymphocytes where IFN- α favors the differentiation of naive CD4+ T cells into helper T cells and directly activates CD8+ T cells, augmenting their IFN- γ production and survival.

IFN- α was one of the first cytokines clinically tested as a therapy for patients with cancer. Encouraging clinical benefit, although limited, resulted in regulatory approvals for the treatment of several hematological malignancies and solid tumors, such as chronic myelogenous leukemia, lymphoma and malignant melanoma. Widespread use of IFN- α for hematologic and oncologic indications has unfortunately been hampered by adverse events linked to the on-target, off-tumor activity of the native or pegylated formulations of the molecule and its use in clinical practice has been supplanted by other therapies. In our preclinical studies, we observed the potential benefit of IFN- α treatment in syngeneic mouse tumor models using colon, melanoma and breast tumor cell lines and the superior response obtained by the INDUKINE molecule format when compared to the dosing of recombinant cytokine.

We designed WTX-613 to improve the pharmacological properties of IFN- α to support less frequent systemic administration and potentially enhance its therapeutic index compared to current IFN- α based therapies. WTX-613 is inactive in the periphery and is activated preferentially in the TME to release wild-type IFN- α in the tumor and potentially stimulate an anti-tumor immune response without the peripheral toxicities associated with systemic administration of approved rIFN- α therapy. Key features of WTX-613 include high efficiency blockade of IFN α – IFNR interaction in systemic circulation and non-tumor tissues, half-life extension for optimal tumor exposure and proprietary conditional protease activation. In preclinical studies, an IFN- α INDUKINE surrogate molecule has exhibited robust anti-tumor activity mediated through stimulation of a type I interferon immune response with favorable pharmacokinetics and tolerability.

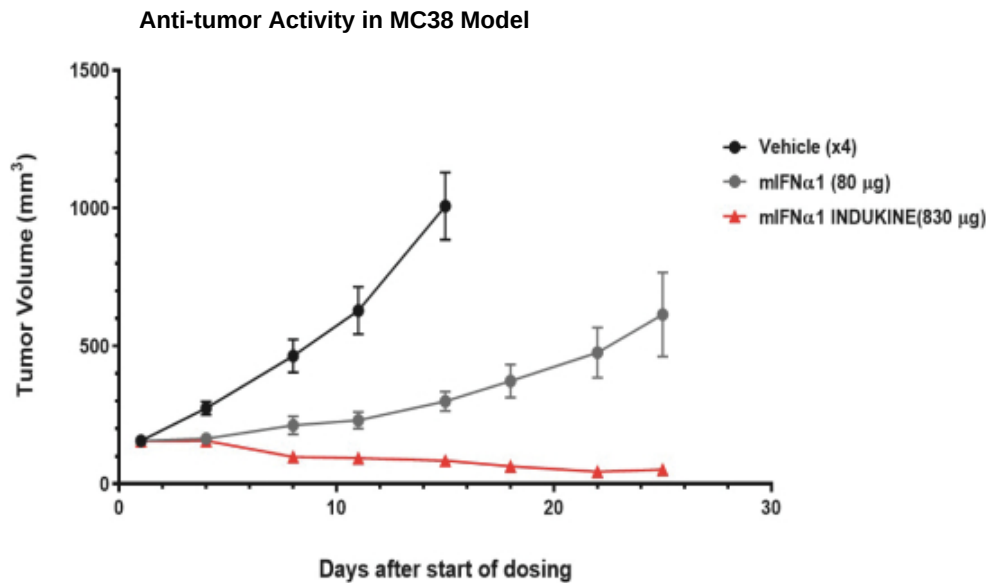
WTX-613 Preclinical Results

We have conducted multiple preclinical studies to assess the pharmacological activity of WTX-613.

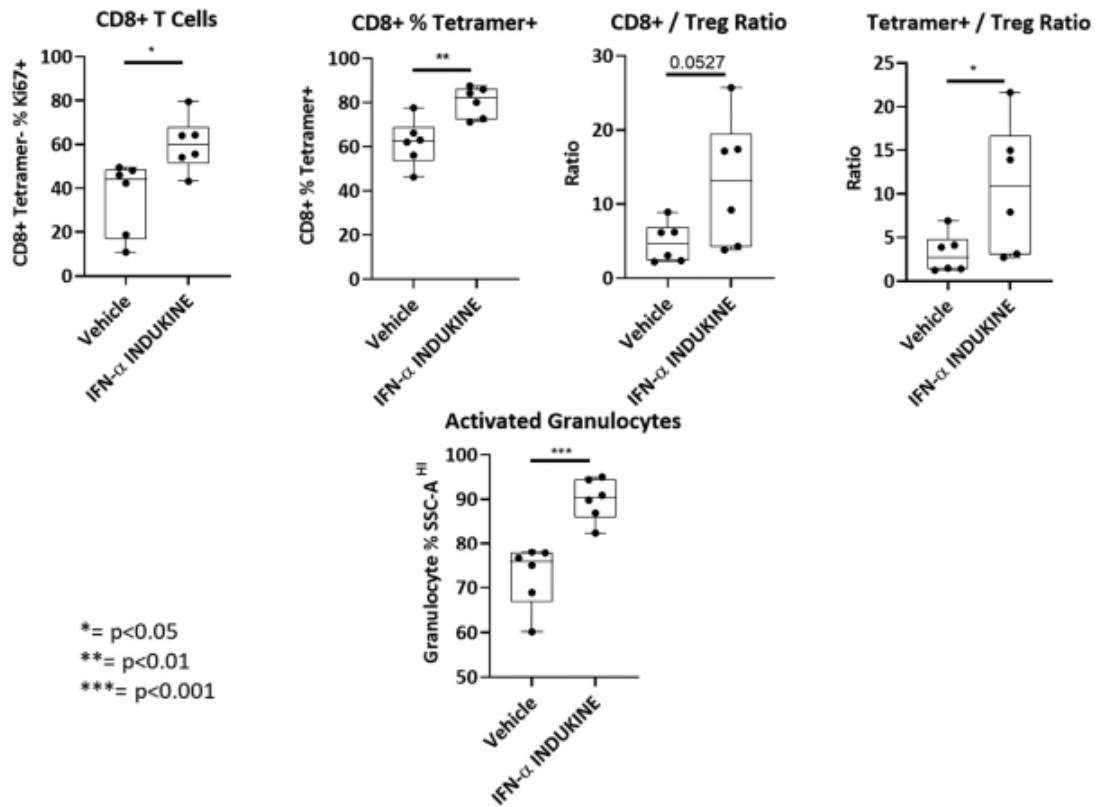
The cytokine domain of WTX-613 consists of human IFN- α 2b, which does not bind to the mouse IFNR. As a result, laboratory mice cannot be used to study the pharmacology of WTX-613. Accordingly, we have utilized a surrogate IFN- α INDUKINE molecule consisting of mouse IFN- α which is otherwise identical to WTX-613, to assess its pharmacological properties. To assess anti-tumor activity, we treated MC38 mice twice each week with vehicle or the

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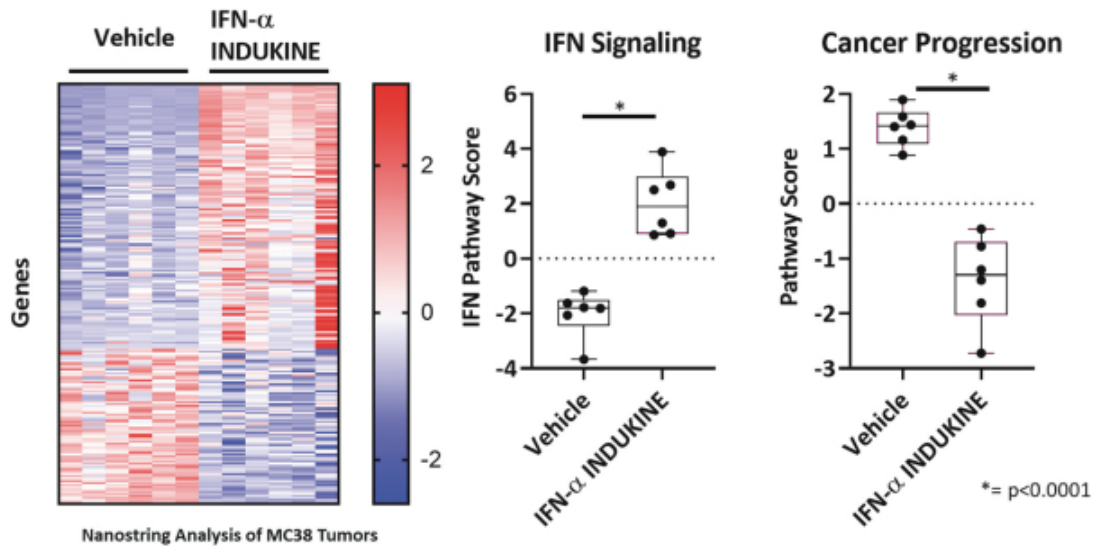
IFN- α INDUKINE molecule at a dose of 830 μg . A total of six doses were administered. In addition, an 80 μg dose of recombinant mouse IFN- α 1, or mIFN- α 1, was administered to a third group of mice twice per day, for 5 days on, 2 days' rest, 5 days on for a total of 20 doses. This 80 μg dose of mIFN- α 1 was equimolar to the dose of the IFN- α INDUKINE molecule. As shown in the figure below, animals treated with the IFN- α INDUKINE molecule displayed long-lasting tumor growth control resulting in durable tumor stasis. Overall anti-tumor activity of mIFN- α 1 was modest, even though the treatment initially provided some tumor growth control. Both treatments were well tolerated at these dose levels with no signs of body weight loss or premature death. These data suggest that the IFN- α INDUKINE molecule could be dosed less frequently and with lower molar amount than mIFN- α 1 while still maintaining greater anti-tumor activity and acceptable tolerability.



To better understand the mechanism by which the IFN- α INDUKINE molecule treatment induced tumor regression, MC38 tumors from animals treated with either vehicle or the IFN- α INDUKINE molecule were harvested 24 hours after their second dose in the first week, and tumor infiltrating lymphocytes were collected and analyzed by flow cytometry. As shown in the figure below, within five days after the initial dose, treatment with the IFN- α INDUKINE molecule resulted in a large influx and activation of immune cells, specifically CD8⁺ T effector cells and tumor specific tetramer⁺ CD8⁺ T effector cells which resulted in a significant increase in the CD8⁺/Treg ratio. Furthermore, granulocytes were strongly activated following treatment with the IFN- α INDUKINE molecule, providing evidence of induction of a pro-inflammatory phenotype in the tumors.



To determine changes in gene expression following treatment with the INDUKINE molecule, we subjected the same tumor material to Nanostring analysis using mRNA extracted from MC38 tumors isolated from animals treated with either vehicle or the IFN- α INDUKINE molecule. A comparison of the gene expression changes in tumors isolated from mice treated with the INDUKINE molecule or vehicle control is shown in the heat-map in the figure below. We observed that genes in the IFN pathway were strongly upregulated, while genes representing cancer progression were downregulated. Together, these data demonstrate that treatment with an IFN- α INDUKINE molecule increased immune cell tumor infiltration and activation, thereby driving anti-tumor immunity in this model.



In addition to these studies completed to date, we plan to conduct additional *in vivo* and *in vitro* pharmacology and toxicology studies to support our planned submission to the FDA of an IND for WTX-330.

Clinical Development Plan for WTX-613

We plan to submit an IND to the FDA in the first half of 2023 for a clinical trial of WTX-613, which we anticipate will evaluate safety and tolerability, pharmacokinetics, biomarker changes and preliminary signs of anti-tumor activity.

Our Early Stage Programs

In addition to IL-2, IL-12 and IFN- α , we are also applying our novel engineering approach to other targets. We believe that additional pro-inflammatory cytokines have the potential to empower the immune system in its fight against cancer. The most efficacious immune responses to tumors require a coordinated activation of both the innate and adaptive immune responses. Cytokines are diverse in the nature and extent of their effect, with some having a more direct impact on the innate immune system and others favoring or aiding the activation of the adaptive immune system.

Our goal is to better understand how the localized tumor delivery of these cytokines using our INDUKINE molecules might contribute to control tumor progression while reducing the toxicity that in many cases accompany the systemic delivery of these cytokines.

Competition

The pharmaceutical industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary drugs. We face potential competition from many different sources, including major pharmaceutical, specialty pharmaceutical and biotechnology companies, academic institutions, governmental agencies and public and private research institutions. Any product candidates that we successfully develop and commercialize will compete with existing treatments and new treatments that may become available in the future.

We compete with other companies working to develop immunotherapies for the treatment of cancer including divisions of large pharmaceutical and biotechnology companies of various sizes. These companies are developing cytokines as immunotherapies using different modalities, including monoclonal antibodies, cell therapies, oncolytic viruses and vaccines.

Our lead product candidate, WTX-124, if approved, may face competition from other IL-2 based cancer therapies. Proleukin (aldesleukin) has been approved and is marketed for the treatment of metastatic RCC and melanoma. In addition, we are aware of numerous clinical and preclinical IL-2 programs using different platforms being developed for oncology indications, including programs from Alkermes, BioNTech, Medicenna, Nektar Therapeutics (Bristol-Myers Squibb), Neoleukin Therapeutics, Roche, Synthorx (Sanofi) and Xilio Therapeutics.

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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 pre-clinical development for oncology indications, including programs from DragonFly Therapeutics, Juno Therapeutics (Bristol-Myers Squibb), Oncorus, Turnstone Biologics and Oncosec.

If approved, WTX-613 may face competition from other IFN- α cancer therapies. Intron-A, a recombinant IFN- α 2b molecule marketed by Merck, has been approved by the FDA for the treatment of several forms of cancer, including specific types of leukemia and lymphoma, and we are aware of other IFN- α programs targeting the treatment of cancer in development by Immunomedics, International Center for Genetic Engineering and Biotechnology (ICGEB) and Takeda. Roferon A, a recombinant IFN- α 2a molecule developed and marketed by Roche for the treatment of specific types of leukemia, was discontinued globally in 2020.

We are developing WTX-124, WTX-330 and WTX-613 as potential monotherapies in relapsed or refractory tumor types or in combination with checkpoint inhibitors or other standard of care therapies in advanced or metastatic malignancies with high unmet medical need. Standard of care therapies include chemotherapy, targeted therapy, and more recently, immunotherapies, including monoclonal antibodies and bispecific formats, antibody drug conjugates, adoptive cellular therapies, and cytokines. In addition, there are numerous investigational agents in clinical development. Combining agents to improve patient outcomes and prevent emergence of resistance has become the norm for treatment of cancer.

Many of our competitors, either alone or with their collaboration partners, have significantly greater financial resources and expertise in research and development, preclinical testing, clinical trials, manufacturing and marketing than we do. Future collaborations and mergers and acquisitions may result in further resource concentration among a smaller number of competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors will also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and subject registration for clinical trials, as well as in acquiring technologies complementary to, or that may be necessary for, our programs.

Our commercial potential could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market or make our development more complicated. The key competitive factors affecting the success of all of our programs are likely to be efficacy, safety and convenience.

Manufacturing

To date, we have produced limited quantities of our product candidates at our own facilities for preclinical evaluation. We do not own manufacturing facilities capable producing drug product at for clinical trials or at clinical scale. We must manufacture drug product for clinical trial use in compliance with current Good Manufacturing Practices, or cGMPs, or similar foreign standards. The cGMP regulations include requirements relating to organization of personnel, buildings and facilities, equipment, control of components and drug product containers and closures, production and process controls, packaging and labeling controls, holding and distribution, laboratory controls, records and reports, and returned or salvaged products. We do not have and we do not currently plan to acquire or develop the facilities or capabilities to manufacture cGMP drug substance or filled drug product for use in human clinical trials. Going forward, we will rely on third-party contract manufacturers to manufacture some of our preclinical product candidate supplies and will rely on third-party contract manufacturers to manufacture all of our clinical trial product supplies. We will also contract with additional third parties for the filling, labeling, packaging, storage and distribution of our product candidates investigational drug products.

The manufacturing facilities for our product candidates must meet cGMP requirements and FDA satisfaction before any product is approved and we can manufacture commercial products. Our third-party manufacturers will also be subject to periodic inspections of facilities by the FDA and other authorities, including procedures and operations used in the testing and manufacture of our products to assess our compliance with applicable regulations.

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We have entered into a contract manufacturing services agreement with Lonza Biologics, or Lonza, pursuant to which we agreed to retain their services for 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. We have entered into a contract manufacturing services agreement with Catalent for cell line development and manufacturing of our third program WTX-613. We have entered into a contract manufacturing services agreement with Patheon Manufacturing Services, or Patheon, pursuant to which we agreed to retain their services for drug product manufacturing process development and to manufacture clinical supply of WTX-124 and WTX-330 vialled drug product to cGMP specifications. To support the manufacture of clinical vialled drug product, Lonza will conduct substantial analytical testing of WTX-124 and WTX-330 vialled drug product. If Lonza or Patheon are unable to supply us with sufficient preclinical and/or 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 third-party contract manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements or capacity could be limited at each of the qualified replacements. 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 planned combination clinical trials of WTX-124 and WTX-330 and WTX-613 with immune checkpoint inhibitors, we will need to procure supply of the immune checkpoint inhibitors 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.

Commercialization Plan

We intend to retain significant development and commercial rights to our product candidates and, if marketing approval is obtained, to commercialize our product candidates on our own, or potentially with a partner, in the United States and other major pharmaceutical markets. We currently have no sales, marketing or commercial product distribution capabilities and have no experience as a company commercializing products. We intend to build the necessary infrastructure and capabilities over time for the United States, and potentially other regions, following further advancement of our product candidates. Clinical data, the size of the addressable patient population, the size of the commercial infrastructure and manufacturing needs may all influence or alter our commercialization plans.

Intellectual Property

Our intellectual property is critical to our business and we strive to protect it, including by seeking to obtain and maintaining patent protection in the United States and internationally to cover our product candidates, their methods of use and processes for their manufacture and any other inventions that are commercially important to the development of our business. We also rely on trade secrets and proprietary know-how to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our patent portfolio includes patents and patent applications with composition of matter and method of use claims with respect to our product candidates, WTX-124, WTX-330 and WTX-613, and claims directed to our PREDATOR platform technology. For our product candidates, we will, in general, initially pursue patent protection covering compositions of matter and methods of use. Throughout the development of our product candidates, we will seek to identify additional opportunities for obtaining patent protection that would potentially enhance commercial success, including through additional methods of use, processes for manufacture, formulation and dosing regimen-related claims.

Our commercial success depends in part on our ability to obtain and maintain proprietary protection for our current and future product candidates, platform technologies, novel discoveries, product development technologies and know-how, to operate without infringing on the proprietary rights of others and to prevent others from infringing our proprietary rights. We seek to protect our proprietary position by, among other methods, filing or in-licensing U.S. and foreign patents and patent applications related to technology, inventions and improvements that are important to the development and implementation of our business. We also rely on or may rely in the future on trademarks,

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trade secrets, copyright protection, know-how, continuing technological innovation and confidential information to develop and maintain our proprietary position. For the product candidates we develop and plan to commercialize, as a normal course of business, we have been granted and intend to continue to pursue composition and method of manufacture and use, including therapeutic use patents, as well as novel indications for our product candidates. We also have obtained and will continue to seek patent protection with respect to novel discoveries. We have sought and plan to continue to seek patent protection, either alone or jointly with our collaborators, as our agreements may dictate.

In some instances, we submit patent applications directly with the USPTO as provisional patent applications. Provisional applications for patents were designed to provide a lower-cost first patent filing in the United States. Corresponding non-provisional patent applications must be filed not later than 12 months after the provisional application filing date. The corresponding non-provisional application benefits in that the priority date(s) of the patent application is/are the earlier provisional application filing date(s), and the patent term of the finally issued patent is calculated from the later non-provisional application filing date. This system allows us to obtain an early priority date, add material to the patent application(s) during the priority year, obtain a later start to the patent term and to delay prosecution costs, which may be useful in the event that we decide not to pursue examination in an application. While we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage.

We file U.S. non-provisional applications and Patent Cooperation Treaty, or PCT, applications that claim the benefit of the priority date of earlier filed provisional applications, when applicable. The PCT system allows a single application to be filed within 12 months of the original priority date of the patent application, and to designate all of the 153 PCT member states in which national patent applications can later be pursued based on the international patent application filed under the PCT. The PCT searching authority performs a patentability search and issues a non-binding patentability opinion which can be used to evaluate the chances of success for the national applications in foreign countries prior to having to incur the filing fees. Although a PCT application does not issue as a patent, it allows the applicant to seek protection in any of the member states through national-phase applications.

At the end of the period of two and a half years from the first priority date of the patent application, separate patent applications can be pursued in any of the PCT member states either by direct national filing or, in some cases by filing through a regional patent organization, such as the European Patent Organization. The PCT system delays expenses, allows a limited evaluation of the chances of success for national/regional patent applications and enables substantial savings where applications are abandoned within the first two and a half years of filing.

For all patent applications, we determine claiming strategy on a case-by-case basis. Advice of counsel and our business model and needs are always considered. We file patent applications containing claims for protection of all useful applications of our proprietary technologies and any products, as well as all new applications and/or uses we discover for existing technologies and products, assuming these are strategically valuable. We continuously reassess the number and type of patent applications, as well as the existing patent claims to ensure that maximum coverage and value are obtained for our processes and compositions, given existing patent office rules and regulations. Further, claims may be modified during patent prosecution to meet our intellectual property and business needs.

We recognize that the ability to obtain patent protection and the degree of such protection depends on a number of factors, including the extent of the prior art, the novelty and non-obviousness of the invention and the ability to satisfy the enablement requirement of the patent laws. The patent positions of therapeutic polypeptide companies like ours are generally uncertain and involve complex legal, scientific and factual questions. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted or further altered even after patent issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our future product candidates or for our platform technology. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

Regardless of the coverage we seek under our existing patent applications, there is always a risk that an alteration to the product or process may provide sufficient basis for a competitor to avoid infringement claims. In addition, the

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coverage claimed in a patent application can be significantly reduced before a patent is issued, and courts can reinterpret patent scope after issuance. Moreover, many jurisdictions, including the United States, permit third parties to challenge allowed or issued patents in administrative proceedings, which may result in further narrowing or even cancellation of patent claims. Moreover, we cannot provide any assurance that any patents will be issued from our pending or any future applications or that any current or future issued patents will adequately protect our products.

Our patent portfolio, including patents and patent applications that we own and that we license from Harpoon Therapeutics, Inc., or Harpoon, comprises eight patent families that are in various stages of the patent application filing and examination process in various jurisdictions worldwide, and include claims to our product candidates and claims directed to our PREDATOR platform technology for potential products and developments. The patents and patent applications that we own include two issued patents in the United States, six pending U.S. provisional or non-provisional patent applications, two pending international patent applications filed under the PCT and 39 pending foreign patent applications, including pending applications in Australia, Brazil, Canada, China, European Patent Office, India, Israel, Japan, Republic of Korea, Mexico, Russian Federation, Singapore, and South Africa. These patent applications, if issued, are expected to expire on various dates from 2039 through to 2041, in each case without taking into account any possible patent term extension that may be available.

Our patent portfolio on our PREDATOR platform technology includes one pending international patent application filed under the PCT, and one pending U.S. provisional application. These pending patent applications claim protease cleavable linkers and libraries of protease cleavable linkers, as well as polypeptides that contain such linkers and methods of making libraries and screening libraries to identify linkers with desired properties. We intend to file national phase applications in the United States and various foreign jurisdictions based on this PCT application before applicable deadlines, and we also plan to file an international patent application under the PCT based on this provisional application before applicable deadlines.

Our patent portfolio for each of the product candidates is summarized below.

WTX-124

We own two patent families directed to IL-2 INDUKINE molecules and our WTX-124 product candidate. One of the families includes an issued U.S. patent with certain composition of matter claims with respect to WTX-124. We have also filed a pending U.S. application and pending foreign patent applications in Australia, Brazil, Canada, China, European Patent Office, India, Israel, Japan, Republic of Korea, Mexico, Russian Federation, Singapore and South Africa that claim certain compositions of matter and methods of use with respect to WTX-124. The 20-year term for patents in this family runs through 2039, excluding any extension of patent term that may be available. A second patent family currently includes one pending international patent application filed under the PCT that claims certain compositions of matter and methods of use with respect to WTX-124. This PCT application also claims certain compositions of matter and method of use with respect to WTX-613. We intend to file national phase applications in the United States and various foreign jurisdictions based on this PCT application before applicable deadlines. The 20-year term for patents in this family runs through to 2040, excluding any extension of patent term that may be available.

WTX-330

We own two families directed to IL-12 INDUKINE molecules and our WTX-330 product candidate. One of the families includes an issued U.S. patent with certain composition of matter claims with respect to IL-12 INDUKINE molecules. We have also filed a pending U.S. application and pending foreign applications in Australia, Brazil, Canada, China, European Patent Office, India, Israel, Japan, Republic of Korea, Mexico, Russian Federation, Singapore and South Africa that claim certain compositions of matter and methods of use with respect to IL-12 INDUKINE molecules and WTX-330. The 20-year term for patents in this family runs through 2039, excluding any extension of patent term that may be available. A second patent family currently consists of a pending U.S. provisional application directed to certain compositions of matter and methods of use with respect to WTX-330. The 20-year term for patents in this family runs through to 2041, excluding any extension of patent term that may be available.

WTX-613

We own two patent families directed to our INF- α INDUKINE molecules and our WTX-613 product candidate. We own a first patent family that includes pending foreign applications in Australia, Brazil, Canada, China, European Patent Office, India, Israel, Japan, Republic of Korea, Mexico, Russian Federation, Singapore and South Africa that claim certain compositions of matter and methods of use with respect to WTX-613. The 20-year term for patents in

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this family runs through 2039, excluding any extension of patent term that may be available. A second patent family currently includes one pending international patent application filed under the PCT that claims certain compositions of matter and methods of use with respect to WTX-613. This PCT application also claims certain compositions of matter and method of use with respect to WTX-124. We intend to file national phase applications in various foreign jurisdictions based on this PCT application before applicable deadlines. We filed a pending application in the United States that combined the disclosures of the first and second families, and claims compositions of matter and certain methods of use with respect to WTX-613. The 20-year term for patents based on the pending U.S. application will run through to 2039 or 2040, depending on the particular claims, excluding any extension of patent term that may be available.

In-Licensed Patents

We have licensed from Harpoon certain patents that are directed to single immunoglobulin variable domains that bind human serum albumin. We use the licensed technology in our current product candidates and may use the technology in additional development candidates we discover in the future. The licensed patent family includes granted U.S. patents and pending applications, and pending applications in Brazil, India, Canada, Japan, Mexico, Singapore, Australia, Eurasian Patent Organization, Republic of Korea, European Patent Office, China, and Israel. The 20-year term for the licensed patents runs through 2037, excluding any extension of patent term that may be available. See “Business—License and Royalty Agreements—License Agreement with Harpoon Therapeutics, Inc.” for more information regarding our license agreement with Harpoon.

Patent Term and Patent Term Extensions

The term of individual patents depends upon the legal term for patents in the countries in which they are obtained. In most countries, including the United States, the patent term is 20 years from the earliest filing date of a non-provisional patent application. In addition, in certain instances, the term of a U.S. patent can be extended to compensate a patentee for administrative delays by the USPTO in examining and granting a patent. The term of a patent that covers a drug, biological product or medical device approved pursuant to a pre-market approval may also be eligible for patent term extension when FDA approval is granted, provided statutory and regulatory requirements are met. The length of the patent term extension is related to the length of time the drug is under regulatory review while the patent is in force. The Drug Price Competition and Patent Term Restoration Act of 1984, or the Hatch-Waxman Amendments, permits a patent term extension of up to five years beyond the expiration date set for the patent. Patent extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent applicable to each regulatory review period may be granted an extension and only those claims reading on the approved drug are extended. Similar provisions are available in Europe and other foreign jurisdictions to extend the term of a patent that covers an approved drug. We will, in general, pursue available patent term extensions in the United States and in foreign jurisdictions that provide for patent term extensions, however, there is no guarantee that the applicable authorities, including the FDA in the United States, will agree with our assessment of whether such extensions should be granted, and if granted, the length of such extensions.

Trademarks, Trade Secrets and Know-How

In connection with the ongoing development and advancement of our product candidates in the United States and various international jurisdictions, we seek to create protection for our marks and enhance their value by pursuing trademarks where available and when appropriate. In addition to patent and trademark protection, we rely upon trade secrets and know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, using confidentiality agreements with our commercial partners, collaborators, employees and consultants and invention assignment agreements with our employees and selected consultants. We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations and systems, agreements or security measures may be breached and our trade secrets and other proprietary information may be disclosed. We may not have adequate remedies for any breach and could lose our trade secrets and other proprietary information through such a breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting trade secrets, know-how and inventions.

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Our commercial success will also depend in part on not infringing the proprietary rights of third parties. In addition, we have licensed rights under proprietary technologies of third parties to develop, manufacture and commercialize specific aspects of our future products and services. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, alter our processes, obtain licenses or cease certain activities. The expiration of patents or patent applications licensed from third parties or our breach of any license agreements or failure to obtain a license to proprietary rights that we may require to develop or commercialize our future technology may have a material adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference proceedings in the USPTO to determine priority of invention.

For more information regarding the risks related to our intellectual property, please see “Risk Factors—Risks Related to Our Intellectual Property.”

License and Royalty Agreements

License Agreement with Harpoon Therapeutics, Inc.

In March 2018, we entered into an assignment and license agreement, or the Harpoon Agreement, with Harpoon, pursuant to which we assigned to Harpoon certain patents related to adoptive cell therapies and binding moieties for conditional activation of immunoglobulin and non-immunoglobulin molecules, and Harpoon assigned to us certain patents related to certain inducible polypeptides and a binding moiety for conditional activation of certain polypeptides. Harpoon also granted to us a worldwide, non-exclusive, royalty-bearing, sublicensable license under certain other patents owned by Harpoon and related to certain proteins to make, have made, use, sell, offer for sale and import products that are covered by such patents in the field of molecules comprising a certain polypeptide. Under the Harpoon Agreement, we agreed to pay to Harpoon an upfront fee of \$0.5 million and, if we commercialize any products covered by these licensed patents, a low single digit percentage royalty on net sales of such products by us or any of our affiliates or licensees, subject to an obligation to make a minimum annual royalty payment at an amount in the low hundreds of thousands of dollars beginning with the first commercial sale of any such product by us.

In December 2019, we and Harpoon amended the Harpoon Agreement by entering into a Second Amended and Restated Assignment and License Agreement, or the Second Amended Harpoon Agreement, which granted to us an additional worldwide, exclusive, irrevocable, royalty-bearing, transferable, assignable, sublicensable license under certain patents owned by Harpoon and related to certain proteins, to make, have made, use, sell, offer for sale and import products that are covered by such patents in the field of molecules comprising a certain protein. Under the Second Amended Harpoon Agreement, we agreed to pay to Harpoon a low single digit percentage royalty on net sales by us or any of our affiliates or licensees of any products that we commercialize covered by these additional licensed patents. In addition, we also agreed to grant to Harpoon, and Harpoon agreed to grant to us, a perpetual, non-exclusive, irrevocable, royalty-free license under certain other patents directed to a certain binding domain of a certain protein, to make, have made, use, sell, offer for sale and import products that are covered by such patents in a field defined by a certain type of molecule with respect to each party.

Unless earlier terminated, our obligations to pay any royalties under the Second Amended Harpoon Agreement will expire on a country-by-country basis upon expiration of the last to expire valid claim of the relevant patents covering the manufacture, use or sale of such covered products in the applicable country. Harpoon may terminate the Second Amended Harpoon Agreement in the event of a material breach by us and our failure to cure such breach within a specified period and may terminate certain licenses if we become insolvent or bankrupt. We may terminate the Second Amended Harpoon Agreement voluntarily with prior written notice to Harpoon.

Amended and Restated Royalty Transfer Agreement

In December 2017, in connection with our sale of convertible promissory notes, we entered into a royalty transfer agreement with MPM Oncology Impact Fund Charitable Foundation, Inc., or MPM Charitable Foundation, and UBS Optimus Foundation, or the Royalty Transfer Agreement. Under the Royalty Transfer Agreement, we agreed to pay a royalty of 0.5% of net sales of our products to each of MPM Charitable Foundation and UBS Optimus Foundation. In August 2019, we amended the Royalty Transfer Agreement by entering into an amended and restated royalty transfer agreement, or the Amended Royalty Transfer Agreement, which provided that only products in our product pipeline

at the time of our initial public offering or a change in control would be subject to the royalty on net sales. Under the Amended Royalty Transfer Agreement, our obligation to pay a royalty expires on a product-by-product and country-by-country basis upon the later of the 12th anniversary of the first commercial sale of such product in such country and expiration of the last valid claim in such country covering such product. The royalty rate is subject to a specified reduction for lack of any valid claim covering such product in a country. The obligation to pay royalties under the Amended Royalty Transfer Agreement shall not apply to any product that would only infringe our intellectual property rights that are discovered or developed after this offering or to any product of an acquirer, assignee of the agreement or merger partner of the company so long as such product does not incorporate any of our pre-acquisition intellectual property.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions, including the European Union, or EU, extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, sales, pricing, reimbursement, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

Review and Approval of Drugs and Biologics in the United States

In the United States, the FDA approves and regulates drugs under the Federal Food, Drug, and Cosmetic Act, or FDCA, and related regulations. Biological products are licensed for marketing under the Public Health Service Act, or PHSA, and subject to regulation under the FDCA and related regulations. An applicant seeking approval to market and distribute a new drug or biological product in the United States must typically secure the following:

- completion of preclinical laboratory tests in compliance with the FDA's good laboratory practice, or GLP, regulations;
- submission to the FDA of an investigational new drug application, or IND, which must take effect before human clinical trials may begin;
- approval by an independent institutional review board, or IRB, representing each clinical site before each clinical trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with good clinical practices, or GCPs, to establish the safety and efficacy of the proposed drug product for each proposed indication;
- submission to the FDA of an NDA for a drug candidate product and a biological licensing application, or BLA, for a biological product requesting marketing for one or more proposed indications;
- review of the request for approval by an FDA advisory committee, where appropriate or if applicable;
- completion of one or more FDA inspections of the manufacturing facility or facilities at which the product, or components thereof, are produced to assess compliance with cGMPs to assure the product's identity, strength, quality and purity;
- completion of FDA audits of clinical trial sites to assure compliance with GCPs and the integrity of the clinical data;
- payment of user fees and securing FDA approval of the NDA or BLA; and
- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy, or REMS, and the potential requirement to conduct post-approval studies.

Preclinical Studies

Before an applicant begins testing a compound with potential therapeutic value in humans, the product candidate enters the preclinical testing stage. Preclinical studies include laboratory evaluation of the purity and stability of the manufactured substance or active pharmaceutical ingredient and the formulated product, as well as *in vitro* and animal studies to assess the safety and activity of the product candidate for initial testing in humans and to establish a rationale for therapeutic use. The conduct of preclinical studies is subject to federal regulations and

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requirements, including GLP regulations. Some long-term preclinical testing, such as animal tests of reproductive adverse events and carcinogenicity, and long-term toxicity studies, may continue after the IND is submitted.

The IND and IRB Processes

An IND is a request for FDA authorization to administer an investigational product candidate to humans. Such authorization must be secured prior to interstate shipment and administration of any new drug or biologic that is not the subject of an approved NDA or BLA. In support of a request for an IND, applicants must submit a protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and plans for clinical trials, among other things, are submitted to the FDA as part of an IND. The FDA requires a 30-day waiting period after the filing of each IND before clinical trials may begin. This waiting period is designed to allow the FDA to review the IND to determine whether human research subjects and patients will be exposed to unreasonable health risks. At any time during this 30-day period, or thereafter, the FDA may raise concerns or questions about the conduct of the trials as outlined in the IND and impose a clinical hold or partial clinical hold. In this case, the IND sponsor and the FDA must resolve any outstanding concerns before clinical trials can begin. The FDA's primary objectives in reviewing an IND are to assure the safety and rights of patients and to help assure that the quality of the investigation will be adequate to permit an evaluation of the drug's effectiveness and safety and of the biological product's safety, purity and potency.

Following commencement of a clinical trial under an IND, the FDA may also place a clinical hold or partial clinical hold on that trial. Clinical holds are imposed by the FDA whenever there is concern for patient safety and may be a result of new data, findings, or developments in clinical, nonclinical, and/or chemistry, manufacturing, and controls, or CMC. A clinical hold is an order issued by the FDA to the sponsor to delay a proposed clinical investigation or to suspend an ongoing investigation. A partial clinical hold is a delay or suspension of only part of the clinical work requested under the IND. For example, a specific protocol or part of a protocol is not allowed to proceed, while other protocols may do so. No more than 30 days after imposition of a clinical hold or partial clinical hold, the FDA will provide the sponsor a written explanation of the basis for the hold. Following issuance of a clinical hold or partial clinical hold, an investigation may only resume after the FDA has notified the sponsor that the investigation may proceed. The FDA will base that determination on information provided by the sponsor correcting the deficiencies previously cited or otherwise satisfying the FDA that the investigation can proceed.

A sponsor may choose, but is not required, to conduct a foreign clinical study under an IND. When a foreign clinical study is conducted under an IND, all IND requirements must be met unless waived. When a foreign clinical study is not conducted under an IND, the sponsor must ensure that the study complies with certain regulatory requirements of the FDA in order to use the study as support for an IND or application for marketing approval in the United States. The FDA's regulations are intended to help ensure the protection of human subjects enrolled in non-IND foreign clinical studies, as well as the quality and integrity of the resulting data. They further help ensure that non-IND foreign studies are conducted in a manner comparable to that required for IND studies.

In addition to the foregoing IND requirements, an IRB representing each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution, and the IRB must conduct continuing review and reapprove the trial at least annually. The IRB must review and approve, among other things, the trial protocol and informed consent information to be provided to trial subjects. An IRB must operate in compliance with FDA regulations. An IRB can suspend or terminate approval of a clinical trial at its institution, or an institution it represents, if the clinical trial is not being conducted in accordance with the IRB's requirements or if the product candidate has been associated with unexpected serious harm to patients.

Additionally, some trials are overseen by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board, or DSMB, or committee. This group provides authorization for whether a trial may move forward at designated check points based on access that only the group maintains to available data from the trial. Suspension or termination of development during any phase of clinical trials can occur if it is determined that the participants or patients are being exposed to an unacceptable health risk. Other reasons for suspension or termination may be made based on evolving business objectives and/or competitive climate.

Information about clinical trials must be submitted within specific timeframes to the National Institutes of Health, or NIH, for public dissemination on its ClinicalTrials.gov website.

Human Clinical Studies in Support of an NDA or BLA

Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCP requirements, which include, among other things, the requirement that all research subjects provide their informed consent in writing before their participation in any clinical trial. Clinical trials are conducted under written trial protocols detailing, among other things, the inclusion and exclusion criteria, the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated.

The clinical investigation of an investigational drug or biological product is generally divided into four phases. Although the phases are usually conducted sequentially, they may overlap or be combined. The four phases of an investigation are as follows:

- **Phase 1.** Phase 1 studies include the initial introduction of an investigational new drug or biological product into humans. These studies are designed to evaluate the safety, dosage tolerance, metabolism and pharmacologic actions of the investigational drug or biological product in humans, the side effects associated with increasing doses, and if possible, to gain early evidence on effectiveness.
- **Phase 2.** Phase 2 includes the controlled clinical trials conducted to preliminarily or further evaluate the effectiveness of the investigational drug or biological product for a particular indication(s) in patients with the disease or condition under trial, to determine dosage tolerance and optimal dosage, and to identify possible adverse side effects and safety risks associated with the drug or biological product. Phase 2 clinical trials are typically well-controlled, closely monitored, and conducted in a limited patient population.
- **Phase 3.** Phase 3 clinical trials are generally controlled clinical trials conducted in an expanded patient population generally at geographically dispersed clinical trial sites. They are performed after preliminary evidence suggesting effectiveness of the drug or biological product has been obtained, and are intended to further evaluate dosage, clinical effectiveness and safety, to establish the overall benefit-risk relationship of the investigational drug or biological product, and to provide an adequate basis for product approval.
- **Phase 4.** Post-approval studies may be conducted after initial marketing approval. These studies are used to gain additional experience from the treatment of patients in the intended therapeutic indication.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and more frequently if serious adverse events occur. In addition, IND safety reports must be submitted to the FDA for any of the following: serious and unexpected suspected adverse reactions; findings from other studies or animal or *in vitro* testing that suggest a significant risk in humans exposed to the drug; and any clinically important increase in the case of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The FDA will typically inspect one or more clinical sites to assure compliance with GCP and the integrity of the clinical data submitted.

In August 2018, the FDA released a draft guidance entitled “Expansion Cohorts: Use in First-In-Human Clinical Trials to Expedite Development of Oncology Drugs and Biologics,” which outlines how developers can utilize an adaptive trial design commonly referred to as a seamless trial design in early stages of oncology biological product development (i.e., the first-in-human clinical trial) to compress the traditional three phases of trials into one continuous trial called an expansion cohort trial. Information to support the design of individual expansion cohorts are included in IND applications and assessed by FDA. Expansion cohort trials can potentially bring efficiency to biological product development and reduce developmental costs and time.

Concurrent with clinical trials, companies often complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the candidate product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the drug candidate and, among other things, must develop methods for testing the identity, strength, quality, purity, and potency of the final drug. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the drug candidate does not undergo unacceptable deterioration over its shelf life.

Pediatric Studies

Under the Pediatric Research Equity Act of 2003, an application or supplement thereto must contain data that are adequate to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. Sponsors must also submit pediatric study plans prior to the assessment data. Those plans must contain an outline of the proposed pediatric study or studies the applicant plans to conduct, including study objectives and design, any deferral or waiver requests and other information required by regulation. The applicant, the FDA, and the FDA's internal review committee must then review the information submitted, consult with each other and agree upon a final plan. The FDA or the applicant may request an amendment to the plan at any time.

For investigational products intended to treat a serious or life-threatening disease or condition, the FDA must, upon the request of an applicant, meet to discuss preparation of the initial pediatric study plan or to discuss deferral or waiver of pediatric assessments. In addition, the FDA will meet early in the development process to discuss pediatric study plans with sponsors, and the FDA must meet with sponsors by no later than the end-of-phase 1 meeting for serious or life-threatening diseases and by no later than ninety (90) days after the FDA's receipt of the study plan.

The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements. Additional requirements and procedures relating to deferral requests and requests for extension of deferrals are contained in the Food and Drug Administration Safety and Innovation Act, or FDASIA. The FDA maintains a list of diseases that are exempt from PREA requirements due to low prevalence of disease in the pediatric population. In 2017, with the passage of the FDA Reauthorization Act of 2017, or FDARA, Congress further modified these provisions. Previously, drugs that had been granted orphan drug designation were exempt from the requirements of the Pediatric Research Equity Act. Under the amended section 505B, beginning on August 18, 2020, the submission of a pediatric assessment, waiver or deferral will be required for certain molecularly targeted cancer indications with the submission of an application or supplement to an application.

FDARA also established new requirements to govern certain molecularly targeted cancer indications. Any company that submits an application three years after the date of enactment of that statute must submit pediatric assessments with the application if the product is intended for the treatment of an adult cancer and is directed at a molecular target that the FDA determines to be substantially relevant to the growth or progression of a pediatric cancer. The investigation must be designed to yield clinically meaningful pediatric study data regarding the dosing, safety and preliminary efficacy to inform pediatric labeling for the product.

Submission and Review of an NDA or BLA by the FDA

In order to obtain approval to market a drug or biological product in the United States, a marketing application must be submitted to the FDA that provides data establishing the safety and effectiveness of the proposed drug product for the proposed indication, and the safety, purity and potency of the biological product for its intended indication. The application includes all relevant data available from pertinent preclinical and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and effectiveness of the investigational drug product and the safety, purity and potency of the biological product to the satisfaction of the FDA.

The application is the vehicle through which applicants formally propose that the FDA approve a new product for marketing and sale in the United States for one or more indications. Every new product candidate must be the subject of an approved NDA or BLA before it may be commercialized in the United States. Under federal law, the submission of most applications is subject to an application user fee. The sponsor of an approved application is also subject to an annual program fee. Certain exceptions and waivers are available for some of these fees, such as an exception from the application fee for products with orphan designation and a waiver for certain small businesses. If an application is withdrawn prior to the FDA acceptance for filing, 75% of these fees may be refunded to the sponsor. If an application is withdrawn after filing, a lower portion of these fees may be refunded in certain circumstances.

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Following submission of an NDA or BLA, the FDA conducts a preliminary review of the application generally within 60 calendar days of its receipt and strives to inform the sponsor by the 74th day after the FDA's receipt of the submission to determine whether the application is sufficiently complete to permit substantive review. The FDA may request additional information rather than accept the application for filing. In this event, the application must be resubmitted with the additional information. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA has agreed to specified performance goals in the review process of NDAs and BLAs. Under that agreement, 90% of applications seeking approval of New Molecular Entities, or NMEs, are meant to be reviewed within ten months from the date on which FDA accepts the NDA for filing, and 90% of applications for NMEs that have been designated for "priority review" are meant to be reviewed within six months of the filing date. The review process and the Prescription Drug User Fee Act goal date may be extended by the FDA for three additional months to consider new information or clarification provided by the applicant to address an outstanding deficiency identified by the FDA following the original submission.

Before approving an application, the FDA typically will inspect the facility or facilities where the product is or will be manufactured. These pre-approval inspections may cover all facilities associated with an NDA or BLA submission, including drug component manufacturing (e.g., active pharmaceutical ingredients), finished drug product manufacturing, and control testing laboratories. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP.

If the FDA decides not to license or approve the application, it will issue a Complete Response letter, or CRL. A CRL will describe all of the deficiencies that the FDA has identified in the application, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the application in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of an application if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

In addition, as a condition of approval, the FDA may require an applicant to develop a REMS. REMS use risk minimization strategies beyond the professional labeling to ensure that the benefits of the product outweigh the potential risks. To determine whether a REMS is needed, the FDA will consider the size of the population likely to use the product, seriousness of the disease, expected benefit of the product, expected duration of treatment, seriousness of known or potential adverse events, and whether the product is a new molecular entity. Under FDARA, the FDA must implement a protocol to expedite review of responses to inspection reports pertaining to certain applications, including applications for products in shortage or those for which approval is dependent on remediation of conditions identified in the inspection report.

The FDA may refer an application for a novel product to an advisory committee or explain why such referral was not made. Typically, an advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

The FDA's Decision on an NDA or BLA

On the basis of the FDA's evaluation of the application and accompanying information, including the results of the inspection of the manufacturing facilities, the FDA may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing or information in order for the FDA to reconsider the application. If and when those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

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If the FDA approves a product, it may limit the approved indications for use for the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including phase 4 clinical trials, be conducted to further assess the drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution restrictions or other risk management mechanisms, including REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-market studies or surveillance programs. After approval, many types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Fast Track, Breakthrough Therapy and Priority Review Designations

The FDA is authorized to designate certain products for expedited review if they are intended to address an unmet medical need in the treatment of a serious or life-threatening disease or condition. These programs include fast track designation, breakthrough therapy designation and priority review designation.

Specifically, the FDA may designate a product for Fast Track review if it is intended, whether alone or in combination with one or more other products, for the treatment of a serious or life-threatening disease or condition, and it demonstrates the potential to address unmet medical needs for such a disease or condition. For Fast Track products, sponsors may have greater interactions with the FDA and the FDA may initiate review of sections of a Fast Track product's application before the application is complete. This rolling review may be available if the FDA determines, after preliminary evaluation of clinical data submitted by the sponsor, that a Fast Track product may be effective. The sponsor must also provide, and the FDA must approve, a schedule for the submission of the remaining information and the sponsor must pay applicable user fees. However, the FDA's time period goal for reviewing a Fast Track application does not begin until the last section of the application is submitted. In addition, the Fast Track designation may be withdrawn by the FDA if the FDA believes that the designation is no longer supported by data emerging in the clinical trial process.

Second, a product may be designated as a Breakthrough Therapy if it is intended, either alone or in combination with one or more other products, to treat a serious or life-threatening disease or 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. The FDA may take certain actions with respect to Breakthrough Therapies, including holding meetings with the sponsor throughout the development process; providing timely advice to the product sponsor regarding development and approval; involving more senior staff in the review process; assigning a cross-disciplinary project lead for the review team; and taking other steps to help the sponsor design the clinical trials in an efficient manner.

Third, the FDA may designate a product for priority review if it is a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness. The FDA determines, on a case-by-case basis, whether the proposed product represents a significant improvement when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting product reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, and evidence of safety and effectiveness in a new subpopulation. A priority designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on a marketing application from ten months to six months.

Accelerated Approval Pathway

The FDA may grant accelerated approval to a product for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a condition when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, or IMM, and that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. Products granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

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For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval where the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate clinical benefit of a product.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a product, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. Thus, accelerated approval has been used extensively in the development and approval of products for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large trials to demonstrate a clinical or survival benefit. Thus, the benefit of accelerated approval derives from the potential to receive approval based on surrogate endpoints sooner than possible for trials with clinical or survival endpoints, rather than deriving from any explicit shortening of the FDA approval timeline, as is the case with priority review.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the product's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of phase 4 or post-approval clinical trials to confirm the effect on the clinical endpoint. Failure to conduct required post-approval studies, or confirm a clinical benefit during post-marketing studies, would allow the FDA to initiate expedited proceedings to withdraw approval of the product. All promotional materials for product candidates approved under accelerated regulations are subject to prior review by the FDA.

Post-Approval Regulation

Drugs and biologics manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

In addition, manufacturers and other entities involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, suspension of the approval, or complete withdrawal of the product from the market or product recalls;

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- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Products may be promoted only for the approved indications and in accordance with the provisions of the approved label. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. If a company is found to have promoted off-label uses, it may become subject to adverse public relations and administrative and judicial enforcement by the FDA, the Department of Justice, or the Office of the Inspector General of the Department of Health and Human Services, as well as state authorities. This could subject a company to a range of penalties that could have a significant commercial impact, including civil and criminal fines and agreements that materially restrict the manner in which a company promotes or distributes drug products.

Generic Drugs

In 1984, with passage of the Hatch-Waxman Amendments to the FDCA, Congress established an abbreviated regulatory scheme authorizing the FDA to approve generic drugs that are shown to contain the same active ingredients as, and to be bioequivalent to, drugs previously approved by the FDA pursuant to NDAs. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application, or ANDA, to the agency. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, bioequivalence, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. ANDAs are “abbreviated” because they generally do not include preclinical and clinical data to demonstrate safety and effectiveness. Instead, in support of such applications, a generic manufacturer may rely on the preclinical and clinical testing previously conducted for a drug product previously approved under an NDA, known as the reference-listed drug, or RLD.

Under the Hatch-Waxman Amendments, the FDA may not approve an ANDA until any applicable period of non-patent exclusivity for the RLD has expired. The FDCA provides a period of five years of non-patent data exclusivity for a new drug containing a new chemical entity. For the purposes of this provision, a new chemical entity, or NCE, is a drug that contains no active moiety that has previously been approved by the FDA in any other NDA. An active moiety is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been granted, an ANDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a Paragraph IV certification, in which case the applicant may submit its application four years following the original product approval. The FDCA also provides for a period of three years of exclusivity if the NDA includes reports of one or more new clinical investigations, other than bioavailability or bioequivalence studies, that were conducted by or for the applicant and are essential to the approval of the application.

Biosimilars

The 2010 Patient Protection and Affordable Care Act, or ACA, which was signed into law on March 23, 2010, included a subtitle called the Biologics Price Competition and Innovation Act of 2009, or BPCIA. The BPCIA established a regulatory scheme authorizing the FDA to approve biosimilars and interchangeable biosimilars. As of January 1, 2021, the FDA has approved 29 biosimilar products for use in the United States. No interchangeable biosimilars, however, have been approved. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars. Additional guidance is expected to be finalized by FDA in the near term.

Under the BPCIA, a manufacturer may submit an application for licensure of a biologic product that is “biosimilar to” or “interchangeable with” a previously approved biological product or “reference product.” In order for the FDA to approve a biosimilar product, it must find that there are no clinically meaningful differences between the reference product and proposed biosimilar product in terms of safety, purity, and potency. For the FDA to approve a biosimilar product as interchangeable with a reference product, the agency must find that the biosimilar product can be expected to produce the same clinical results as the reference product, and (for products administered multiple

times) that the biologic and the reference biologic may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date of approval of the reference product. The FDA may not approve a biosimilar product until 12 years from the date on which the reference product was approved. Even if a product is considered to be a reference product eligible for exclusivity, another company could market a competing version of that product if the FDA approves a full BLA for such product containing the sponsor's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product. The BPCIA also created certain exclusivity periods for biosimilars approved as interchangeable products. At this juncture, it is unclear whether products deemed "interchangeable" by the FDA will, in fact, be readily substituted by pharmacies, which are governed by state pharmacy law.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may designate a drug product as an "orphan drug" if it is intended to treat a rare disease or condition, generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a drug product available in the United States for treatment of the disease or condition will be recovered from sales of the product. A company must request orphan drug designation before submitting an NDA or BLA for the candidate product. If the request is granted, the FDA will disclose the identity of the therapeutic agent and its potential use. Orphan drug designation does not shorten the Prescription Drug User Fee Act, or PDUFA, goal dates for the regulatory review and approval process, although it does convey certain advantages such as tax benefits and exemption from the PDUFA application fee.

If a product with orphan designation receives the first FDA approval for the disease or condition for which it has such designation or for a select indication or use within the rare disease or condition for which it was designated, the product generally will receive orphan drug exclusivity. Orphan drug exclusivity means that the FDA may not approve another sponsor's marketing application for the same drug for the same indication for seven years, except in certain limited circumstances. Orphan exclusivity does not block the approval of a different product for the same rare disease or condition, nor does it block the approval of the same product for different indications. If a drug or biologic designated as an orphan drug ultimately receives marketing approval for an indication broader than what was designated in its orphan drug application, it may not be entitled to exclusivity. Orphan exclusivity will not bar approval of another product under certain circumstances, including if a company with orphan drug exclusivity is not able to meet market demand and in cases where a subsequent product with the same drug or biologic for the same indication is shown to be clinically superior to the approved product on the basis of greater efficacy or safety, or providing a major contribution to patient care. Under Omnibus legislation signed by President Trump on December 27, 2020, the requirement for a subsequent product to show clinical superiority in order to break the previous product's orphan drug exclusivity applies to drugs and biologics that received orphan drug designation before enactment of FDARA in 2017 but have not yet been approved or licensed by FDA.

Pediatric Exclusivity

Pediatric exclusivity is another type of non-patent marketing exclusivity in the United States and, if granted, provides for the attachment of an additional six months of marketing protection to the term of any existing regulatory exclusivity, including the non-patent and orphan exclusivity. This six-month exclusivity may be granted if an NDA or BLA sponsor submits pediatric data that fairly respond to a written request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. If reports of requested pediatric studies are submitted to and accepted by the FDA within the statutory time limits, whatever statutory or regulatory periods of non-patent exclusivity for drugs and biologics, or patent protection that covers a drug product, are extended by six months. This is not a patent term extension, but it effectively extends the regulatory period during which the FDA cannot approve another application.

Patent Term Restoration and Extension

A patent claiming a new drug product may be eligible for a limited patent term extension under the Hatch-Waxman Amendments, which permits a patent restoration of up to five years for patent term lost during product development

and the FDA regulatory review. The restoration period granted on a patent covering a product is typically one-half the time between the effective date of the IND approval and the submission date of an application, plus the time between the submission date of an application and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an approved product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple products for which approval is sought can only be extended in connection with one of the approvals. The United States Patent and Trademark Office reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

Pharmaceutical Coverage, Pricing and Reimbursement

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Significant uncertainty exists as to the coverage and reimbursement status of products approved by the FDA and other government authorities. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, the product. The process for determining whether a payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable marketing approvals. Nonetheless, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover a product candidate could reduce physician utilization once the product is approved and have a material adverse effect on sales, results of operations and financial condition. Additionally, a payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor.

Healthcare Law and Regulation

Health care providers and third-party payors play a primary role in the recommendation and prescription of drug products that are granted marketing approval. Arrangements with providers, consultants, third-party payors and customers are subject to broadly applicable fraud and abuse, anti-kickback, false claims laws, patient privacy laws and regulations and other health care laws and regulations that may constrain business and/or financial arrangements.

Restrictions under applicable federal and state health care laws and regulations, include the federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, 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, in whole or in part, under a federal health care program such as Medicare and Medicaid; the federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious or fraudulent or knowingly making, using or causing to be made or used a false record or statement to avoid, decrease or conceal an obligation to pay money to the federal government; the Foreign Corrupt Practices Act, or FCPA, which prohibits companies and their intermediaries from making, or offering or promising to make, improper payments to non-U.S. officials for the purpose of obtaining or retaining business or otherwise seeking favorable treatment; and the federal transparency requirements known as the

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federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services, or CMS, within the United States Department of Health and Human Services, information related to payments and other transfers of value made by that entity to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these federal transparency reporting obligations will extend to include transfers of value made during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified registered nurse anesthetists and certified nurse midwives. In addition, the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended, among other things, imposes limitations on certain covered healthcare providers, health plans, and healthcare clearinghouses and their respective business associates and their covered subcontractors that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information.

Further, 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 health care providers or marketing expenditures. Additionally, some state and local laws require the registration of pharmaceutical sales representatives in the jurisdiction.

State and foreign laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. In particular, numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of health-related and other personal information.

Violation of the laws described above or any other governmental laws and regulations may result in significant penalties, including civil, criminal, and administrative penalties, damages, fines, the curtailment or restructuring of operations, the exclusion from participation in federal and state healthcare programs, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, imprisonment, and additional reporting requirements and oversight if a manufacturer becomes subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws. Furthermore, efforts to ensure that business activities and business arrangements comply with applicable healthcare laws and regulations can be costly.

Healthcare Reform

The containment of health care costs also has become a priority of federal, state and foreign governments and the prices of products have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive marketing approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

There have been a number of federal and state proposals during the last few years regarding the pricing of pharmaceutical and biopharmaceutical products, limiting coverage and reimbursement for drugs and biologics and other medical products, government control and other changes to the health care system in the United States. In March 2010, President Obama signed into law the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or collectively the ACA. In addition, other legislative changes have been proposed and adopted since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress including 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 2030. However, these reductions were temporarily suspended from May 1, 2020 through March 31, 2021 under certain COVID-19 relief legislation. Legislation is currently pending in Congress that would further extend the suspension through December 31, 2021. The American Taxpayer Relief Act of 2012, among other

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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.

Since enactment of the ACA, there have been numerous legal challenges and executive and Congressional actions to repeal and replace provisions of the law. For example, with enactment of the Tax Cuts and Jobs Act of 2017, which was signed by President Trump on December 22, 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, on December 14, 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 inseparable feature of the ACA, and therefore because the mandate was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the Court of Appeals for the Fifth Circuit court affirmed the lower court's ruling that the individual mandate portion of the ACA is unconstitutional and it remanded the case to the district court for reconsideration of the severability question and additional analysis of the provisions of the ACA. Thereafter, the U.S. Supreme Court agreed to hear this case. Oral argument in the case took place on November 10, 2020. On February 10, 2021, the Biden Administration withdrew the Department of Justice's support for this lawsuit. Although the U.S. Supreme Court has yet to rule on the constitutionality of the ACA, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance through the ACA marketplace. It is unclear how the U.S. Supreme Court ruling, or other such litigation, and the healthcare reform measures of the Biden Administration will impact the ACA.

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. However, President Biden's Executive Order issued on January 28, 2021 rescinded the Executive Orders issued by President Trump and 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.

The costs of prescription pharmaceuticals have also been the subject of considerable discussion in the United States. In recent years, there have been several recent U.S. congressional inquiries, executive orders and policy initiatives, as well as proposed and enacted state and federal legislation designed to, among other things, implement drug pricing reform, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. To those ends, the Trump Administration used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives, and several agencies, including the FDA, CMS and the U.S. Department of Health and Human Services, issued rulemaking related to drug pricing reform during the Trump Administration. It is unclear whether the Biden Administration will work to reverse these measures or pursue similar policy initiatives.

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

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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.

Employees and Human Capital Resources

As of March 31, 2021, we had 28 full-time employees, including a total of 16 employees with M.D. or Ph.D. degrees. Of these full-time employees, 19 employees are engaged in research and development. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards. We value our employees and regularly benchmark total rewards we provide, such as short and long term compensation, 401(k) contributions, health, welfare and quality of life benefits, paid time off and personal leave, against our industry peers to ensure we remain competitive and attractive to potential new hires.

Facilities

Our principal facilities consist of office and laboratory space. We occupy 9,949 square feet of office and laboratory space in Cambridge, Massachusetts under a lease that currently expires in March 2024. In March 2021, we entered into a short-term lease for approximately 7,500 square feet of office and laboratory space in Watertown, Massachusetts that expires in May 2022. We believe that our existing and planned facilities will be adequate and suitable for our needs for the foreseeable future.

Legal Proceedings

We are not currently subject to any material legal proceedings.

MANAGEMENT

The following table sets forth information about our executive officers and directors, including their ages as of March 31, 2021.

<u>NAME</u>	<u>AGE</u>	<u>POSITION(S)</u>
Executive Officers		
Daniel J. Hicklin, Ph.D.	57	Chief Executive Officer, President and Director
Randi Isaacs, M.D.	65	Chief Medical Officer
Reid Leonard, Ph.D.	62	Chief Operating Officer
Ellen Lubman, M.B.A.	45	Chief Business Officer
Cynthia Seidel-Dugan, Ph.D.	62	Chief Scientific Officer
Timothy W. Trost	63	Chief Financial Officer and Treasurer
Non-Employee Directors		
Luke Evnin, Ph.D. (1)(2)(3)	57	Chairman of the Board of Directors
Sakae Asanuma, C.F.A.	54	Director
Derek DiRocco, Ph.D. (1)(3)	40	Director
Alon Lazarus, Ph.D. (1)(2)	46	Director
Briggs Morrison, M.D. (2)(3)	62	Director
Elise Wang, M.B.A.	61	Director

(1) Member of the audit committee.

(2) Member of the compensation committee.

(3) Member of the nominating and corporate governance committee.

Executive Officers

Daniel J. Hicklin, Ph.D., has served as our President and Chief Executive Officer since August 2019. Dr. Hicklin founded Werewolf Therapeutics in October 2017 and served as a consultant until his appointment as our President and Chief Executive Officer. Previously, Dr. Hicklin was a founder of Potenza Therapeutics, Inc., a privately held biotechnology company, and served as its President and Chief Executive Officer from April 2014 until its acquisition by Astellas Pharma Inc. in December 2018. From August 2013 until February 2014, Dr. Hicklin was President and Chief Scientific Officer of CoStim Pharmaceuticals, Inc., a privately held biotechnology company that was acquired by Novartis in February 2014. Dr. Hicklin has also served as an Executive Partner from 2014 to December 2019 and an advisor at MPM Capital since January 2020. Prior to joining CoStim Pharmaceuticals, Dr. Hicklin held several positions at Merck Research Laboratories (formerly the Schering-Plough Research Institute prior to its acquisition by Merck), including leading its Biologics Strategy for Oncology and the Immuno-Modulation Discovery team. Dr. Hicklin also previously held several positions at Imclone Systems Incorporated, including Vice President, Experimental Therapeutics. Dr. Hicklin has served as a member of the board of directors of several private biotechnology companies. Dr. Hicklin also currently serves on the Industry Advisory Committee for The Mark Foundation for Cancer Research. Dr. Hicklin holds an M.S. and Ph.D. in Microbiology and Immunology from New York Medical College, where he trained with Dr. Soldano Ferrone, and a B.S. from the University of Iowa. We believe that Dr. Hicklin's operational and historical experience with our company gained from being a founder and serving as our President and Chief Executive Officer and member of our board of directors, combined with his extensive experience in oncology drug discovery, qualifies him to serve as a member of our board of directors.

Randi Isaacs, M.D., has served as our Chief Medical Officer since November 2020. Previously, from May 2010 until November 2020, Dr. Isaacs held roles of increasing responsibility as Clinical Program Leader, Deputy Site Head, and, from August 2015 to November 2020, Executive Director and Clinical Site Head of Translational Clinical Oncology at the Novartis Institutes for Biomedical Research. She previously held executive leadership roles in oncology and clinical development at Merck, Schering Plough and Sandoz. Prior to transitioning to the biopharmaceutical industry, Dr. Isaacs held various academic appointments, including Assistant Professor of Medicine in the Division of Hematology/Oncology at the State University of New York Health Sciences Center and Clinical Assistant Professor of Hematology/Oncology at the University of Medicine and Dentistry of New Jersey.

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Dr. Isaacs earned her B.A. in Chemistry from Wellesley College and holds an M.D. with honors from Dartmouth Medical School. She completed her residency and postdoctoral training at the University of California San Francisco and University of Pennsylvania and hematology/medical oncology fellowship training at the Memorial Sloan-Kettering Cancer Center.

Reid Leonard, Ph.D., has served as our Chief Operating Officer since April 2019. From July 2014 until December 2018, Dr. Leonard served in various roles at Potenza Therapeutics, including Chief Operating Officer from January 2018 to December 2018, Senior Vice President of Corporate Development from January 2016 to December 2017 and Vice President of Corporate Development from July 2014 to December 2015. Dr. Leonard served as a venture partner at MPM Capital from September 2016 until September 2017 and has also served as a consultant to several private biotechnology companies. Dr. Leonard began his career with Merck & Co., where he served for over 25 years. Dr. Leonard graduated from Brandeis University with an A.B. in Biology and Psychology, holds a Ph.D. in Biology from Purdue University and completed a postdoctoral fellowship in molecular pharmacology at Caltech with Profs. Henry Lester and Norman Davidson.

Ellen Lubman, M.B.A., has served as our Chief Business Officer since August 2020. From October 2018 to July 2020, Ms. Lubman served as the Chief Business Officer at Impel NeuroPharma, Inc., a privately held biotechnology company focused on neurological diseases. Prior to Impel, she was the Vice President of External Science & Innovation at Forest Labs, from February 2014 until its acquisition by Actavis plc in July 2014, and served in the same role at Actavis through June 2018 during which time Actavis merged with and renamed itself Allergan plc. Prior to Allergan, Ms. Lubman held numerous executive and leadership roles at Kadmon Pharmaceuticals, Bristol Myers Squibb, Celtic Pharma Management, L.P., Robertson Stephens Investment Bank and Abbott Labs. She serves on the board of directors of GeneCentric Therapeutics and Intrepida Bio, as well as the Advisory Board of TMRW.org. Ms. Lubman also currently serves on the Scientific Advisory Board of the Daedalus Innovation Fund of Weill-Cornell and board of directors of Gilda's Club of NYC and is the Southern California Chairwoman of Executive Women in BIO. Ms. Lubman earned her M.B.A. from Stanford Graduate School of Business with a focus on Global Management and her B.A. in Biology from Rutgers College.

Cynthia Seidel-Dugan, Ph.D., has served as our Chief Scientific Officer since April 2019. From May 2014 until December 2018, Dr. Seidel-Dugan served in several positions at Potenza Therapeutics, including most recently Chief Scientific Officer from January 2018 to December 2018, and previously Senior Vice President of Research from January 2016 to December 2017 and Vice President of Research from May 2014 to December 2015. Prior to joining Potenza Therapeutics, Dr. Seidel-Dugan served as Vice President, Biology for CoStim Pharmaceuticals from May 2013 until February 2014. Early in her career, Dr. Seidel-Dugan served in various roles at Ariad Pharmaceuticals, Exelixis Pharmaceuticals, Schering-Plough Research Institute and (upon merger) Merck Research Laboratories. Dr. Seidel-Dugan earned a B.S. in Biology from the College of William and Mary and holds a Ph.D. in Microbiology and Molecular Biology from the University of Pennsylvania. She also completed a postdoctoral fellowship with Dr. Joan Brugge at the University of Pennsylvania.

Timothy W. Trost has served as our Chief Financial Officer and Treasurer since February 2021. Previously, Mr. Trost served as Chief Financial Officer of Asklepios Biopharmaceutical, Inc., or AskBio, a biotechnology company, from May 2020 until it was acquired by Bayer AG in December 2020. Prior to joining AskBio, from March 2011 until May 2019, Mr. Trost served as Senior Vice President, Chief Financial Officer, of Chimerix, Inc., a biopharmaceutical company, and also served as its Corporate Secretary from February 2012 until May 2019. Previously, Mr. Trost served as Vice President and Chief Financial Officer at Argos Therapeutics, Inc., a venture-backed immunotherapy company; Senior Vice President and Chief Financial Officer at InteCardia, Inc., a venture-backed cardiac imaging company that was acquired by Syncor International Corporation; and as Executive Vice President and Chief Financial Officer of Coastal Physician Group, Inc., a contract provider of emergency room physicians, having joined as Vice President of Corporate Development. Mr. Trost previously served with PricewaterhouseCoopers LLP, last serving as a Senior Manager in the Research Triangle practice. Mr. Trost holds a B.S. in accounting from the University of Illinois at Urbana-Champaign and is a Certified Public Accountant.

Non-Employee Directors

Luke Evnin, Ph.D., is a co-founder of our company, served as our President and Chief Executive Officer from December 2017 until August 2019 and has served on our board of directors since October 2017 and as chairman of

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the board of directors since August 2019. Dr. Evnin serves on the board of directors of Oncorus, Inc, a publicly traded biotechnology company, and is Chief Executive Officer of Turmeric Acquisition Corp., a publicly traded special purpose acquisition company formed by MPM Capital. In 2015, Dr. Evnin co-founded Harpoon Therapeutics, Inc., a publicly held immunotherapy company, and served as chairman of its board of directors until July 2020. Dr. Evnin served on the board of directors of Syndax Pharmaceuticals, Inc., a publicly traded biotechnology company, from May 2012 until September 2018. Over the past eight years, as a component of his MPM activities, Dr. Evnin has been a co-founder and served as chairman of the board for seven MPM portfolio companies. Dr. Evnin has also served on the board of directors of a number of public and private companies over his 28-year venture capital career and currently serves, on behalf of MPM Capital, as a director for seven private companies. Dr. Evnin co-founded MPM Capital, an early-stage life sciences venture investing firm, in 1997, where he currently serves as Managing Director. Prior to co-founding MPM Capital, Dr. Evnin spent seven years as a venture capitalist at Accel Partners. Dr. Evnin also serves as chairman of the board of directors of the Scleroderma Research Foundation, a not-for-profit entity. Dr. Evnin holds an A.B. in molecular biology from Princeton University and a Ph.D. in biochemistry from the University of California, San Francisco. We believe that Dr. Evnin's depth and expertise in the life sciences and venture capital industries including significant experience serving on boards of directors and his educational background provide him with the qualifications and skills to serve on our board of directors.

Sakae Asanuma, C.F.A., has served on our board of directors since August 2019. Mr. Asanuma established and has served since April 2016 as President of Taiho Ventures, LLC, the corporate venture arm of Taiho Pharmaceutical Co., Ltd., a Japanese specialty pharmaceutical company focusing on oncology, allergy and immunology and urology. Previously, Mr. Asanuma was President and Chief Executive Officer at Astellas Venture Management LLC, the corporate venture capital arm of Astellas Pharma, Inc. from April 2012 until January 2016, and U.S. Head of Astellas Innovation Management from 2013 to 2015. Before joining Astellas, he worked for Yasuda Enterprise, a Japan/US-based venture capital firm. Mr. Asanuma has served on the boards of directors of many private biotechnology companies and has been involved in numerous biotechnology and pharmaceutical partnering transactions. Mr. Asanuma holds a Master of Science in Industrial Administration (MBA) from Carnegie Mellon University. We believe Mr. Asanuma's experience working with and serving on the boards of directors of life sciences companies and his experience working in the venture capital industry qualifies him to serve on our board of directors.

Derek DiRocco, Ph.D., has served on our board of directors since December 2020. Dr. DiRocco has been a partner at RA Capital Management, L.P. since December 2020 and was previously a principal from December 2017 until December 2020, an analyst from June 2015 to December 2017 and an associate from July 2013 to June 2015. Dr. DiRocco has served on the board of directors of iTeos Therapeutics, Inc. since March 2020 and 89bio, Inc. since April 2018, each of which is a publicly traded biotechnology company. Dr. DiRocco also serves on the board of directors of several privately held biotechnology companies. Dr. DiRocco holds a B.A. in biology from College of the Holy Cross and a Ph.D. in pharmacology from the University of Washington. He conducted his postdoctoral research at Brigham and Women's Hospital/Harvard Medical School. We believe that Dr. DiRocco is qualified to serve as a member of our board of directors because of his experience as an investor in biotechnology companies and role in early-stage companies.

Alon Lazarus, Ph.D., has served as a member of our board of directors since August 2019. Dr. Lazarus has held the position of Biotech Investment Manager of the Pharma Division of Arkin Holdings, Ltd., an investment firm, focused in the healthcare and pharmaceutical sectors, since August 2013. Prior to joining Arkin Holdings, Ltd., Dr. Lazarus worked for the Healthcare Business Development Department of Yissum Research Development Company of the Hebrew University of Jerusalem from January 2012 until August 2013, and as an Analyst for Integra Holdings, Ltd., an Israel-based healthcare investment company. Dr. Lazarus served as a member of the board of directors of Keros Therapeutics, Inc, a publicly traded biotechnology company, from April 2016 to December 2020. Dr. Lazarus also serves as a member of the board of directors of several private life science companies. Dr. Lazarus holds a Ph.D. in Molecular Biology from the Hadassah Medical School of Hebrew University of Jerusalem in Israel, an M.B.A. from the School of Business Administration of Hebrew University of Jerusalem in Israel and a B.Sc. in Biology from Hebrew University of Jerusalem in Israel. We believe that Dr. Arkin's extensive experience in the biotechnology industry and his service on numerous life sciences board of directors qualify him to serve on our board of directors.

Briggs W. Morrison, M.D., has served as a member of our board of directors since November 2019. He has served as Executive Partner at MPM Capital, Inc. since June 2015 and as Chief Executive Officer and a member of the board

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of directors of Syndax Pharmaceuticals, Inc., a publicly traded biopharmaceutical company, since June 2015. Dr. Morrison has also served as a member of the board of directors of NextCure Inc. since April 2019, Arvinas Holding Company, LLC since June 2018, Repare Therapeutics Inc. since June 2017, and Codiak BioSciences, Inc. since February 2018, all of which are publicly traded biopharmaceutical companies. Before that, Dr. Morrison was the Chief Medical Officer and Head of Global Medicines Development at AstraZeneca plc from 2012 to 2015. Before joining AstraZeneca, he held several positions at Pfizer Inc., including Head, Medical Affairs, Safety and Regulatory Affairs for Pfizer's human health business. Dr. Morrison also previously held several positions at Merck Research Laboratories, a division of Merck & Co., Inc., including Vice President, Clinical Sciences, Oncology. He was a member of the executive committee of the Clinical Trials Transformation Initiative sponsored by the FDA and is on the board of the Alliance for Clinical Research Excellence and Safety. Dr. Morrison also serves on the board of directors for multiple private pharmaceutical companies. Dr. Morrison has a B.S. in biology from Georgetown University and an M.D. from the University of Connecticut Medical School. He completed residency training in internal medicine at Massachusetts General Hospital and a fellowship in medical oncology at the Dana-Farber Cancer Institute. We believe Dr. Morrison is qualified to serve as a member of our board of directors due to his extensive executive leadership experience, his medical background and training and his service on the boards of other public and private biopharmaceutical and biotechnology companies.

Elise Wang, M.B.A., has served as a member of our board of directors since December 2020. She is currently a Partner on the Public Structured Finance group at Deerfield and joined Deerfield in 2010. Ms. Wang provides extensive research and analysis on individual companies operating in the healthcare industry in both the United States and Europe for Deerfield. Prior to joining Deerfield, from 2001 to 2007, Ms. Wang was a Senior Research Analyst and Managing Director in healthcare primarily covering the biotechnology industry at Citigroup. From 1996 to 2001, Ms. Wang was a Senior Research Analyst and Managing Director at PaineWebber Inc., where she covered biotechnology. Ms. Wang began her career in healthcare in 1987 as a venture capitalist and banker at PaineWebber Inc. and was an officer of PaineWebber Development Corporation, which managed entities invested in biotechnology and high technology companies. Ms. Wang holds an A.B. in Engineering Sciences with a specialty in Biomechanics from Harvard University and an M.B.A. from Harvard Business School. We believe Ms. Wang is qualified to serve as a member of our board of directors due to her breadth of investment experience in the life sciences industry and her financial background. Ms. Wang resigned from our board of directors effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part.

Our Board of Directors

Our board of directors currently consists of six members. Effective immediately prior to the effectiveness of the registration statement of which this prospectus forms a part, the number of seats on our board of directors was fixed to six following the resignation of Ms. Wang. Our directors hold office until their successors have been elected and qualified or until the earlier of their death, resignation or removal. Our restated certificate of incorporation and amended and restated bylaws that will become effective upon the closing of this offering provide that the authorized number of directors may be changed only by resolution of our board of directors. Our restated certificate of incorporation and amended and restated bylaws will also provide that our directors may be removed only for cause by the affirmative vote of the holders of two-thirds of our shares of capital stock present in person or by proxy and entitled to vote, and that any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

In accordance with the terms of our restated certificate of incorporation and amended and restated bylaws that will become effective upon the closing of this offering, our board of directors will be divided into three classes, Class I, Class II and Class III, with members of each class serving staggered three-year terms. As a result, only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Upon the closing of this offering, the members of the classes will be divided as follows:

- the Class I directors will be Briggs Morrison, M.D. and Sakae Asanuma, C.F.A., and their term will expire at the first annual meeting of stockholders to be held after the closing of this offering;
- the Class II directors will be Daniel J. Hicklin, Ph.D. and Derek DiRocco, Ph.D., and their term will expire at the second annual meeting of stockholders to be held after the closing of this offering; and

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- the Class III directors will be Luke Evnin, Ph.D. and Alon Lazarus, Ph.D., and their term will expire at the third annual meeting of stockholders to be held after the closing of this offering.

Upon the expiration of the term of a class of directors, directors in that class will be eligible to be elected for a new three-year term at the annual meeting of stockholders in the year in which their term expires.

The classification of our board of directors may have the effect of delaying or preventing changes in our control or management. See “Description of Capital Stock—Delaware Anti-takeover Law and Certain Charter and Bylaw Provisions.”

Director Independence

The rules of the Nasdaq Stock Market, or Nasdaq, require a majority of a listed company's board of directors to be comprised of independent directors within one year of listing. In addition, Nasdaq rules require that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent. Audit committee members must also satisfy the independence criteria set forth in Rule 10A-3 under the Securities Exchange Act of 1934, as amended, or the Exchange Act, and compensation committee members must also satisfy the independence criteria set forth in Rule 10C-1 under the Exchange Act. Under applicable Nasdaq rules, a director will only qualify as an “independent director” if, in the opinion of the listed company's board of directors, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries. In order to be considered independent for purposes of Rule 10C-1, the board must consider, for each member of a compensation committee of a listed company, all factors specifically relevant to determining whether a director has a relationship to such company which is material to that director's ability to be independent from management in connection with the duties of a compensation committee member, including, but not limited to: (1) the source of compensation of the director, including any consulting advisory or other compensatory fee paid by such company to the director; and (2) whether the director is affiliated with the company or any of its subsidiaries or affiliates.

In April 2021, our board of directors undertook a review of the composition of our board of directors and its committees and the independence of each director. Based upon information requested from and provided by each director concerning his or her background, employment and affiliations, including family relationships, our board of directors has determined that each of our directors, with the exception of Daniel J. Hicklin, is an “independent director” as defined under applicable Nasdaq rules, including, in the case of all the members of our audit committee, the independence criteria set forth in Rule 10A-3 under the Exchange Act, and in the case of all the members of our compensation committee, the independence criteria set forth in Rule 10C-1 under the Exchange Act. In making such determination, our board of directors considered the relationships that each such non-employee director has with our company and all other facts and circumstances that our board of directors deemed relevant in determining his or her independence, including the beneficial ownership of our capital stock by each non-employee director. Daniel J. Hicklin is not an independent director under these rules because he is an executive officer of our company.

There are no family relationships among any of our directors or executive officers.

Board Leadership Structure

Currently, the roles of chair of our board of directors and Chief Executive Officer are separated. Luke Evnin is the chairman of our board of directors and Daniel J. Hicklin is our Chief Executive Officer. We believe that separating these positions allows our Chief Executive Officer to focus on our day-to-day business, while allowing our chairman of the board to lead the board of directors in providing advice to, and independent oversight of, our management. While our amended and restated bylaws and corporate governance guidelines that will become effective upon the completion of this offering will not require that chair of our board of directors and Chief Executive Officer positions be separate, our board of directors believes that having separate positions is the appropriate leadership structure for us at this time and demonstrates our commitment to good corporate governance.

Board's Role in Risk Oversight

One of the key functions of our board of directors is informed oversight of our risk management process. Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through the board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. In particular, our board of directors is responsible for monitoring and assessing strategic risk exposure, and our audit committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The audit committee also monitors compliance with legal and regulatory requirements.

Committees of Our Board of Directors

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee, each of which operates under a charter approved by our board of directors. We have posted current copies of each committee's charter on our website, <http://www.werewolftx.com>.

Audit Committee

The members of our audit committee are Derek DiRocco, Ph.D., Luke Evin, Ph.D. and Alon Lazarus, Ph.D., and Dr. Evin is the chair of the audit committee. Our board of directors has determined that Dr. Evin is an "audit committee financial expert" as defined by applicable SEC rules and that each of the members of our audit committee possesses the financial sophistication required for audit committee members under Nasdaq rules. We believe that the composition of our audit committee meets the requirements for independence under current Nasdaq and SEC rules and regulations. Our audit committee's responsibilities include:

- appointing, approving the compensation of, and assessing the independence of our registered public accounting firm;
- overseeing the work of our independent registered public accounting firm, including through the receipt and consideration of reports from such firm;
- reviewing and discussing with management and our independent registered public accounting firm our annual and quarterly financial statements and related disclosures;
- monitoring our internal control over financial reporting, disclosure controls and procedures and code of business conduct and ethics;
- overseeing our risk assessment and risk management policies;
- establishing policies regarding hiring employees from our independent registered public accounting firm and procedures for the receipt and retention of accounting-related complaints and concerns;
- meeting independently with our internal auditing staff, if any, our independent registered public accounting firm and management;
- reviewing and approving or ratifying any related person transactions; and
- preparing the audit committee report required by SEC rules.

All audit and non-audit services, other than *de minimis* non-audit services, to be provided to us by our independent registered public accounting firm must be approved in advance by our audit committee.

Compensation Committee

The members of our compensation committee are Luke Evin, Ph.D., Alon Lazarus, Ph.D. and Briggs Morrison, M.D., and Dr. Lazarus is the chair of the compensation committee. Our compensation committee's responsibilities include:

- reviewing and approving, or making recommendations to our board of directors with respect to, the compensation of our Chief Executive Officer and our other executive officers;
- overseeing an evaluation of our senior executives;
- overseeing and administering our cash and equity incentive plans;

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- reviewing and making recommendations to our board of directors with respect to director compensation;
- reviewing and discussing annually with management our “Compensation Discussion and Analysis” disclosure if and to the extent required by SEC rules; and
- preparing the compensation committee report if and to the extent then required by SEC rules.

We believe that the composition of our compensation committee meets the requirements for independence under current Nasdaq and SEC rules and regulations.

Nominating and Corporate Governance Committee

The members of our nominating and corporate governance committee are Derek DiRocco, Ph.D., Luke Evin, Ph.D. and Briggs Morrison, M.D., and Dr. Morrison is the chair of the nominating and corporate governance committee. Our nominating and corporate governance committee's responsibilities include:

- recommending to our board of directors the persons to be nominated for election as directors and to each of our board's committees;
- reviewing and making recommendations to our board with respect to our board leadership structure;
- reviewing and making recommendations to our board with respect to management succession planning;
- developing and recommending to our board of directors corporate governance principles; and
- overseeing a periodic evaluation of our board of directors.

We believe that the composition of our nominating and corporate governance committee meets the requirements for independence under current Nasdaq and SEC rules and regulations.

Compensation Committee Interlocks and Insider Participation

No member of our compensation committee is or has been a current or former officer or employee of our company. None of our executive officers currently serves, or in the past fiscal year has served, as a member of the board of directors or compensation committee, or other committee serving an equivalent function, of any entity that has one or more of its executive officers serving on our board of directors or our compensation committee.

Code of Business Conduct and Ethics

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer, or persons performing similar functions. A current copy of the code is posted on the investor relations section of our website, which is located at <http://www.werewolftx.com>. If we make any substantive amendments to, or grant any waivers from, the code of business conduct and ethics for any officer or director, we will disclose the nature of such amendment or waiver on our website. We have included our website in this prospectus solely as an inactive textual reference.

EXECUTIVE COMPENSATION

The following discussion relates to the compensation of our President and Chief Executive Officer, Daniel J. Hicklin, Ph.D., our Chief Medical Officer, Randi Isaacs, M.D., and our Chief Scientific Officer, Cynthia Seidel-Dugan, Ph.D., for 2020. Drs. Hicklin, Isaacs and Seidel-Dugan are collectively referred to in this prospectus as our named executive officers.

In preparing to become a public company, we have begun a thorough review of all elements of our executive compensation program, including the function and design of our equity incentive programs. We have evaluated the need for, and adopted, revisions to our executive compensation program to ensure that our program is competitive with the companies with which we compete for executive talent and is appropriate for a public company.

Summary Compensation Table

The following table sets forth information regarding compensation awarded to, earned by, or paid to each of our named executive officers during the year ended December 31, 2020.

NAME AND PRINCIPAL POSITION	YEAR	SALARY (\$)	BONUS (\$)⁽¹⁾	OPTION AWARDS (\$)⁽²⁾	TOTAL (\$)
Daniel J. Hicklin, Ph.D. (3) <i>President and Chief Executive Officer</i>	2020	425,000	193,936	2,370,987	2,989,923
Randi Isaacs, M.D. (4) <i>Chief Medical Officer</i>	2020	55,529	—	832,010	887,539
Cynthia Seidel-Dugan, Ph.D. <i>Chief Scientific Officer</i>	2020	311,250	133,153	392,891	837,294

(1) Amounts shown for 2020 represent the annual bonus earned by each of Dr. Hicklin and Dr. Seidel-Dugan based on our attainment of corporate goals as determined by the board of directors in its sole discretion.

(2) The amounts reported in the "Option Awards" column reflect the aggregate fair value of stock-based compensation awarded during the year computed in accordance with the provisions of the Financial Accounting Standard Board Accounting Standards Codification Topic 718. See Note 11 to our consolidated financial statements appearing elsewhere in this prospectus regarding assumptions underlying the valuation of equity awards. These amounts reflect the accounting cost for these stock options and do not reflect the actual economic value that may be realized by the named executive officer upon the vesting of the stock options, the exercise of the stock options, or the sale of the common stock underlying such stock options.

(3) Dr. Hicklin is also a member of our board of directors, but did not receive any additional compensation in his capacity as a director.

(4) Dr. Isaacs commenced employment with us as our Chief Medical Officer in November 2020. The 2020 salary reported reflects the pro rata portion of Dr. Isaacs' annual salary earned from commencement of her employment through December 31, 2020.

Narrative Disclosure to Summary Compensation Table**Base Salary**

During 2020, the base salaries for Dr. Hicklin and Dr. Seidel-Dugan were \$425,000 and \$311,250, respectively. Dr. Isaacs' annual salary of \$385,000 was established at the time she commenced employment with us in November 2020. Effective upon the effectiveness of the registration statement of which this prospectus forms a part, Dr. Hicklin's, Dr. Isaacs' and Dr. Seidel-Dugan's annual base salaries increased to \$510,000, \$425,000 and \$400,000, respectively.

Annual Bonuses

The employment offer letters for Dr. Hicklin, Dr. Isaacs and Dr. Seidel-Dugan provide that they are eligible to receive an annual bonus at a target amount expressed as a percentage of base salary. For 2020, the target bonus amounts for Dr. Hicklin and Dr. Seidel-Dugan were 40% and 30%, respectively. Because Dr. Isaacs commenced employment with us in November 2020, she did not receive a bonus for 2020. Annual bonuses for 2020 for our named executive officers were based on our attainment of corporate goals as determined by our board of directors, in its sole discretion. The corporate performance goals for 2020 related to building the company and advancing our research and development pipeline. Effective upon the effectiveness of the registration statement of which this prospectus forms a part, Dr. Hicklin's, Dr. Isaacs' and Dr. Seidel-Dugan's target bonus amounts for 2021, expressed as a percentage of base salary, increased to 50%, 40% and 40%, respectively.

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With respect to 2020 performance, our board of directors awarded bonuses of \$193,936 and \$133,153 to Dr. Hicklin and Dr. Seidel-Dugan, respectively.

Equity Incentives

Although we do not have a formal policy with respect to the grant of equity incentive awards to our executive officers, or any formal equity ownership guidelines applicable to them, we believe that equity grants provide our executive officers with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executive officers and our stockholders. In addition, we believe that equity grants with a time-based vesting feature promote executive retention because this feature incentivizes our executive officers to remain in our employment during the vesting period. Accordingly, our board of directors periodically reviews the equity incentive compensation of our executive officers, including our named executive officers, and from time to time may grant equity incentive awards to them in the form of stock options.

We granted a stock option to purchase 727,377 shares of our common stock to Dr. Hicklin on December 8, 2020. This option is scheduled to vest with respect to 25% of the shares underlying the stock option on December 8, 2021, and thereafter with respect to an additional 2.0833% of the shares underlying the stock option in monthly installments, subject to continuous service. The vesting of Dr. Hicklin's stock option is subject to acceleration in full upon certain terminations of Dr. Hicklin's employment.

We granted stock options to purchase 61,136 and 99,163 shares of our common stock to Dr. Seidel-Dugan on May 20, 2020 and December 8, 2020, respectively. Each stock option is scheduled to vest with respect to 25% of the shares underlying such stock option on the first anniversary of its grant date, and thereafter with respect to an additional 2.0833% of the shares underlying such stock option in monthly installments, subject to continuous service. The vesting of each of Dr. Seidel-Dugan's stock options is subject to partial and full acceleration upon certain terminations of Dr. Seidel-Dugan's employment.

We granted stock options to purchase 176,966 and 140,208 shares of our common stock to Dr. Isaacs on November 9, 2020 and December 8, 2020, respectively. Each stock option is scheduled to vest with respect to 25% of the shares underlying such stock option on the first anniversary of its grant date, and thereafter with respect to an additional 2.0833% of the shares underlying such stock option in monthly installments, subject to continuous service. The vesting of each of Dr. Isaacs' stock options is subject to partial and full acceleration upon certain terminations of Dr. Isaacs' employment.

Prior to this offering, our executive officers were eligible to participate in our 2017 Stock Incentive Plan, as amended, or the 2017 Plan. During 2020 and 2021 (and through the effectiveness of the registration statement of which this prospectus forms a part), all stock options were granted pursuant to the 2017 Plan. We did not grant any restricted common stock awards during 2020 or 2021. Following this offering, our employees and executive officers will be eligible to receive stock options and other stock-based awards pursuant to our 2021 Stock Incentive Plan, or the 2021 Plan. We have also agreed to grant to Drs. Hicklin, Isaacs and Seidel-Dugan options to purchase that number of shares of common stock equal to 4.5%, 1.1% and 1.0% times the number of fully diluted shares outstanding following the closing of this offering minus the total number of shares of common stock held by each such officer assuming the exercise of all stock options held by them, which we refer to as the IPO Grants. The IPO Grants will be granted pursuant to the 2021 Plan and will have an exercise price per share equal to the public offering price in this offering. The IPO Grants will be effective upon the commencement of trading of our common stock on the Nasdaq Global Select Market and will vest as to 2.0833% (1/48th) of the shares underlying the option for each month of continuous service following the date of grant.

We have used stock options to compensate our executive officers in the form of initial grants in connection with the commencement of employment. Prior to this offering, awards of stock options and restricted common stock to our executive officers have been made by our board of directors. The stock options and restricted common stock that we have granted to our executive officers are typically subject to time-based vesting, generally over four years following the vesting commencement date. Vesting rights cease upon termination of employment and exercise rights for stock options cease shortly after termination of employment. Prior to the exercise of a stock option, the holder has no rights as a stockholder with respect to the shares subject to such stock option, including no voting rights and no right to receive dividends or dividend equivalents.

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We have historically awarded stock options and restricted common stock with exercise prices or purchase prices, as applicable, that are equal to the fair market value of our common stock on the date of grant as determined by our board of directors.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information regarding all outstanding equity awards for each of our named executive officers as of December 31, 2020:

NAME	OPTION AWARDS				STOCK AWARDS	
	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS (#) EXERCISABLE	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS (#) UNEXERCISABLE	OPTION EXERCISE PRICE (\$)	OPTION EXPIRATION DATE	NUMBER OF SHARES OR UNITS OF STOCK THAT HAVE NOT VESTED (#)	MARKET VALUE OF SHARES OR UNITS OF STOCK THAT HAVE NOT VESTED (\$) ⁽¹⁾
Daniel J. Hicklin, Ph.D.	—	—	—	—	323,524 ⁽²⁾	\$ 5,176,384
	—	727,377 ⁽³⁾	\$ 4.77	12/7/2030	—	—
Randi Isaacs, M.D.	—	176,966 ⁽⁴⁾	\$ 3.03	11/8/2030	—	—
	—	140,208 ⁽⁵⁾	\$ 4.77	12/7/2030	—	—
Cynthia Seidel-Dugan, Ph.D.	—	—	—	—	41,719 ⁽⁶⁾	\$ 667,504
	—	61,136 ⁽⁷⁾	\$ 1.56	5/19/2030	—	—
	—	99,163 ⁽⁸⁾	\$ 4.77	12/7/2030	—	—

(1) The market price of our common stock is based on the initial public offering price of \$16.00 per share.

(2) Represents the unvested portion of Dr. Hicklin's restricted stock award for 611,058 shares of our common stock. Of these shares 93,419 shares were fully vested on the date of grant and 517,639 shares vest over four years, with 25% of such shares vesting on June 1, 2020, and the remainder vesting in equal monthly installments thereafter, subject to continuous service.

(3) Dr. Hicklin's stock option for 727,377 shares of our common stock vests over four years, with 25% of the shares vesting on December 8, 2021, and the remainder vesting in equal monthly installments thereafter, subject to continuous service.

(4) Dr. Isaacs' stock option for 176,966 shares of our common stock vests over four years, with 25% of the shares vesting on November 9, 2021, and the remainder vesting in equal monthly installments thereafter, subject to continuous service.

(5) Dr. Isaacs' stock option for 140,208 shares of our common stock vests over four years, with 25% of the shares vesting on December 8, 2021, and the remainder vesting in equal monthly installments thereafter, subject to continuous service.

(6) Represents the unvested portion of Dr. Seidel-Dugan's restricted stock award for 125,157 shares of our common stock which vests over four years, with 25% of the shares vesting on April 1, 2019, and the remainder vesting in equal monthly installments thereafter, subject to continuous service.

(7) Dr. Seidel-Dugan's stock option for 61,136 shares of our common stock vests over four years, with 25% of the shares vesting on June 1, 2021, and the remainder vesting in equal monthly installments thereafter, subject to continuous service.

(8) Dr. Seidel-Dugan's stock option for 99,163 shares of our common stock vests over four years, with 25% of the shares vesting on December 8, 2021, and the remainder vesting in equal monthly installments thereafter, subject to continuous service.

Employment Arrangements and Severance Agreements with our Named Executive Officers

In April 2021, we entered into employment agreements with each of our named executive officers that became effective upon the date that the registration statement of which this prospectus forms a part became effective. These employment agreements set forth the terms and conditions of each executive's continued employment with us, including base salary, target annual bonus opportunity, standard employee benefit plan participation and certain benefits upon termination of the executive under specified conditions. The employment of all of our named executive officers is at will.

Under the employment agreements, Dr. Hicklin's base salary is \$510,000 and his annual target bonus amount is 50%, Dr. Isaac's base salary is \$425,000 and her annual target bonus amount is 40%, and Dr. Seidel-Dugan's base salary is \$400,000 and her annual target bonus amount is 40%. The employment agreements provide that, in the event that the executive's employment is terminated by us without "cause" or by the executive for "good reason," then subject to the execution and effectiveness of a separation and release agreement, the executive will be entitled to receive (i) an amount equal to (x) 12 months of base salary in the case of Dr. Hicklin if such termination occurs more than three months prior to or more than 12 months following a "change in control," and nine months of base

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salary in the case of Drs. Isaacs and Seidel-Dugan if such termination occurs prior to or more than 12 months following a change in control, in each case, payable on our regular payroll practices, or (y) 18 months of base salary in the case of Dr. Hicklin if such termination occurs within three months prior to or 12 months following a change in control, and 12 months base salary in the case of Drs. Isaacs and Seidel-Dugan if such termination occurs within 12 months following a change in control, in each case, payable in a lump sum; (ii) an amount equal to the executive's full target bonus for the year in which the executive's date of termination occurs payable as a lump sum, if such termination occurs within three months prior to or 12 months following a change in control in the case of Dr. Hicklin or if such termination occurs within 12 months following a change in control in the case of Drs. Isaacs and Seidel-Dugan; and (iii) payment of the monthly employer COBRA premium for a period corresponding to the months of base salary paid. In addition, the employment agreements provide that in the event of a termination of the executive's employment by us without cause or by the executive for good reason then, subject to the timely execution of the separation and release agreement, the vesting of all unvested equity awards that vest solely on the passage of time held by the executive will be accelerated (i) as to six additional months of vesting if such termination occurs more than three months prior to or more than 12 months following a change in control in the case of Dr. Hicklin, or prior to or more than 12 months following a change in control in the case of Drs. Isaacs and Seidel-Dugan, provided that, if Dr. Isaacs has been employed by us for less than six months as of the date of termination, the vesting of such equity awards will not be accelerated and, if Dr. Isaacs has been employed by us for more than six months but less than one year as of the date of termination, the vesting of such equity awards will be accelerated as to 25% of such equity awards, and (ii) in full if such termination occurs within three months prior to or 12 months following a change in control in the case of Dr. Hicklin, or within 12 months following a change in control in the case of Drs. Isaacs and Seidel-Dugan.

Employee Benefit and Equity Compensation Plans

In this section we describe the 2017 Plan, the 2021 Plan, and our 2021 Employee Stock Purchase Plan, or the 2021 ESPP. Prior to this offering, we granted awards to eligible participants under the 2017 Plan. Following this offering, we expect to grant awards to eligible participants from time to time only under the 2021 Plan. These summaries of the equity incentive plans are qualified in their entirety by reference to the actual text of the plans, which are filed as exhibits to the registration statement of which this prospectus is a part.

2017 Stock Incentive Plan

The 2017 Plan was initially approved by our board of directors and our stockholders in December 2017, and was subsequently amended to increase the total number of shares reserved for issuance thereunder. The 2017 Plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, awards of restricted stock, restricted stock units and other stock-based awards. Our employees, officers, directors, consultants and advisors are eligible to receive awards under the 2017 Plan; however, incentive stock options may only be granted to our employees. The type of award granted under the 2017 Plan and the terms of such award are set forth in the applicable award agreement. Pursuant to the terms of the 2017 Plan, our board of directors (or a committee delegated by our board of directors) administers the plan and, subject to any limitations in the plan, selects the recipients of awards and determines:

- the number of shares of our common stock covered by options and the dates upon which the options become exercisable;
- the type of options to be granted;
- the duration of options, which may not be in excess of ten years;
- the exercise price of options, which must be at least equal to the fair market value of our common stock on the date of grant; and
- the number of shares of our common stock subject to, and the terms and conditions of, any stock appreciation rights, awards of restricted stock, restricted stock units or other stock-based awards, including conditions for repurchase or cancellation, measurement price, issue price and repurchase price, if any (though the measurement price of stock appreciation rights must be at least equal to the fair market value of our common stock on the date of grant and the duration of such awards may not be in excess of ten years) and any performance conditions.

The maximum number of shares of common stock authorized for issuance under the 2017 Plan is 3,728,334 shares. Our board of directors may amend, suspend or terminate the 2017 Plan at any time, except that stockholder approval may be required to comply with applicable law.

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Effect of Certain Changes in Capitalization

In the event of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any dividend or distribution to holders of our common stock other than an ordinary cash dividend, we are required by the 2017 Plan to make equitable adjustments (or make substitute awards, if applicable), in the manner determined by our board of directors, to:

- the number and class of securities available under the 2017 Plan;
- the number and class of securities and exercise price per share of each outstanding option;
- the share and per-share provisions and measurement price of each outstanding stock appreciation right;
- the number of shares and the repurchase price per share subject to each outstanding award of restricted stock; and
- the share and per-share related provisions and purchase price, if any, of each outstanding restricted stock unit award and each other stock-based award.

Effect of Certain Corporate Transactions

Upon the occurrence of a merger or other reorganization event (as defined in the 2017 Plan), our board of directors may, on such terms as our board of directors determines (except to the extent specifically provided otherwise in an applicable award agreement or other agreement between the participant and us), take any one or more of the following actions pursuant to the 2017 Plan as to all or any (or any portion of) outstanding awards, other than awards of restricted stock:

- provide that outstanding awards will be assumed, or substantially equivalent awards will be substituted, by the acquiring or succeeding corporation (or an affiliate of the acquiring or succeeding corporation);
- upon written notice to a participant, provide that all of the participant's unexercised and/or unvested awards will terminate immediately prior to the consummation of such transaction unless exercised, to the extent exercisable, by the participant within a specified period following the date of such notice;
- provide that outstanding awards will become exercisable, realizable or deliverable, or restrictions applicable to an award will lapse, in whole or in part, prior to or upon the reorganization event;
- in the event of a reorganization event pursuant to which holders of our common stock will receive a cash payment for each share surrendered in the reorganization event, make or provide for a cash payment to participants with respect to each award held by a participant equal to (1) the number of shares of our common stock subject to the vested portion of the award (after giving effect to any acceleration of vesting that occurs upon or immediately prior to such reorganization event) multiplied by (2) the excess, if any, of the cash payment for each share surrendered in the reorganization event over the exercise, measurement or purchase price of such award and any applicable tax withholdings, in exchange for the termination of such award;
- provide that, in connection with our liquidation or dissolution, awards convert into the right to receive liquidation proceeds (if applicable, net of the exercise, measurement or purchase price thereof and any applicable tax withholdings); or
- any combination of the foregoing.

In taking any of the foregoing actions, our board of directors is not obligated by the 2017 Plan to treat all awards, all awards held by a participant, or all awards of the same type, identically.

In the case of certain restricted stock units, no assumption or substitution is permitted, and the restricted stock units will instead be settled in accordance with the terms of the applicable restricted stock unit agreement.

Upon the occurrence of a reorganization event other than our liquidation or dissolution, our repurchase and other rights with respect to outstanding awards of restricted stock will continue for the benefit of the succeeding company and will, unless our board of directors determines otherwise, apply to the cash, securities or other property which our common stock was converted into or exchanged for pursuant to the reorganization event in the same manner and to the same extent as they applied to the common stock subject to the restricted stock award. However, our board of directors may provide for the termination or deemed satisfaction of such repurchase or other rights under the restricted stock award agreement or any other agreement between a participant and us, either initially or by amendment, or provide for forfeiture of such restricted stock if issued at no cost. Upon the occurrence of a reorganization event involving our liquidation or dissolution, except to the extent specifically provided to the contrary

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in the restricted stock award agreement or any other agreement between the participant and us, all restrictions and conditions on all outstanding restricted stock awards will automatically be deemed terminated or satisfied.

Our board of directors may at any time provide that any award under the 2017 Plan shall become immediately exercisable in whole or in part, free of some or all restrictions or conditions, or otherwise realizable in whole or in part, as the case may be.

As of March 31, 2021, there were options to purchase an aggregate of 2,401,085 shares of common stock outstanding under the 2017 Plan at a weighted-average exercise price of \$4.16 per share and 28,983 shares of common stock were available for future issuance under the 2017 Plan. No further awards will be made under the 2017 Plan; however, awards outstanding under the 2017 Plan will continue to be governed by their existing terms.

2021 Stock Incentive Plan

Our board of directors adopted and our stockholders approved the 2021 Plan, which became effective immediately prior to the effectiveness of the registration statement for this offering. The 2021 Plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock units and other stock-based awards. The number of shares of our common stock reserved for issuance under the 2021 Plan is the sum of (1) 2,843,116 shares; plus (2) the number of shares as is equal to the sum of (x) the number of shares of our common stock reserved for issuance under the 2017 Plan that remained available for grant under the 2017 Plan immediately prior to the effectiveness of the registration statement for this offering and (y) the number of shares of our common stock subject to outstanding awards granted under the 2017 Plan that expire, terminate or are otherwise surrendered, cancelled, forfeited or repurchased by us at their original issuance price pursuant to a contractual repurchase right; plus (3) an annual increase, to be added on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2022 and continuing until, and including, the fiscal year ending December 31, 2031, equal to the lesser of (i) 5% of the number of shares of our common stock outstanding on such date, and (ii) an amount determined by our board of directors. The number of shares of common stock available for issuance under the 2021 Plan that may be issued as incentive stock options is equal to the sum of 2,843,116 shares, plus an annual increase, to be added on the first day of each fiscal year, equal to the lesser of the number of shares subject to the annual increase described in the foregoing sentence for such year and 3,000,000 shares.

Our employees, officers, directors, consultants and advisors are eligible to receive awards under the 2021 Plan; however, incentive stock options may only be granted to our employees. We have agreed to grant stock options to purchase an aggregate of 92,800 shares of our common stock to certain of our non-employee directors pursuant to our director compensation program. See “—Director Compensation—Non-Employee Director Compensation Policy”. In addition to the IPO Grants we have agreed to make to Drs. Hicklin, Isaacs and Seidel-Dugan, we have also agreed to grant similar stock options to our other executive officers for the purchase, in the aggregate, of that number of shares of common stock equal to 0.28% of the number of fully diluted shares outstanding following the closing of this offering. Each of these stock options will be granted under the 2021 Plan, have an exercise price per share equal to the public offering price, be granted effective upon the commencement of trading of our common stock on the Nasdaq Global Select Market and vest as to 2.0833% (1/48th) of the shares underlying the option for each month of continuous service following the date of grant. The IPO Grants, together with these options we will grant to our other executive officers, will in the aggregate cover a total of 400,632 shares of our common stock.

Pursuant to the terms of the 2021 Plan, our board of directors (or a committee delegated by our board of directors) administers the 2021 Plan and, subject to any limitations set forth in the 2021 Plan, selects the recipients of awards and determines:

- the number of shares of our common stock covered by options and the dates upon which the options become exercisable;
- the type of options to be granted;
- the exercise price of options, which price must be at least equal to the fair market value of our common stock on the date of grant;
- the duration of options, which may not be in excess of ten years;

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- the methods of payment of the exercise price of options; and
- the number of shares of our common stock subject to and the terms and conditions of any stock appreciation rights, awards of restricted stock, restricted stock units or other stock-based awards, including conditions for repurchase, measurement price, issue price and repurchase price, if any (though the measurement price of stock appreciation rights must be at least equal to the fair market value of our common stock on the date of grant and the duration of such awards may not be in excess of ten years) and any performance conditions.

If our board of directors delegates authority to one or more of our officers to grant awards under the 2021 Plan, the officer will have the power to make awards to all of our employees, except officers and executive officers (as such terms are defined in the 2021 Plan). Our board of directors will fix the terms of the awards to be granted by any such officer, the maximum number of shares subject to awards that any such officer may grant, and the time period in which such awards may be granted.

The 2021 Plan contains limits on the compensation that may be paid to our non-employee directors. The maximum amount of cash and value (calculated based on grant date fair value for financial reporting purposes) of awards granted under the plan in any calendar year to any individual non-employee director in his or her capacity as a non-employee director may not exceed \$750,000, or in the case of a new director during his or her first year of service, \$1,000,000; provided, however, that fees paid by us on behalf of any non-employee director in connection with regulatory compliance and any amounts paid to a non-employee director as reimbursement of an expense shall not count against the foregoing limit. Our board of directors may make additional exceptions to this limit for individual non-employee directors in extraordinary circumstances, as the board of directors may determine in its discretion, provided that the non-employee director receiving such additional compensation may not participate in the decision to award such compensation. For the avoidance of doubt, the maximum amount set forth above will not apply to cash or awards granted under the 2021 Plan to a non-employee director in his or her capacity as a consultant or advisor to us.

Effect of Certain Changes in Capitalization

In the event of any stock split, reverse stock split, stock dividend, recapitalization, combination of shares, reclassification of shares, spin-off or other similar change in capitalization or event, or any dividend or distribution to holders of our common stock other than an ordinary cash dividend, we are required by the 2021 Plan to make equitable adjustments (or make substitute awards, if applicable), in the manner determined by our board of directors, to:

- the number and class of securities available under the 2021 Plan;
- the share counting rules of the 2021 Plan;
- the number and class of securities and exercise price per share of each outstanding option;
- the share and per-share provisions and measurement price of each outstanding stock appreciation right;
- the number of shares and the repurchase price per share subject to each outstanding award of restricted stock; and
- the share and per-share related provisions and purchase price, if any, of each outstanding restricted stock unit award and each other stock-based award.

Effect of Certain Corporate Transactions

Upon the occurrence of a merger or other reorganization event (as defined in the 2021 Plan), our board of directors may, on such terms as our board of directors determines (except to the extent specifically provided otherwise in an applicable award agreement or other agreement between the participant and us), take any one or more of the following actions pursuant to the 2021 Plan as to all or any (or any portion of) outstanding awards, other than awards of restricted stock:

- provide that outstanding awards will be assumed, or substantially equivalent awards will be substituted, by the acquiring or succeeding corporation (or an affiliate of the acquiring or succeeding corporation);
- upon written notice to a participant, provide that all of the participant's unvested awards will be forfeited immediately prior to the consummation of the reorganization event and/or vested but unexercised awards will terminate immediately prior to the consummation of such transaction unless exercised, to the extent exercisable, by the participant within a specified period following the date of such notice;
- provide that outstanding awards will become exercisable, realizable or deliverable, or restrictions applicable to an award will lapse, in whole or in part, prior to or upon the reorganization event;

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- in the event of a reorganization event pursuant to which holders of our common stock will receive a cash payment for each share surrendered in the reorganization event, make or provide for a cash payment to participants with respect to each award held by a participant equal to (1) the number of shares of our common stock subject to the vested portion of the award (after giving effect to any acceleration of vesting that occurs upon or immediately prior to such reorganization event) multiplied by (2) the excess, if any, of the cash payment for each share surrendered in the reorganization event over the exercise, measurement or purchase price of such award and any applicable tax withholdings, in exchange for the termination of such award;
- provide that, in connection with our liquidation or dissolution, awards convert into the right to receive liquidation proceeds (if applicable, net of the exercise, measurement or purchase price thereof and any applicable tax withholdings); or
- any combination of the foregoing.

In taking any of the foregoing actions, our board of directors is not obligated by the 2021 Plan to treat all awards, all awards held by a participant, or all awards of the same type, identically.

In the case of certain restricted stock units, no assumption or substitution is permitted, and the restricted stock units will instead be settled in accordance with the terms of the applicable restricted stock unit agreement.

Upon the occurrence of a reorganization event other than our liquidation or dissolution, our repurchase and other rights with respect to each outstanding award of restricted stock will continue for the benefit of the acquiring or succeeding company (or any affiliate of the acquiring or succeeding corporation) and will, unless our board of directors determines otherwise, apply to the cash, securities, or other property which our common stock is converted into or exchanged for pursuant to the reorganization event in the same manner and to the same extent as they applied to the common stock subject to the restricted stock award. However, our board of directors may provide for the termination or deemed satisfaction of such repurchase or other rights under the restricted stock award agreement or in any other agreement between a participant and us, either initially or by amendment. Upon the occurrence of a reorganization event involving our liquidation or dissolution, except to the extent specifically provided to the contrary in the restricted stock award agreement or any other agreement between the participant and us, all restrictions and conditions on each outstanding restricted stock award will automatically be deemed terminated or satisfied.

Our board of directors may, at any time, provide that any award under the 2021 Plan will become immediately exercisable in whole or in part, free of some or all restrictions or conditions, or otherwise realizable in whole or in part, as the case may be.

Except with respect to certain actions requiring stockholder approval under the Internal Revenue Code of 1986, as amended, or the Code, or Nasdaq Stock Market rules, our board of directors may amend, modify or terminate any outstanding award under the 2021 Plan, including but not limited to, substituting for the award another award of the same or a different type, changing the date of exercise or realization, and converting an incentive stock option to a nonstatutory stock option, subject to certain participant consent requirements. However, unless our stockholders approve such action, the 2021 Plan provides that we may not (except as otherwise permitted in connection with a change in capitalization or reorganization event):

- amend any outstanding stock option or stock appreciation right granted under the 2021 Plan to provide an exercise or measurement price per share that is lower than the then-current exercise or measurement price per share of such outstanding award;
- cancel any outstanding stock option or stock appreciation right (whether or not granted under the 2021 Plan) and grant a new award under the 2021 Plan in substitution for the cancelled award (other than substitute awards permitted in connection with a merger or consolidation of an entity with us or our acquisition of property or stock of another entity) covering the same or a different number of shares of our common stock and having an exercise or measurement price per share lower than the then-current exercise or measurement price per share of the cancelled award;
- cancel in exchange for a cash payment any outstanding option or stock appreciation right with an exercise or measurement price per share above the then-current fair market value of our common stock (valued in the manner determined by (or in the manner approved by) our board of directors); or

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- take any other action that constitutes a “repricing” within the meaning of Nasdaq Stock Market rules or rules of any other exchange or marketplace on which our common stock is listed or traded.

No award may be granted under the 2021 Plan on or after the date that is ten years from the effectiveness of the 2021 Plan. Our board of directors may amend, suspend or terminate the 2021 Plan at any time, except that stockholder approval may be required to comply with applicable law or stock market requirements.

2021 Employee Stock Purchase Plan

Our board of directors adopted and our stockholders approved the 2021 ESPP, which became effective immediately prior to the effectiveness of the registration statement for this offering. The 2021 ESPP is administered by our board of directors or by a committee appointed by our board of directors. The 2021 ESPP initially provides participating employees with the opportunity to purchase up to an aggregate of 244,000 shares of our common stock. The number of shares of our common stock reserved for issuance under the 2021 ESPP will automatically increase on the first day of each fiscal year, beginning with the fiscal year ending December 31, 2022 and continuing for each fiscal year until, and including, the fiscal year ending on December 31, 2032, in an amount equal to the lowest of (1) 488,000 shares of our common stock, (2) 1% of the number of shares of our common stock outstanding on such date, and (3) an amount determined by our board of directors.

All of our employees and employees of any designated subsidiary, as defined in the 2021 ESPP, are eligible to participate in the 2021 ESPP, provided that:

- such person is customarily employed by us or a designated subsidiary for more than 20 hours a week and for more than five months in a calendar year; and
- such person was our employee or an employee of a designated subsidiary on the first day of the applicable offering period under the 2021 ESPP.

We retain the discretion to determine which eligible employees may participate in an offering under applicable regulations.

We expect to make one or more offerings to our eligible employees to purchase stock under the 2021 ESPP beginning at such time and on such dates as our board of directors may determine, or on the first business day thereafter. Each offering will consist of a six-month offering period during which payroll deductions will be made and held for the purchase of our common stock at the end of the offering period. Our board of directors or a committee designated by the board of directors may, at its discretion, choose a different period of not more than 12 months for offerings.

On each offering commencement date, each participant will be granted an option to purchase, on the last business day of the offering period, up to a number of shares of our common stock determined by multiplying \$2,083 by the number of full months in the offering period and dividing that product by the closing price of our common stock on the first day of the offering period. No employee may be granted an option under the 2021 ESPP that permits the employee's rights to purchase shares under the 2021 ESPP and any other employee stock purchase plan of ours or of any of our subsidiaries to accrue at a rate that exceeds \$25,000 of the fair market value of our common stock (determined as of the first day of each offering period) for each calendar year in which the option is outstanding. In addition, no employee may purchase shares of our common stock under the 2021 ESPP that would result in the employee owning 5% or more of the total combined voting power or value of our stock or the stock of any of our subsidiaries.

Each eligible employee may authorize up to a maximum of 15% of his or her compensation to be deducted by us during the offering period. Each employee who continues to be a participant in the 2021 ESPP on the last business day of the offering period will be deemed to have exercised an option to purchase from us the number of whole shares of our common stock that his or her accumulated payroll deductions on such date will pay for, not in excess of the maximum numbers set forth above. Under the terms of the 2021 ESPP, the purchase price will be determined by our board of directors or the committee for each offering period and will be at least 85% of the applicable closing price of our common stock. If our board of directors or the committee does not make a determination of the purchase price, the purchase price will be 85% of the lesser of the closing price of our common stock on the first business day of the offering period or on the last business day of the offering period.

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An employee may at any time prior to the close of business on the fifteenth business day (or such other number of days as is determined by us) prior to the end of the offering period, and for any reason, permanently withdraw from participating in the offering and permanently withdraw the balance accumulated in the employee's account. Partial withdrawals are not permitted. If an employee elects to discontinue his or her payroll deductions during an offering period but does not elect to withdraw his or her funds, funds previously deducted will be applied to the purchase of common stock at the end of the offering period. If a participating employee's employment ends before the last business day of an offering period, no additional payroll deductions will be taken and the balance in the employee's account will be paid to the employee.

We will be required to make equitable adjustments to the extent determined by our board of directors or a committee thereof to the number and class of securities available under the 2021 ESPP, the share limitations under the 2021 ESPP, and the purchase price for an offering period under the 2021 ESPP to reflect stock splits, reverse stock splits, stock dividends, recapitalizations, combinations of shares, reclassifications of shares, spin-offs and other similar changes in capitalization or events or any dividends or distributions to holders of our common stock other than ordinary cash dividends.

In connection with a merger or other reorganization event, as defined in the 2021 ESPP, our board of directors or a committee of our board of directors may take any one or more of the following actions as to outstanding options to purchase shares of our common stock under the 2021 ESPP on such terms as our board of directors or committee thereof determines:

- provide that options will be assumed, or substantially equivalent options will be substituted, by the acquiring or succeeding corporation (or an affiliate of the acquiring or succeeding corporation);
- upon written notice to employees, provide that all outstanding options will be terminated immediately prior to the consummation of such reorganization event and that all such outstanding options will become exercisable to the extent of accumulated payroll deductions as of a date specified by the board of directors or committee thereof in such notice, which date will not be less than ten days preceding the effective date of the reorganization event;
- upon written notice to employees, provide that all outstanding options will be cancelled as of a date prior to the effective date of the reorganization event and that all accumulated payroll deductions will be returned to participating employees on such date;
- in the event of a reorganization event under the terms of which holders of our common stock will receive upon consummation thereof a cash payment for each share surrendered in the reorganization event, change the last day of the offering period to be the date of the consummation of the reorganization event and make or provide for a cash payment to each employee equal to (1) the cash payment for each share surrendered in the reorganization event times the number of shares of our common stock that the employee's accumulated payroll deductions as of immediately prior to the reorganization event could purchase at the applicable purchase price, where the cash payment for each share surrendered in the reorganization event is treated as the fair market value of our common stock on the last day of the applicable offering period for purposes of determining the purchase price and where the number of shares that could be purchased is subject to the applicable limitations under the 2021 ESPP minus (2) the result of multiplying such number of shares by the purchase price; and/or
- provide that, in connection with our liquidation or dissolution, options convert into the right to receive liquidation proceeds (net of the purchase price thereof).

Our board of directors may at any time, and from time to time, amend or suspend the 2021 ESPP or any portion of the 2021 ESPP. We will obtain stockholder approval for any amendment if such approval is required by Section 423 of the Code. Further, our board of directors may not make any amendment that would cause the 2021 ESPP to fail to comply with Section 423 of the Code. The 2021 ESPP may be terminated at any time by our board of directors. Upon termination, we will refund all amounts in the accounts of participating employees.

401(k) Plan

We maintain a defined contribution employee retirement plan for our employees, including our named executive officers. The plan is intended to qualify as a tax-qualified 401(k) plan so that contributions to the 401(k) plan, and

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income earned on such contributions, are not taxable to participants until withdrawn or distributed from the 401(k) plan (except in the case of contributions under the 401(k) plan designated as Roth contributions). Under the 401(k) plan, each employee is fully vested in his or her deferred salary contributions and any qualified nonelective contributions made by us. Employee contributions are held and invested by the plan's trustee as directed by participants. The 401(k) plan provides us with the discretion to match employee contributions.

Health/Welfare Plans

All of our full-time employees, including our named executive officers, are eligible to participate in our health and welfare plans, including medical and dental benefits, short-term and long-term disability insurance, and life insurance. We believe these benefits are necessary and appropriate to provide a competitive compensation package to our named executive officers.

Rule 10b5-1 Plans

Our directors and executive officers may adopt written plans, known as Rule 10b5-1 plans, in which they will contract with a broker to buy or sell shares of our common stock on a periodic basis. Under a Rule 10b5-1 plan, a broker executes trades pursuant to parameters established by the director or officer when entering into the plan, without further direction from the director or officer. It also is possible that the director or officer could amend the plan in certain circumstances when not in possession of material nonpublic information or terminate the plan. In addition, our directors and executive officers may buy or sell additional shares outside of a Rule 10b5-1 plan when they are not in possession of material nonpublic information.

Limitations on Liability and Indemnification Matters

Our restated certificate of incorporation, which will become effective upon the closing of this offering, limits the liability of our directors for breach of fiduciary duty to the maximum extent permitted by the Delaware General Corporation Law, or the DGCL, and provides that no director will have personal liability to us or to our stockholders for monetary damages for breach of fiduciary duty as a director. However, these provisions do not eliminate or limit the liability of any of our directors:

- for any breach of the director's duty of loyalty to us or our stockholders;
- for acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law;
- for voting for or assenting to unlawful payments of dividends, stock repurchases or other distributions; or
- for any transaction from which the director derived an improper personal benefit.

Any amendment to or repeal of these provisions will not eliminate or reduce the effect of these provisions in respect of any act, omission or claim that occurred or arose prior to such amendment or repeal. If the DGCL is amended to provide for further limitations on the personal liability of directors of corporations, then the personal liability of our directors will be further limited to the greatest extent permitted by the DGCL.

In addition, our restated certificate of incorporation, which will become effective upon the closing of this offering, provides that we must indemnify our directors and officers and we must advance expenses, including attorneys' fees, to our directors and officers in connection with legal proceedings, subject to very limited exceptions.

We maintain a general liability insurance policy that covers specified liabilities of our directors and officers arising out of claims based on acts or omissions in their capacities as directors or officers. In addition, we have entered into or intend to enter into new indemnification agreements with all of our executive officers and directors prior to the completion of this offering. These indemnification agreements may require us, among other things, to indemnify each such executive officer or director for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by him or her in any action or proceeding arising out of his or her service as one of our executive officers or directors.

Some of our non-employee directors may, through their relationships with their employers, be insured or indemnified against specified liabilities incurred in their capacities as members of our board of directors.

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Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, executive officers or persons controlling us, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act of 1933, as amended and is therefore unenforceable.

Director Compensation

During the year ended December 31, 2020, no compensation was paid to our non-employee directors. Daniel J. Hicklin, our President and Chief Executive Officer, is also a member of our board of directors, but he did not receive any additional compensation for service as a director. Dr. Hicklin's compensation as an executive officer is set forth above under "—Summary Compensation Table."

As of December 31, 2020, none of our non-employee directors held shares of our common stock or stock options for the purchase of our common stock other than Dr. Morrison who held 12,612 shares of our common stock issued upon exercise of a stock option and an outstanding stock option to purchase 33,958 shares of our common stock at an exercise price of \$1.56.

Non-Employee Director Compensation Policy

We have historically reimbursed our non-employee directors for reasonable travel and out-of-pocket expenses incurred in connection with attending board of director and committee meetings.

In April 2021, our board of directors approved a non-employee director compensation program, which became effective upon the effectiveness of the registration statement of which this prospectus is a part, that is designed to enable us to attract and retain, on a long-term basis, highly qualified non-employee directors. Under this director compensation program, we will pay our non-employee directors a cash retainer for service on the board of directors and for service on each committee on which the director is a member. The chair of the board and of each committee will receive higher retainers for such service. These fees are payable in arrears in four equal quarterly installments on the last day of each quarter, provided that the amount of such payment will be prorated for any portion of such quarter that the director is not serving on our board of directors and no fee will be payable in respect of any period prior to the completion of this offering. The fees paid to non-employee directors for service on the board of directors and for service on each committee of the board of directors on which the director is a member are as follows:

	MEMBER ANNUAL FEE	CHAIR ADDITIONAL ANNUAL FEE
Board of Directors	\$ 35,000	\$ 30,000
Audit Committee	7,500	7,500
Compensation Committee	5,000	5,000
Nominating and Corporate Governance Committee	4,000	4,000

We also will continue to reimburse our non-employee directors for reasonable travel and other expenses incurred in connection with attending meetings of our board of directors and any committee of our board of directors on which they serve.

In addition, under our director compensation program, each non-employee director (other than Mr. Asanuma) serving on our board at the time of effectiveness of the registration statement of which this prospectus forms a part and each non-employee director elected to our board of directors after this offering upon his or her election or appointment to our board of directors will receive an option to purchase 23,200 shares of our common stock under the 2021 Plan. The grants to our existing directors will have an exercise price equal to the initial public offering price. Each of these options will vest with respect to one-third of such shares on the first anniversary of the grant date and thereafter in equal monthly installments until all shares are vested on the third anniversary of the grant date, subject to the non-employee director's continued service as a director. Further, on the date of each annual meeting of stockholders, each non-employee director will receive, under the 2021 Plan, an option to purchase 11,600 shares of our common stock under the 2021 Plan provided that if any director is initially elected to the board of directors in the twelve months preceding the annual meeting, the number of shares subject to the option will be pro rated on a monthly

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basis for time in service (including partial months). Each of these options will vest in full on the earlier of the first anniversary of the grant date and the next annual meeting of stockholders following the grant date, subject to the non-employee director's continued service as a director. All options issued to our non-employee directors under our director compensation program will be issued at exercise prices equal to the fair market value of our common stock on the date of grant and will have a term of ten years. Upon a change of control of our company any unvested options held by our non-employee directors will automatically vest.

CERTAIN RELATIONSHIPS AND RELATED PERSON TRANSACTIONS

Since January 1, 2018, we have engaged in the following transactions in which the amounts involved exceeded \$120,000 and any of our directors, executive officers or holders of more than 5% of our voting securities, or any member of the immediate family of, or person sharing the household with, the foregoing persons, had or will have a direct or indirect material interest. We believe that all of the transactions described below were made on terms no less favorable to us than could have been obtained from unrelated third parties.

Private Placement of Securities

Convertible Promissory Notes

From December 2017 to August 2018, we issued and sold convertible promissory notes, or Convertible Notes, in the aggregate principal amount of \$11,000,000. The Convertible Notes accrued interest at a rate of 8% per annum. The following table sets forth the aggregate principal amount of the Convertible Notes issued to our directors, officers and holders of more than 5% of our capital stock and their affiliates.

<u>PURCHASER ⁽¹⁾</u>	<u>AGGREGATE PRINCIPAL AMOUNT</u>
Entities affiliated with MPM Capital	\$ 6,000,000
UBS Oncology Impact Fund, L.P.	\$ 5,000,000

⁽¹⁾ See "Principal Stockholders" for additional information about shares held by these entities.

In August 2019, all interest and principal under the Convertible Notes were converted into 17,103,716 shares of our Series A preferred stock in connection with the initial closing of our Series A preferred stock financing, as described in further detail below.

Common Stock Warrants

From April 2018 to August 2018, we simultaneously issued to each purchaser of a Convertible Note a warrant, or Warrant, to purchase shares of our common at an exercise price of \$0.09 per share. Each Warrant was originally exercisable for the number of shares of common stock equal to 20% of the original principal amount of the corresponding Convertible Note divided by a price per share to be determined at the time the Convertible Notes were converted into shares of our preferred stock. On August 2, 2019, the Warrants were amended such that each Warrant would be exercisable for the number of shares of common stock equal to 3.25% of the original principal amount of the corresponding Convertible Note divided by \$0.70, the purchase price per share of the Series A preferred stock issued in connection with our Series A preferred stock financing.

The following table sets forth the number of shares of common stock issuable upon exercise of Warrants issued to our directors, officers and holders of more than 5% of our capital stock and their affiliates between April 2018 and August 2018.

<u>PURCHASER ⁽¹⁾</u>	<u>SHARES OF COMMON STOCK</u>
Entities affiliated with MPM Capital	32,128
UBS Oncology Impact Fund, L.P.	26,776

⁽¹⁾ See "Principal Stockholders" for additional information about shares held by these entities.

Series A Preferred Stock Financing

From August 2019 to November 2019, in connection with the initial closing of our Series A preferred stock financing, we issued and sold 31,571,424 shares of our Series A preferred stock at a price per share of \$0.70 in cash, for an aggregate purchase price of \$22,099,997 and also issued 17,103,716 shares of our Series A preferred stock upon conversion of the Convertible Notes. The following table sets forth the aggregate number of shares of our

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Series A preferred stock that we issued and sold between August 2019 and November 2019 to our directors, officers and holders of more than 5% of our capital stock and their affiliates in the initial closing of our Series A preferred stock financing and the aggregate amount of consideration for such shares:

PURCHASER ⁽¹⁾	SHARES OF SERIES A PREFERRED STOCK	TOTAL PURCHASE PRICE
Entities affiliated with MPM Capital	16,606,964	\$11,624,876 ⁽²⁾
UBS Oncology Impact Fund, L.P.	11,353,893	\$ 7,947,726 ⁽³⁾
Taiho Ventures, LLC	5,714,285	\$ 4,000,000
Arkin Bio Ventures 2 L.P.	5,357,142	\$ 3,749,999
Longwood Fund III, L.P.	4,642,857	\$ 3,250,000
UPMC	3,571,428	\$ 2,500,000

⁽¹⁾ See "Principal Stockholders" for additional information about shares held by these entities.

⁽²⁾ Includes \$6,524,876.71 of interest and principal that was converted into 9,321,251 shares of Series A preferred stock upon conversion of the Convertible Notes held by these purchasers. See "—Convertible Promissory Notes."

⁽³⁾ Includes \$5,447,726.03 of interest and principal that was converted into 7,782,465 shares of Series A preferred stock upon conversion of the Convertible Notes held by this purchaser. See "—Convertible Promissory Notes."

In June 2020, in connection with the second closing of our Series A preferred stock financing, we issued an aggregate of 31,571,425 additional shares of our Series A preferred stock at a price per share of \$0.70 in cash, for an aggregate purchase price of \$22,099,998. The following table sets forth the aggregate number of shares of our Series A preferred stock that we issued in June 2020 to our directors, officers and holders of more than 5% of our capital stock and their affiliates in the second closing of our Series A preferred stock financing and the aggregate amount of consideration for such shares:

PURCHASER ⁽¹⁾	SHARES OF SERIES A PREFERRED STOCK	TOTAL PURCHASE PRICE
Entities affiliated with MPM Capital	7,285,713	\$5,099,999
UBS Oncology Impact Fund, L.P.	3,571,428	\$2,500,000
Taiho Ventures, LLC	5,714,285	\$4,000,000
Arkin Bio Ventures 2 L.P.	5,357,142	\$3,749,999
Longwood Fund III, L.P.	4,642,857	\$3,250,000
UPMC	3,571,429	\$2,500,000

⁽¹⁾ See "Principal Stockholders" for additional information about shares held by these entities.

Each share of Series A preferred stock is convertible into approximately 0.1154 shares of common stock.

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Series B Preferred Stock Financing

In December 2020, we issued and sold 78,222,173 shares of our Series B preferred stock at a price per share of \$0.92 in cash, for an aggregate purchase price of \$72,069,999. The following table sets forth the aggregate number of shares of our Series B preferred stock that we issued and sold to our directors, officers and holders of more than 5% of our capital stock and their affiliates and the aggregate amount of consideration for such shares:

PURCHASER ⁽¹⁾	SHARES OF SERIES B PREFERRED STOCK	TOTAL PURCHASE PRICE
Entities affiliated with RA Capital	19,536,550	\$18,000,000
Deerfield Partners, L.P.	15,195,094	\$14,000,000
Entities affiliated with MPM Capital	7,939,970	\$ 7,315,491
UBS Oncology Impact Fund, L.P.	4,959,955	\$ 4,569,855
Taiho Ventures, LLC	3,797,921	\$ 3,499,215
Arkin Bio Ventures 2 L.P.	3,560,551	\$ 3,280,514
Longwood Fund III, L.P.	3,085,811	\$ 2,843,112
UPMC	2,373,701	\$ 2,187,009

(1) See "Principal Stockholders" for additional information about shares held by these entities.

Each share of Series B preferred stock is convertible into approximately 0.1154 shares of common stock.

License Agreement with Harpoon Therapeutics, Inc.

In March 2018, we entered into an assignment and license agreement, or the Harpoon Agreement, with Harpoon Therapeutics, Inc., or Harpoon, which was a portfolio company of MPM Capital and UBS Oncology Impact Fund, L.P., each of which is a holder of more than 5% of our capital stock. Dr. Luke Evnin, the chairman of our board of directors, founded Harpoon in 2015 and served as the chairman of the board of directors of Harpoon from its inception until June 2020. Under the Harpoon Agreement, we assigned to Harpoon, and Harpoon assigned to us, certain patent rights held by each respective party. Harpoon also granted to us a license under certain other patents owned by Harpoon. Under the Harpoon Agreement, we agreed to pay to Harpoon an upfront fee of \$0.5 million and, if we commercialize any products covered by the licensed patents, a low single digit percentage royalty on net sales of such products, subject to an obligation to make a minimum annual royalty payment at an amount in the low hundreds of thousands of dollars beginning with the first commercial sale of any such product by us.

In December 2019, we and Harpoon amended the Harpoon Agreement by entering into the Second Amended and Restated Assignment and License Agreement, or the Second Amended Harpoon Agreement, which granted to us an additional license under certain patents owned by Harpoon. Under the Second Amended Harpoon Agreement, we agreed to pay to Harpoon a low single digit percentage royalty on net sales of any products that we commercialize covered by these additional licensed patents, subject to an obligation to make a minimum annual royalty payment at an amount in the low hundreds of thousands of dollars beginning with the first commercial sale of any such product by us. In addition, we also agreed to grant to Harpoon, and Harpoon agreed to grant to us, a license under certain other patents owned by each respective party. In 2018, in addition to the upfront payment we made to Harpoon, we made a payment of \$75,000 in reimbursement of Harpoon legal fees. See "Business—License and Royalty Agreements—License Agreement with Harpoon Therapeutics, Inc." for additional information regarding this agreement.

Amended and Restated Royalty Transfer Agreement

In December 2017, we entered into a royalty transfer agreement with MPM Oncology Impact Fund Charitable Foundation, Inc., or MPM Charitable Foundation, and UBS Optimus Foundation, or the Royalty Transfer Agreement. MPM Charitable Foundation is affiliated with MPM Capital, a holder of more than 5% of our capital stock. UBS Optimus Foundation is affiliated with UBS Oncology Impact Fund L.P., a holder of more than 5% of our capital stock. Under the Royalty Transfer Agreement, we are obligated to pay a royalty of 0.5% of net sales of our products to each of MPM Charitable Foundation and UBS Optimus Foundation. In August 2019, we amended the Royalty Transfer Agreement by entering into an amended and restated royalty transfer agreement, or the Amended Royalty

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Transfer Agreement, which provided that only products in our product pipeline at the time of our initial public offering or a change in control would be subject to the royalty on net sales. Under the Amended Royalty Transfer Agreement, our obligation to pay a royalty expires on a product-by-product and country-by-country basis upon the later of the 12th anniversary of the first commercial sale of such product in such country and expiration of the last valid claim in such country covering such product. The royalty rate is subject to a specified reduction for lack of any valid claim covering such product in a country. The obligation to pay royalties under the Amended Royalty Transfer Agreement shall not apply to any product that would only infringe our intellectual property rights that are discovered or developed after our initial public offering or to any product of an acquirer, assignee of the agreement or merger partner of ours so long as such product does not incorporate any of our pre-acquisition intellectual property.

Additionally, in December 2017, we entered into a royalty direction letter, which was amended and restated in August 2019, with MPM Charitable Foundation, UBS Optimus Foundation and UBS Oncology Impact Fund L.P., pursuant to which we agreed that a portion of the consideration received from UBS Oncology Impact Fund L.P. for the purchase of shares of Series A preferred stock in connection with our Series A preferred stock financing was to be treated as consideration for the royalty on net sales under the Amended Royalty Transfer Agreement. Affiliates of MPM Capital and UBS Oncology Impact Fund L.P. that own shares of our preferred and common stock hold interests in MPM Charitable Foundation and UBS Optimus Foundation.

Consulting Agreement with Briggs Morrison, M.D.

In December 2019, we entered into a consulting agreement with Briggs Morrison, M.D., a member of our board of directors, for the provision of consulting, advisory and related services. Pursuant to the consulting agreement, in December 2019, we issued Dr. Morrison a stock option for 46,570 shares of our common stock, and have agreed to reimburse certain of Dr. Morrison's expenses in connection with the performance of services under the agreement. The stock option has an exercise price of \$1.56 per share and is scheduled to vest with respect to 2.0833% of the shares underlying the stock option in equal monthly installments over four years following November 2019, subject to continuous service.

Registration Rights

We are a party to an amended and restated investors' rights agreement, or investors' rights agreement, with the holders of our preferred stock, including the holders of more than 5% of our capital stock and their affiliates. This investors' rights agreement provides these stockholders the right, subject to certain conditions, beginning 180 days after the effective date of the registration statement of which this prospectus is a part, to demand that we file a registration statement or to request that their shares be covered by a registration statement that we are otherwise filing.

See "Description of Capital Stock—Registration Rights" for additional information regarding these registration rights.

Indemnification Agreements

Our restated certificate of incorporation, which will become effective upon the closing of this offering, provides that we will indemnify our directors and officers to the fullest extent permitted by Delaware law. In addition, we have entered into or intend to enter into new indemnification agreements with all of our directors and executive officers prior to the completion of this offering. These indemnification agreements may require us, among other things, to indemnify each such director or executive officer for some expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by him or her in any action or proceeding arising out of his or her service as one of our directors or executive officers. See "Executive Compensation—Limitations on Liability and Indemnification Matters" for additional information.

Policies and Procedures for Related Person Transactions

Our board of directors has adopted written policies and procedures for the review of any transaction, arrangement or relationship in which our company is a participant, the amount involved exceeds \$120,000, and one of our executive officers, directors, director nominees or holders of more than 5% of our capital stock (or their immediate family members), each of whom we refer to as a "related person," has a direct or indirect material interest.

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If a related person proposes to enter into such a transaction, arrangement or relationship, which we refer to as a “related person transaction,” the related person must report the proposed related person transaction to our Chief Executive Officer or Chief Financial Officer. The policy calls for the proposed related person transaction to be reviewed and, if deemed appropriate, approved by our audit committee. Whenever practicable, the reporting, review and approval will occur prior to entry into the transaction. If advance review and approval is not practicable, the audit committee will review, and, in its discretion, may ratify the related person transaction. The policy also permits the chair of the audit committee to review and, if deemed appropriate, approve proposed related person transactions that arise between audit committee meetings, subject to ratification by the audit committee at its next meeting. Any related person transactions that are ongoing in nature will be reviewed annually.

A related person transaction reviewed under the policy will be considered approved or ratified if it is authorized by the audit committee after full disclosure of the related person’s interest in the transaction. As appropriate for the circumstances, the audit committee will review and consider:

- the related person’s interest in the related person transaction;
- the approximate dollar value of the amount involved in the related person transaction;
- the approximate dollar value of the amount of the related person’s interest in the transaction without regard to the amount of any profit or loss;
- whether the transaction was undertaken in the ordinary course of our business;
- whether the terms of the transaction are no less favorable to us than terms that could have been reached with an unrelated third party;
- the purpose of, and the potential benefits to us of, the transaction; and
- any other information regarding the related person transaction or the related person in the context of the proposed transaction that would be material to investors in light of the circumstances of the particular transaction.

Our audit committee may approve or ratify the transaction only if it determines that, under all of the circumstances, the transaction is in, or is not inconsistent with, our best interests. Our audit committee may impose any conditions on the related person transaction that it deems appropriate.

In addition to the transactions that are excluded by the instructions to the SEC’s related person transaction disclosure rule, our board of directors has determined that the following transactions do not create a material direct or indirect interest on behalf of related persons and, therefore, are not related person transactions for purposes of this policy:

- interests arising solely from the related person’s position as an executive officer of another entity, whether or not the person is also a director of such entity, that is a participant in the transaction, where the related person and all other related persons own in the aggregate less than a 10% equity interest in such entity, the related person and his or her immediate family members are not involved in the negotiation of the terms of the transaction and do not receive any special benefits as a result of the transaction, and the amount involved in the transaction is less than the greater of \$200,000 or 5% of the annual gross revenues of the company receiving payment under the transaction; and
- a transaction that is specifically contemplated by provisions of our certificate of incorporation or bylaws.

The policy provides that transactions involving compensation of executive officers shall be reviewed and approved by our compensation committee in the manner specified in the compensation committee’s charter.

We did not have a written policy regarding the review and approval of related person transactions prior to this offering. Nevertheless, with respect to such transactions, it has been the practice of our board of directors to consider the nature of and business reasons for such transactions, how the terms of such transactions compared to those which might be obtained from unaffiliated third parties and whether such transactions were otherwise fair to and in the best interests of, or not contrary to, our best interests.

PRINCIPAL STOCKHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common stock as of March 31, 2021 by:

- each of our directors;
- each of our named executive officers;
- all of our executive officers and directors as a group; and
- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock.

The column entitled "Percentage of Shares Beneficially Owned—Before Offering" is based on a total of 20,039,359 shares of our common stock outstanding as of March 31, 2021, assuming the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 18,279,712 shares of our common stock upon the closing of this offering. The column entitled "Percentage of Shares Beneficially Owned—After Offering" is based on 27,539,359 shares of our common stock to be outstanding after this offering, including the shares of our common stock that we are selling in this offering, but not including any additional shares issuable upon exercise of outstanding stock options or warrants or any additional shares issuable upon the underwriters' option to purchase additional shares.

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Beneficial ownership is determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to our common stock. Shares of our common stock that an individual has a right to acquire within 60 days after March 31, 2021 are considered outstanding and beneficially owned by the person holding such right for the purpose of calculating the percentage ownership of that person but not for the purpose of calculating the percentage ownership of any other person, except with respect to the percentage ownership of all directors and executive officers. Except as otherwise noted, the persons and entities in this table have sole voting and investing power with respect to all of the shares of our common stock beneficially owned by them, subject to community property laws, where applicable. Unless otherwise indicated, the address of each beneficial owner is c/o Werewolf Therapeutics, Inc., 1030 Massachusetts Avenue, Cambridge, MA 02138.

NAME OF BENEFICIAL OWNER	NUMBER OF SHARES BENEFICIALLY OWNED	PERCENTAGE OF SHARES BENEFICIALLY OWNED	
		BEFORE OFFERING	AFTER OFFERING
5% Stockholders:			
Entities affiliated with MPM Capital (1)	4,165,501	20.75%	15.11%
UBS Oncology Impact Fund, L.P. (2)	2,320,586	11.56	8.42
Entities affiliated with RA Capital (3)	2,253,583	11.25	8.18
Taiho Ventures, LLC (4)	1,756,409	8.76	6.38
Deerfield Partners, L.P. (5)	1,752,787	8.75	6.36
Arkin Bio Ventures 2 L.P. (6)	1,646,634	8.22	5.98
Longwood Fund III, L.P. (7)	1,427,082	7.12	5.18
UPMC (8)	1,097,756	5.48	3.99
Named Executive Officers and Directors:			
Luke Evnin, Ph.D. (1)	4,165,501	20.75	15.11
Sakae Asanuma C.F.A. (4)	1,756,409	8.76	6.38
Derek DiRocco, Ph.D.	—	—	—
Alon Lazarus, Ph.D. (6)	1,646,634	8.22	5.98
Briggs Morrison, M.D. (9)	17,463	*	*
Elise Wang, M.B.A.	—	—	—
Daniel J. Hicklin, Ph.D. (10)	647,047	3.23	2.35
Randi Isaacs, M.D.	—	—	—
Cynthia Seidel-Dugan, Ph.D. (11)	125,157	*	*
All executive officers and directors as a group (12) (12 persons)	8,483,368	42.26	30.77

* Represents beneficial ownership of less than 1%.

(1) Consists of (i) 461,408 shares of common stock held by MPM Asset Management LLC, (ii) 2,087,358 shares of common stock issuable upon the conversion of shares of Series A preferred stock held by MPM BioVentures 2014 L.P., or MPM 2014, (iii) 139,224 shares of common stock issuable upon the conversion of shares of Series A preferred stock held by MPM BioVentures 2014(B), L.P., or MPM 2014(B), (iv) 71,848 shares of common stock issuable upon the conversion of shares of Series A preferred stock held by MPM Asset Management Investors BV2014 LLC, or MPM BV2014, (v) 457,643 shares of common stock issuable upon the conversion of shares of Series A preferred stock held by MPM Oncology Innovations Fund, L.P., or MPM OIF, (vi) 693,667 shares of common stock issuable upon the conversion of shares of Series B preferred stock held by MPM 2014, (vii) 46,266 shares of common stock issuable upon the conversion of shares of Series B preferred stock held by MPM 2014(B), (viii) 23,876 shares of common stock issuable upon the conversion of shares of Series B preferred stock held by MPM BV2014, (ix) 152,083 shares of common stock issuable upon the conversion of shares of Series B preferred stock held by MPM OIF, (x) 24,317 shares of common stock underlying warrants exercisable within 60 days of March 31, 2021 held by MPM 2014, (xi) 1,621 shares of common stock underlying warrants exercisable within 60 days of March 31, 2021 held by MPM 2014(B), (xii) 835 shares of common stock underlying warrants exercisable within 60 days of March 31, 2021 held by MPM BV2014 and (xiii) 5,355 shares of common stock underlying warrants exercisable within 60 days of March 31, 2021 held by MPM OIF. MPM 2014, MPM 2014(B), MPM BV2014 and MPM OIF are collectively referred to as the MPM Entities. Luke Evnin, a member of our board of directors, Ansbert Gadicke and Todd Foley are the managing directors of MPM BioVentures 2014 LLC, or BV2014 LLC. BV2014 LLC is the manager of MPM BV2014 and managing member of MPM BioVentures 2014 GP LLC, which is the general partner of MPM 2014 and MPM 2014(B). Each of Dr. Evnin, Dr. Gadicke and Mr. Foley shares power to vote, acquire, hold and dispose of the shares held by MPM 2014, MPM 2014(B) and MPM BV2014. Luke Evnin, Stephen Curtis and Ansbert Gadicke are the managers of MPM Oncology Innovations Fund GP LLC, which is the general partner of MPM OIF. Each of Dr. Evnin, Dr. Curtis and Dr. Gadicke shares power to vote, acquire, hold

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- and dispose of the shares held by MPM OIF. Luke Evnin and Ansbert Gadicke are the members of MPM Asset Management LLC. MPM Asset Management LLC is the management company for each of the MPM Entities. Each of Dr. Evnin and Dr. Gadicke shares power to vote, acquire, hold and dispose of the shares held by MPM Asset Management LLC. Each of the entities and individuals listed above expressly disclaims beneficial ownership of the securities listed above except to the extent of any pecuniary interest therein. The address of each of the MPM Entities and MPM Asset Management LLC is 450 Kendall Street, Cambridge, MA 02142.
- (2) Consists of (i) 1,721,669 shares of common stock issuable upon conversion of shares of Series A preferred stock, (ii) 572,141 shares of common stock issuable upon conversion of shares of Series B preferred stock and (iii) a warrant to purchase 26,776 shares of common stock exercisable within 60 days of March 31, 2021, in each case held by UBS Oncology Impact Fund, L.P., or UBS OIF. The general partner of UBS OIF is Oncology Impact Fund (Cayman) Management L.P. The general partner of Oncology Impact Fund (Cayman) Management L.P. is MPM Oncology Impact Management LP. The general partner of MPM Oncology Impact Management LP is MPM Oncology Impact Management GP LLC. Dr. Ansbert Gadicke is the managing director of MPM Oncology Impact Management GP LLC. Each of the entities and individuals listed above expressly disclaims beneficial ownership of the securities listed above except to the extent of any pecuniary interest therein. The address of UBS OIF and Oncology Impact Fund (Cayman) Management LP is UBS Trustees (Cayman) Ltd, 5th Floor, Cayman Corporate Center, 27 Hospital, George Town, Grand Cayman, KY1-1106. The address of MPM Oncology Impact Management LP, MPM Oncology Impact Management GP LLC and the individuals referenced above is 450 Kendall Street, Cambridge, MA 02142.
- (3) Consists of (i) 1,915,546 shares of common stock issuable upon conversion of shares of Series B preferred stock held by RA Capital Healthcare Fund, L.P., or RA Healthcare, and (ii) 338,037 shares of common stock issuable upon conversion of shares of Series B preferred stock held by RA Capital Nexus Fund II, L.P., or Nexus II Fund. RA Capital Management, L.P. is the investment manager for RA Healthcare and Nexus II Fund. The general partner of RA Capital Management, L.P. is RA Capital Management GP, LLC, of which Peter Kolchinsky and Rajeev Shah are the managing members. RA Capital Management, L.P., RA Capital Management GP, LLC, Peter Kolchinsky and Rajeev Shah may be deemed to have voting and investment power over the shares held of record by RA Healthcare and Nexus II Fund. RA Capital Management, L.P., RA Capital Management GP, LLC, Peter Kolchinsky and Rajeev Shah disclaim beneficial ownership of such shares, except to the extent of any pecuniary interest therein. The address for the entities listed above is 200 Berkeley Street, 18th Floor, Boston, MA 02116.
- (4) Consists of (i) 1,318,311 shares of common stock issuable upon conversion of shares of Series A preferred stock and (ii) 438,098 shares of common stock issuable upon conversion of shares of Series B preferred stock, in each case held by Taiho Ventures, LLC. The address for Taiho Ventures, LLC is 2420 Sand Hill Road, Suite 203, Menlo Park, CA 94025.
- (5) Consists of 1,752,787 shares of common stock issuable upon conversion of shares of Series B preferred stock held by Deerfield Partners, L.P., or Deerfield Partners. Deerfield Mgmt, L.P. is the general partner of Deerfield Partners. Deerfield Management Company, L.P. is the investment manager of Deerfield Partners. Mr. James E. Flynn is the sole member of the general partner of Deerfield Mgmt, L.P. and Deerfield Management Company, L.P. Each of Deerfield Mgmt, L.P., Deerfield Management Company, L.P. and Mr. James E. Flynn may be deemed to beneficially own the shares held by Deerfield Partners. The address for Deerfield Partners is 345 Park Avenue South, 12th Floor, New York, NY 10010.
- (6) Consists of (i) 1,235,917 shares of common stock issuable upon conversion of shares of Series A preferred stock and (ii) 410,717 shares of common stock issuable upon conversion of shares of Series B preferred stock, in each case held by Arkin Bio Ventures 2 L.P. Arkin Bio Ventures GPGP Ltd., is the ultimate general partner of Arkin Bio Ventures 2 L.P. and the sole shareholder and chairman of the board of Arkin Bio Ventures GPGP Ltd. is Moshe Arkin. As a result, Mr. Arkin may be deemed to share voting and investment power with respect to the shares held by Arkin Bio Ventures 2 L.P. Alon Lazarus, Ph.D., a member of our board of directors, is the Biotech Investment Manager of Arkin Bio Ventures 2 L.P. and, as a result, may be deemed to share voting and investment power with respect to the shares held by Arkin Bio Ventures 2 L.P. The address for Arkin Bio Ventures 2 L.P. is 6 Hachoshlim Street, Building C, 6th Floor 4672406 Herzliya, Israel.
- (7) Consists of (i) 1,071,127 shares of common stock issuable upon conversion of shares of Series A preferred stock and (ii) 355,955 shares of common stock issuable upon conversion of shares of Series B preferred stock, in each case held by Longwood Fund III, L.P. Longwood Fund III GP, LLC is the general partner of Longwood Fund III, L.P., of which Christoph Westphal M.D., Ph.D. and Rich Aldrich are managing members and John Lawrence is chief financial officer. Longwood Fund III GP, LLC, Dr. Westphal, Mr. Aldrich and Mr. Lawrence may be deemed to have voting and investment power over the shares held of record by Longwood Fund III, L.P. The address for Longwood Fund is 800 Boylston Street, Suite 1555, Boston, MA 02199.
- (8) Consists of (i) 823,945 shares of common stock issuable upon conversion of shares of Series A preferred stock and (ii) 273,811 shares of common stock issuable upon conversion of shares of Series B preferred stock, in each case held by UPMC. The board of directors of UPMC has voting and dispositive power over the shares held by UPMC. The members of such board of directors disclaim beneficial ownership with respect to such shares. The address for UPMC is Bakery Square, Suite 200, 6425 Penn Avenue, Pittsburgh, PA 15206.
- (9) Consists of (i) 15,523 shares of common stock and (ii) 1,940 shares of common stock underlying stock options exercisable within 60 days of March 31, 2021.
- (10) Consists of 647,047 shares of restricted common stock.
- (11) Consists of 125,157 shares of restricted common stock.
- (12) Consists of (i) 476,931 shares of common stock, (ii) 897,361 shares of restricted common stock, (iii) 5,310,301 shares of common stock issuable upon conversion of shares of Series A preferred stock, (iv) 1,764,707 shares of common stock issuable upon conversion of shares of Series B preferred stock, (v) 32,128 shares of common stock underlying warrants exercisable within 60 days of March 31, 2021 and (vi) 1,940 shares of common stock underlying stock options exercisable within 60 days of March 31, 2021.

DESCRIPTION OF CAPITAL STOCK

The following description of our capital stock and provisions of our restated certificate of incorporation and amended and restated bylaws are summaries only and are qualified by reference to the restated certificate of incorporation and amended and restated bylaws that will become effective upon the closing of this offering, each of which is filed as an exhibit to our registration statement of which this prospectus is a part. The description of our common stock reflects changes to our capital structure that will occur upon the closing of this offering.

Upon the closing of this offering, our authorized capital stock will consist of 200,000,000 shares of our common stock, par value \$0.0001 per share, and 5,000,000 shares of our preferred stock, par value \$0.0001 per share, all of which preferred stock will be undesignated.

As of March 31, 2021, we had issued and outstanding:

- 1,759,647 shares of our common stock held by 24 stockholders of record; and
- 80,246,565 shares of our Series A preferred stock held by 10 stockholders of record and 78,222,173 shares of our Series B preferred stock held by 19 stockholders, which shares are convertible into an aggregate of 18,279,712 shares of our common stock.

Upon the closing of this offering, all of the outstanding shares of our Series A preferred stock and Series B preferred stock will automatically convert into an aggregate of 18,279,712 shares of our common stock.

Common Stock

Holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of stockholders and do not have cumulative voting rights. Each election of directors by our stockholders will be determined by a plurality of the votes cast by the stockholders entitled to vote on the election. Holders of common stock are entitled to receive proportionately any dividends as may be declared by our board of directors, subject to any preferential dividend rights of outstanding preferred stock that we may designate and issue in the future.

In the event of our liquidation or dissolution, the holders of our common stock are entitled to receive proportionately all assets available for distribution to stockholders after the payment of all debts and other liabilities and subject to the prior rights of any of our outstanding preferred stock. Holders of our common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of our common stock are subject to and may be adversely affected by the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Preferred Stock

Under the terms of our restated certificate of incorporation that will become effective upon the closing of this offering, our board of directors is authorized to issue shares of preferred stock in one or more series without stockholder approval. Our board of directors has the discretion to determine the rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, of each series of preferred stock.

The purpose of authorizing our board of directors to issue preferred stock and determine its rights and preferences is to eliminate delays associated with a stockholder vote on specific issuances. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions, future financings and other corporate purposes, could have the effect of making it more difficult for a third party to acquire, or could discourage a third party from seeking to acquire, a majority of our outstanding voting stock. Upon the closing of this offering, there will be no shares of preferred stock outstanding, and we have no present plans to issue any shares of preferred stock.

Stock Options and Unvested Restricted Common Stock

As of March 31, 2021, stock options to purchase an aggregate of 2,401,085 shares of our common stock were outstanding under the 2017 Plan, at a weighted average exercise price of \$4.16 per share, and 498,076 shares of unvested restricted common stock were outstanding. See "Executive Compensation—Employee Benefit and Equity Compensation Plans" for additional information regarding the terms of the 2017 Plan.

Common Stock Warrants

As of March 31, 2021, warrants to purchase an aggregate of 58,904 shares of our common stock were outstanding at an exercise price of \$0.09 per share, held by five holders. These warrants expire between December 5, 2024 and August 13, 2025. These warrants contain provisions for the adjustment of the exercise price and the number of shares issuable upon the exercise of the applicable warrant in the event of certain stock dividends, stock splits, reorganizations, reclassifications and consolidations. The warrants also contain net exercise provisions pursuant to which the holder may, in lieu of paying the exercise price in cash, surrender the applicable warrant and receive a net amount of shares based on the fair market value of our common stock at the time of exercise after deducting the aggregate exercise price.

Registration Rights

We entered into our investors' rights agreement on December 23, 2020 with holders of our preferred stock. Beginning 180 days after the effective date of the registration statement of which this prospectus is a part, holders of a total of 18,279,712 shares of our common stock will have the right to require us to register these shares under the Securities Act under specified circumstances. We refer to the shares with these registration rights as registrable securities. After registration pursuant to these rights, the registrable securities will become freely tradable without restriction under the Securities Act. The registration rights under the investors' rights agreement terminate upon the earliest to occur of:

- the closing of a "Deemed Liquidation Event," as such term is defined in our certificate of incorporation;
- following the closing of this offering, with respect to any holder party to the investors' rights agreement, such time as Rule 144 under the Securities Act or another similar exemption under the Securities Act is available for the sale of all of the shares held by such holder without limitation during a three-month period without registration; or
- the third anniversary of the closing of this offering.

Demand Registration Rights

Beginning 180 days after the effective date of the registration statement of which this prospectus is a part, subject to specified limitations set forth in the investors' rights agreement, at any time, the holders of at least 35% of the then outstanding registrable securities may demand that we register registrable securities having an aggregate offering price, net of selling expenses, of at least \$5.0 million under the Securities Act for purposes of a public offering. We are not obligated to file a registration statement pursuant to this provision on more than two occasions.

In addition, subject to specified limitations set forth in the investors' rights agreement, at any time after we become eligible to file a registration statement on Form S-3, holders of at least 15% of the registrable securities then outstanding may request that we register on Form S-3 registrable securities having an aggregate offering price, net of selling expenses, of at least \$1.0 million under the Securities Act for purposes of a public offering. We are not obligated to file a registration statement pursuant to this provision on more than three occasions in any 12-month period.

We are required to use our commercially reasonable efforts to cause such registration statements to become effective.

Incidental Registration Rights

If, at any time after the closing of this offering, we propose to register any of our securities under the Securities Act in connection with a public offering of such securities solely for cash, the holders of registrable securities will be entitled to notice of the registration and, subject to specified exceptions, have the right to require us to register all or a portion of the registrable securities then held by them in that registration. We have the right to terminate or withdraw any registration initiated by us before the effective date of such registration.

In the event that any registration in which the holders of registrable securities participate pursuant to our investors' rights agreement is an underwritten public offering, we have agreed to enter into an underwriting agreement in usual and customary form.

Expenses

Pursuant to the investors' rights agreement, we are required to pay all registration expenses, including all registration, filing and qualification fees; printing and accounting fees; and fees and disbursements not to exceed \$30,000 of one counsel representing the selling stockholders, but excluding underwriting discounts, selling commissions and stock transfer taxes applicable to the sale of registrable securities and the fees and expenses of the selling stockholders' own counsel (other than the counsel selected to represent all selling stockholders).

The investors' rights agreement contains customary cross-indemnification provisions, pursuant to which we are obligated to indemnify the selling stockholders in the event of material misstatements or omissions in the registration statement attributable to us or any violation or alleged violation whether by action or inaction by us under the Securities Act, the Exchange Act, any state securities or Blue Sky law or any rule or regulation promulgated under the Securities Act, the Exchange Act or any state securities or Blue Sky law in connection with such registration statement or the qualification or compliance of the offering, and they are obligated to indemnify us for material misstatements or omissions in the registration statement attributable to them.

Delaware Anti-Takeover Law and Certain Charter and Bylaw Provisions

Delaware Law

We are subject to Section 203 of the Delaware General Corporation Law, or the DGCL. Subject to certain exceptions, Section 203 prevents a publicly held Delaware corporation from engaging in a "business combination" with any "interested stockholder" for three years following the date that the person became an interested stockholder, unless either the interested stockholder attained such status with the approval of the corporation's board of directors, the business combination is approved by the corporation's board of directors and stockholders in a prescribed manner or the interested stockholder acquired at least 85% of the corporation's outstanding voting stock in the transaction in which it became an interested stockholder. A "business combination" includes, among other things, a merger or consolidation involving us and the "interested stockholder" and the sale of more than 10% of our assets. In general, an "interested stockholder" is any entity or person beneficially owning 15% or more of our outstanding voting stock and any entity or person affiliated with or controlling or controlled by such entity or person. The restrictions contained in Section 203 are not applicable to any of our existing stockholders that will own 15% or more of our outstanding voting stock upon the closing of this offering.

Staggered Board; Removal of Directors

Our restated certificate of incorporation and our amended and restated bylaws to be effective upon the closing of this offering divide our board of directors into three classes with staggered three-year terms. In addition, our restated certificate of incorporation and our amended and restated bylaws to be effective upon the closing of this offering provide that directors may be removed only for cause and only by the affirmative vote of the holders of at least two-thirds of our shares of capital stock present in person or by proxy and entitled to vote. Under our restated certificate of incorporation and our amended and restated bylaws to be effective upon the closing of this offering, any vacancy on our board of directors, including a vacancy resulting from an enlargement of our board of directors, may be filled only by vote of a majority of our directors then in office.

Furthermore, our restated certificate of incorporation to be effective upon the closing of this offering provides that the authorized number of directors may be changed only by the resolution of our board of directors. The classification of our board of directors and the limitations on the ability of our stockholders to remove directors, change the authorized number of directors and fill vacancies could make it more difficult for a third party to acquire, or discourage a third party from seeking to acquire, control of our company.

Super-Majority Voting

The DGCL provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation's certificate of incorporation or bylaws, unless a corporation's certificate of incorporation or bylaws, as the case may be, requires a greater percentage. Our amended and restated bylaws to be effective upon the closing of this offering may be amended or repealed by a majority vote of our board of directors or the affirmative vote of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast in any annual election of directors. In addition, the affirmative vote of the holders of at least two-thirds of the votes that all our stockholders would be entitled to cast in any election of directors is required to amend or repeal or to adopt any provisions inconsistent with any of the provisions of our restated certificate of incorporation described above.

Stockholder Action; Special Meeting of Stockholders; Advance Notice Requirements for Stockholder Proposals and Director Nominations

Our restated certificate of incorporation and our amended and restated bylaws to be effective upon the closing of this offering provide that any action required or permitted to be taken by our stockholders at an annual meeting or special meeting of stockholders may only be taken if it is properly brought before such meeting and may not be taken by written action in lieu of a meeting. Our restated certificate of incorporation and our amended and restated bylaws to be effective upon the closing of this offering also provide that, except as otherwise required by law, special meetings of the stockholders can only be called by our board of directors. In addition, our amended and restated bylaws to be effective upon the closing of this offering establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of candidates for election to our board of directors. Stockholders at an annual meeting may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors, or by a stockholder of record on the record date for the meeting who is entitled to vote at the meeting and who has delivered timely written notice in proper form to our secretary of the stockholder's intention to bring such business before the meeting. These provisions could have the effect of delaying until the next stockholder meeting stockholder actions that are favored by the holders of a majority of our outstanding voting securities. These provisions also could discourage a third party from making a tender offer for our common stock because even if the third party acquired a majority of our outstanding voting stock, it would be able to take action as a stockholder, such as electing new directors or approving a merger, only at a duly called stockholders meeting and not by written consent.

Indemnification Agreements

Our restated certificate of incorporation to be effective upon the closing of this offering, provides that we will indemnify our directors and officers to the fullest extent permitted by Delaware law. In addition, we have entered into or intend to enter into new indemnification agreements with all of our directors and executive officers prior to the completion of this offering. These indemnification agreements may require us, among other things, to indemnify each such director or executive officer for some expenses, including attorneys' fees, judgments, fines, and settlement amounts incurred by him or her in any action or proceeding arising out of his or her service as one of our directors or executive officers.

Exclusive Forum Provision

Our restated certificate of incorporation to be effective upon the closing of this offering 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) shall, to the fullest extent permitted by law, be the sole and exclusive forum for the following types of proceedings: (1) any derivative action or proceeding brought on behalf of our company, (2) 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, (3) 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 (4) 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 Securities Act, the Exchange Act, or any other claim for which federal courts have exclusive jurisdiction. Furthermore, our restated certificate of incorporation to be effective upon the closing of this offering 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. Although our restated certificate of incorporation to be effective upon the closing of this offering contains the choice of forum provisions described above, it is possible that a court could rule that such provisions are inapplicable for a particular claim or action or that such provisions are unenforceable. For example, under the Securities Act, federal courts have concurrent jurisdiction over all suits brought to enforce any duty or liability created by the Securities Act, and investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

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Nasdaq Global Select Market

Our common stock has been approved for listing on the Nasdaq Global Select Market under the trading symbol "HOWL."

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock, and a liquid trading market for our common stock may not develop or be sustained after this offering. As described below, only a limited number of shares will be available for sale shortly after this offering due to contractual and legal restrictions on resale. Future sales of substantial amounts of our common stock in the public market, including shares issued upon exercise of outstanding stock options and warrants, or the anticipation of these sales, could adversely affect market prices prevailing from time to time and could impair our ability to raise capital through sales of equity securities.

Upon the closing of this offering, we will have outstanding 27,539,359 shares of our common stock, based on the 20,039,359 shares of our common stock that were outstanding on March 31, 2021, after giving effect to the issuance of 7,500,000 shares of our common stock in this offering, assuming no exercise by the underwriters of their option to purchase additional shares of our common stock and the automatic conversion of all outstanding shares of our preferred stock into an aggregate of 18,279,712 shares of our common stock upon the closing of this offering. Of these shares, all shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act unless purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act.

The remaining 20,039,359 shares of our common stock will be "restricted securities" under Rule 144, and we expect that substantially all of these restricted securities will be subject to the 180-day lock-up period under the lock-up agreements as described below. These restricted securities may be sold in the public market upon release or waiver of any applicable lock-up agreements and only if registered or pursuant to an exemption from registration, such as Rule 144 or Rule 701 under the Securities Act.

Lock-up Agreements

We and each of our officers and directors and holders of substantially all of our outstanding capital stock have agreed that, without the prior written consent of Jefferies LLC, SVB Leerink LLC and Evercore Group L.L.C., on behalf of the underwriters, we and they will not, subject to limited exceptions, during the period ending 180 days after the date of this prospectus, subject to extension in specified circumstances:

- sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open "put equivalent position" within the meaning of Rule 16a-1(h) under the Exchange Act;
- otherwise dispose of any shares of common stock, options or warrants to acquire shares of common stock, or securities exchangeable or exercisable for or convertible into shares of common stock currently or hereafter owned either of record or beneficially; or
- publicly announce an intention to do any of the foregoing.

These agreements are subject to certain exceptions, as described in the section of this prospectus entitled "Underwriting."

Rule 144

In general, under Rule 144 of the Securities Act, beginning 90 days after the date of this prospectus, any person who is not our affiliate and has held their shares for at least six months, including the holding period of any prior owner other than one of our affiliates, may sell those shares without restriction, subject to the availability of current public information about us. In addition, under Rule 144, any person who is not our affiliate and has not been our affiliate at any time during the preceding three months and has held their shares for at least one year, including the holding period of any prior owner other than one of our affiliates, would be entitled to sell an unlimited number of shares immediately upon the closing of this offering without regard to whether current public information about us is available.

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Beginning 90 days after the date of this prospectus, a person who is our affiliate or who was our affiliate at any time during the preceding three months and who has beneficially owned restricted securities for at least six months, including the holding period of any prior owner other than one of our affiliates, is entitled to sell a number of shares within any three-month period that does not exceed the greater of:

- 1% of the number of shares of our common stock then outstanding, which will equal approximately 275,394 shares immediately after this offering; and
- the average weekly trading volume in our common stock on the Nasdaq Global Select Market during the four calendar weeks preceding the date of filing of a Notice of Proposed Sale of Securities Pursuant to Rule 144 with respect to the sale.

Sales under Rule 144 by our affiliates are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us.

Upon waiver or expiration of the 180-day lock-up period described above, approximately 20,039,359 shares of our common stock will be eligible for sale under Rule 144. We cannot estimate the number of shares of our common stock that our existing stockholders will elect to sell under Rule 144.

Rule 701

In general, under Rule 701 under the Securities Act, any of our employees, consultants or advisors, other than our affiliates, who purchased shares from us in connection with a qualified compensatory stock plan or other written agreement is eligible to resell these shares 90 days after the date of this prospectus in reliance on Rule 144, but without compliance with the various restrictions, including the availability of public information about us, holding period and volume limitations, contained in Rule 144. Subject to the 180-day lock-up period described above, approximately 1,298,239 shares of our common stock, based on shares outstanding as of March 31, 2021, will be eligible for sale in accordance with Rule 701.

Stock Options and Form S-8 Registration Statement

Following this offering, we intend to file one or more registration statements on Form S-8 under the Securities Act to register all of the shares of our common stock subject to outstanding awards and reserved for future issuance under the 2017 Plan, the 2021 Plan and the 2021 ESPP. See “Executive Compensation—Employee Benefit and Equity Compensation Plans” for additional information regarding these plans. Accordingly, shares of our common stock registered under the registration statements will be available for sale in the open market, subject to Rule 144 volume limitations applicable to affiliates, and subject to any vesting restrictions and lock-up agreements applicable to these shares.

Registration Rights

Subject to the lock-up agreements described above, beginning 180 days following the closing of this offering, the holders of 18,279,712 shares of common stock will have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. After registration pursuant to these rights, these shares will become freely tradable without restriction under the Securities Act. See “Description of Capital Stock—Registration Rights” for additional information regarding these registration rights.

MATERIAL U.S. TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF COMMON STOCK

The following is a discussion of material U.S. federal income and estate tax considerations relating to ownership and disposition of our common stock by a non-U.S. holder (as defined below). For purposes of this discussion, the term “non-U.S. holder” means a beneficial owner (other than a partnership or other entity or arrangement treated as a pass-through entity for U.S. federal income tax purposes) of our common stock that is not, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation, or other entity treated as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust, if a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons has authority to control all substantial decisions of the trust or if the trust has a valid election in effect to be treated as a U.S. person under applicable U.S. Treasury Regulations.

This discussion is based on current provisions of the Code, existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, each as in effect as of the date of this prospectus, and all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any such change or different interpretation could alter the tax considerations to non-U.S. holders described in this prospectus. In addition, there can be no assurance that the Internal Revenue Service, or the IRS, will not challenge one or more of the tax considerations described in this prospectus.

This discussion addresses only non-U.S. holders that hold shares of our common stock as a capital asset within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all aspects of U.S. federal income and estate taxation that may be relevant to a particular non-U.S. holder in light of that non-U.S. holder’s individual circumstances nor does it address the alternative minimum tax, the Medicare contribution tax on net investment income or any aspects of U.S. state, local or non-U.S. taxes. This discussion also does not consider any specific facts or circumstances that may apply to a non-U.S. holder and does not address the special tax rules applicable to particular non-U.S. holders, such as:

- insurance companies;
- tax-exempt organizations;
- government organizations;
- financial institutions;
- brokers or dealers in securities;
- pension plans;
- non-U.S. holders that hold or receive our common stock pursuant to the exercise of employee stock options or otherwise as compensation;
- controlled foreign corporations;
- passive foreign investment companies;
- non-U.S. holders that hold our common stock as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment; and
- certain U.S. expatriates.

In addition, this discussion does not address the tax treatment of partnerships (or entities or arrangements that are treated as pass-through entities for U.S. federal income tax purposes) or persons who hold their common stock through such partnerships or such entities or arrangements. A partner in a partnership or other pass-through entity that will hold our common stock should consult his, her or its own tax advisor regarding the tax consequences of the purchase, ownership and disposition of our common stock through a partnership or other pass-through entity, as applicable.

Prospective investors should consult their own tax advisors regarding the U.S. federal, state, local and non-U.S. income and other tax considerations of acquiring, holding and disposing of our common stock.

Dividends

If we pay distributions on our common stock, those distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such non-U.S. holder's tax basis in the common stock. Any amount distributed in excess of basis will be treated as capital gain, subject to the tax treatment described below under the heading "—Gain on Disposition of Our Common Stock."

Dividends paid to a non-U.S. holder generally will be subject to withholding of U.S. federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence. A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such non-U.S. holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or successor form) and satisfy applicable certification and other requirements. A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may obtain a refund or credit of any excess amounts withheld by timely filing an appropriate claim with the IRS. Non-U.S. holders are urged to consult their own tax advisors regarding their entitlement to benefits under a relevant income tax treaty.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States and, if an applicable income tax treaty so provides, that are attributable to a permanent establishment or a fixed base maintained by the non-U.S. holder within the United States are generally exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements. To claim the exemption, the non-U.S. holder must furnish to us or the applicable withholding agent a valid IRS Form W-8ECI (or applicable successor form), certifying that the dividends are effectively connected with the non-U.S. holder's conduct of a trade or business within the United States. However, such U.S. effectively connected income is taxed on a net income basis at the same U.S. federal income tax rates applicable to United States persons (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also, under certain circumstances, be subject to an additional "branch profits tax" at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such non-U.S. holder's country of residence.

Gain on Disposition of our Common Stock

A non-U.S. holder generally will not be subject to U.S. federal income tax on gain recognized on a disposition of our common stock unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States and, if an applicable income tax treaty so provides, the gain is attributable to a permanent establishment or fixed base maintained by the non-U.S. holder in the United States; in these cases, the non-U.S. holder will be taxed on a net income basis at the same U.S. federal income tax rates applicable to United States persons (as defined in the Code), and if the non-U.S. holder is a foreign corporation, an additional branch profits tax at a 30% rate, or such lower rate as may be specified by an applicable income tax treaty, may also apply;
- the non-U.S. holder is a nonresident alien individual present in the United States for 183 days or more in the taxable year of the disposition and certain other requirements are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty) on the net gain derived from the disposition, which may be offset by U.S.-source capital losses of the non-U.S. holder, if any, provided the non-U.S. holder has timely filed U.S. federal income tax returns with respect to such losses; or
- we are, or have been at any time during the five-year period preceding such disposition (or the non-U.S. holder's holding period, if shorter), a "U.S. real property holding corporation," unless our common stock is

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regularly traded on an established securities market and the non-U.S. holder held no more than 5% of our outstanding common stock, directly or indirectly, actually or constructively, during the shorter of the five year period ending on the date of the disposition or the period that the non-U.S. holder held our common stock. If we are determined to be a U.S. real property holding corporation and the foregoing exception does not apply, then the non-U.S. holder generally will be taxed on its net gain derived from the disposition at the income tax rates applicable to United States persons (as defined in the Code). Generally, a corporation is a "U.S. real property holding corporation" if the fair market value of its "U.S. real property interests" equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we believe that we are not currently, and we do not anticipate becoming, a "U.S. real property holding corporation" for U.S. federal income tax purposes. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rule described above.

Information Reporting and Backup Withholding

We must report annually to the IRS and to each non-U.S. holder the gross amount of the dividends on our common stock paid to such holder and the tax withheld, if any, with respect to such dividends. Non-U.S. holders may have to comply with specific certification procedures to establish that the non-U.S. holder is not a U.S. person (as defined in the Code) in order to avoid backup withholding at the applicable rate, with respect to dividends on our common stock. Generally, a non-U.S. holder will comply with such procedures if it provides a properly executed IRS Form W-8BEN or W-8BEN-E (or other applicable Form W-8) or otherwise meets documentary evidence requirements for establishing that it is a non-U.S. holder, or otherwise establishes an exemption. Dividends paid to non-U.S. holders subject to withholding of U.S. federal income tax, as described above under the heading "—Dividends," will generally be exempt from U.S. backup withholding.

Information reporting and backup withholding generally will apply to the proceeds of a disposition of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the non-U.S. holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding is not an additional tax. Rather, any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder may be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided that an appropriate claim is timely filed with the IRS.

FATCA

Provisions of the Code commonly referred to as the Foreign Account Tax Compliance Act, or FATCA, generally impose a 30% withholding tax on dividends on, and gross proceeds from the sale or other disposition of, our common stock if paid to a foreign entity unless (1) if the foreign entity is a "foreign financial institution," the foreign entity undertakes certain due diligence, reporting, withholding, and certification obligations, (2) if the foreign entity is not a "foreign financial institution," the foreign entity identifies certain of its U.S. investors, or (3) the foreign entity is otherwise excepted under FATCA.

Withholding under FATCA generally applies to payments of dividends on our common stock. While withholding under FATCA may apply to payments of gross proceeds from a sale or other disposition of our common stock, under proposed U.S. Treasury Regulations, withholding on payments of gross proceeds is not required. Although such regulations are not final, applicable withholding agents may rely on the proposed regulations until final regulations are issued.

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If withholding under FATCA is required on any payment related to our common stock, investors not otherwise subject to withholding (or that otherwise would be entitled to a reduced rate of withholding) on such payment may be able to seek a refund or credit from the IRS. An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this section. Non-U.S. holders should consult their own tax advisors regarding the possible implications of FATCA on their investment in our common stock and the entities through which they hold our common stock.

Federal Estate Tax

Common stock owned or treated as owned by an individual who is a non-U.S. holder (as specially defined for U.S. federal estate tax purposes) at the time of death will be included in the individual's gross estate for U.S. federal estate tax purposes and, therefore, may be subject to U.S. federal estate tax, unless an applicable estate tax or other treaty provides otherwise.

The preceding discussion of material U.S. federal tax considerations is for prospective investors' information only. It is not tax advice. Prospective investors should consult their own tax advisors regarding the particular U.S. federal, state, local, and non-U.S. tax consequences of purchasing, holding, and disposing of our common stock, including the consequences of any proposed changes in applicable laws.

UNDERWRITING

Subject to the terms and conditions set forth in the underwriting agreement, dated April 29, 2021, by and among us, Jefferies LLC, SVB Leerink LLC and Evercore Group L.L.C., as the representatives of the underwriters named below and the joint book-running managers of this offering, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the respective number of shares of common stock shown opposite its name below:

UNDERWRITER	NUMBER OF SHARES
Jefferies LLC	2,700,000
SVB Leerink LLC	2,437,500
Evercore Group L.L.C.	1,987,500
H.C. Wainwright & Co., LLC	375,000
Total	<u>7,500,000</u>

The underwriting agreement provides that the obligations of the several underwriters are subject to certain conditions precedent such as the receipt by the underwriters of officers' certificates and legal opinions and approval of certain legal matters by their counsel. The underwriting agreement provides that the underwriters will purchase all of the shares of common stock if any of them are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the non-defaulting underwriters may be increased or the underwriting agreement may be terminated. We have agreed to indemnify the underwriters and certain of their controlling persons against certain liabilities, including liabilities under the Securities Act, and to contribute to payments that the underwriters may be required to make in respect of those liabilities.

The underwriters have advised us that, following the completion of this offering, they currently intend to make a market in the common stock as permitted by applicable laws and regulations. However, the underwriters are not obligated to do so, and the underwriters may discontinue any market-making activities at any time without notice in their sole discretion. Accordingly, no assurance can be given as to the liquidity of the trading market for the common stock, that you will be able to sell any of the common stock held by you at a particular time or that the prices that you receive when you sell will be favorable.

The underwriters are offering the shares of common stock subject to their acceptance of the shares of common stock from us and subject to prior sale. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part. In addition, the underwriters have advised us that they do not intend to confirm sales to any account over which they exercise discretionary authority.

Commission and Expenses

The underwriters have advised us that they propose to offer the shares of common stock to the public at the initial public offering price set forth on the cover page of this prospectus and to certain dealers, which may include the underwriters, at that price less a concession not in excess of \$0.67200 per share of common stock. After the offering, the initial public offering price, concession and reallowance to dealers may be reduced by the representatives. No such reduction will change the amount of proceeds to be received by us as set forth on the cover page of this prospectus.

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The following table shows the public offering price, the underwriting discounts and commissions that we are to pay the underwriters and the proceeds, before expenses, to us in connection with this offering. Such amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase additional shares.

	PER SHARE		TOTAL	
	WITHOUT OPTION TO PURCHASE ADDITIONAL SHARES	WITH OPTION TO PURCHASE ADDITIONAL SHARES	WITHOUT OPTION TO PURCHASE ADDITIONAL SHARES	WITH OPTION TO PURCHASE ADDITIONAL SHARES
Public offering price	\$ 16.00	\$ 16.00	\$120,000,000	\$138,000,000
Underwriting discounts and commissions paid by us	\$ 1.12	\$ 1.12	\$ 8,400,000	\$ 9,660,000
Proceeds to us, before expenses	\$ 14.88	\$ 14.88	\$111,600,000	\$128,340,000

We estimate expenses payable by us in connection with this offering, other than the underwriting discounts and commissions referred to above, will be approximately \$2.7 million. We have agreed to reimburse the underwriters for expenses relating to clearance of this offering with the Financial Industry Regulatory Authority of up to \$35,000.

Determination of Offering Price

Prior to this offering, there has not been a public market for our common stock. Consequently, the initial public offering price for our common stock was determined by negotiations between us and the representatives. Among the factors to be considered in these negotiations were prevailing market conditions, our financial information, market valuations of other companies that we and the underwriters believe to be comparable to us, estimates of our business potential, the present state of our development and other factors deemed relevant.

We offer no assurances that the initial public offering price will correspond to the price at which the common stock will trade in the public market subsequent to the offering or that an active trading market for the common stock will develop and continue after the offering.

Listing

Our common stock has been approved for listing on the Nasdaq Global Select Market under the trading symbol "HOWL".

Option to Purchase Additional Shares

We have granted to the underwriters an option, exercisable for 30 days from the date of this prospectus, to purchase, from time to time, in whole or in part, up to an aggregate of 1,125,000 shares from us at the public offering price set forth on the cover page of this prospectus, less underwriting discounts and commissions. If the underwriters exercise this option, each underwriter will be obligated, subject to specified conditions, to purchase a number of additional shares proportionate to that underwriter's initial purchase commitment as indicated in the table above. This option may be exercised only if the underwriters sell more shares than the total number set forth on the cover page of this prospectus.

No Sales of Similar Securities

We, our officers, directors and holders of all or substantially all our outstanding capital stock have agreed, subject to specified exceptions, not to directly or indirectly:

- sell, offer, contract or grant any option to sell (including any short sale), pledge, transfer, establish an open "put equivalent position" within the meaning of Rule 16a-1(h) under the Securities Exchange Act of 1934, as amended, or
- otherwise dispose of any shares of common stock, options or warrants to acquire shares of common stock, or securities exchangeable or exercisable for or convertible into shares of common stock currently or hereafter owned either of record or beneficially, or

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- publicly announce an intention to do any of the foregoing for a period of 180 days after the date of this prospectus without the prior written consent of Jefferies LLC, SVB Leerink LLC and Evercore Group L.L.C.

This restriction terminates after the close of trading of the common stock on and including the 180th day after the date of this prospectus.

Jefferies LLC, SVB Leerink LLC and Evercore Group L.L.C. may, in their sole discretion and at any time or from time to time before the termination of the 180-day period release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our shareholders who will execute a lock-up agreement, providing consent to the sale of shares prior to the expiration of the lock-up period.

Stabilization

The underwriters have advised us that they, pursuant to Regulation M under the Securities Exchange Act of 1934, as amended, may engage in short sale transactions, stabilizing transactions, syndicate covering transactions or the imposition of penalty bids in connection with this offering. These activities may have the effect of stabilizing or maintaining the market price of the common stock at a level above that which might otherwise prevail in the open market. Establishing short sales positions may involve either "covered" short sales or "naked" short sales.

"Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares of our common stock in this offering. The underwriters may close out any covered short position by either exercising their option to purchase additional shares of our common stock or purchasing shares of our common stock in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option to purchase additional shares.

"Naked" short sales are sales in excess of the option to purchase additional shares of our common stock. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the shares of our common stock in the open market after pricing that could adversely affect investors who purchase in this offering.

A stabilizing bid is a bid for the purchase of shares of common stock on behalf of the underwriters for the purpose of fixing or maintaining the price of the common stock. A syndicate covering transaction is the bid for or the purchase of shares of common stock on behalf of the underwriters to reduce a short position incurred by the underwriters in connection with the offering. Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. A penalty bid is an arrangement permitting the underwriters to reclaim the selling concession otherwise accruing to a syndicate member in connection with the offering if the common stock originally sold by such syndicate member are purchased in a syndicate covering transaction and therefore have not been effectively placed by such syndicate member.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. The underwriters are not obligated to engage in these activities and, if commenced, any of the activities may be discontinued at any time.

The underwriters may also engage in passive market making transactions in our common stock on The Nasdaq Global Select Market in accordance with Rule 103 of Regulation M during a period before the commencement of offers or sales of shares of our common stock in this offering and extending through the completion of distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid, that bid must then be lowered when specified purchase limits are exceeded.

Electronic Distribution

A prospectus in electronic format may be made available by e-mail or through online services maintained by one or more of the underwriters or their affiliates. In those cases, prospective investors may view offering terms online and may be allowed to place orders online. The underwriters may agree with us to allocate a specific number of shares of common stock for sale to online brokerage account holders. Any such allocation for online distributions will be made by the underwriters on the same basis as other allocations. Other than the prospectus in electronic format, the information on the underwriters' web sites and any information contained in any other web site maintained by any of the underwriters is not part of this prospectus, has not been approved and/or endorsed by us or the underwriters and should not be relied upon by investors.

Other Activities and Relationships

The underwriters and certain of their respective affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The underwriters and certain of their respective affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the underwriters and certain of their respective affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own accounts and for the accounts of their respective customers, and such investment and securities activities may involve securities and/or instruments issued by us and our affiliates. If the underwriters or their respective affiliates have a lending relationship with us, they routinely hedge their credit exposure to us consistent with their customary risk management policies. The underwriters and their respective affiliates may hedge such exposure by entering into transactions which consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the common stock offered hereby. Any such short positions could adversely affect future trading prices of the common stock offered hereby. The underwriters and certain of their respective affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Disclaimers About Non-U.S. Jurisdictions

European Economic Area

In relation to each Member State of the European Economic Area (each, a "Relevant State"), no shares have been offered or will be offered pursuant to the offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which have been approved by the competent authority in that Relevant State or, where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that the shares may be offered to the public in that Relevant State at any time:

- (a) to any legal entity which is a "qualified investor" as defined under Article 2 of the Prospectus Regulation;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the Prospectus Regulation), subject to obtaining the prior consent of representatives for any such offer; or
- (c) in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of the shares shall require us or any of the representatives to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

For the purposes of this provision, the expression "offer to the public" in relation to the shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression "Prospectus Regulation" means Regulation (EU) 2017/1129.

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United Kingdom

No shares have been offered or will be offered pursuant to the offering to the public in the United Kingdom prior to the publication of a prospectus in relation to the shares which has been approved by the Financial Conduct Authority, except that the shares may be offered to the public in the United Kingdom at any time:

- (a) to any legal entity which is a qualified investor as defined under Article 2 of the UK Prospectus Regulation;
- (b) to fewer than 150 natural or legal persons (other than qualified investors as defined under Article 2 of the UK Prospectus Regulation), subject to obtaining the prior consent of the representatives for any such offer; or
- (c) in any other circumstances falling within Section 86 of the Financial Services and Markets Act of 2000, or FSMA,

provided that no such offer of the shares shall require the Issuer or any Manager to publish a prospectus pursuant to Section 85 of the FSMA or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation. For the purposes of this provision, the expression an “offer to the public” in relation to the shares in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any share and the expression “UK Prospectus Regulation” means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018.

Canada

(A) Resale Restrictions

The distribution of shares of common stock in Canada is being made only in the provinces of Ontario, Quebec, Alberta, British Columbia, Manitoba, New Brunswick and Nova Scotia on a private placement basis exempt from the requirement that we prepare and file a prospectus with the securities regulatory authorities in each province where trades of these securities are made. Any resale of the shares of our common stock in Canada must be made under applicable securities laws which may vary depending on the relevant jurisdiction, and which may require resales to be made under available statutory exemptions or under a discretionary exemption granted by the applicable Canadian securities regulatory authority. Purchasers are advised to seek legal advice prior to any resale of the shares of common stock.

(B) Representations of Canadian Purchasers

By purchasing shares of our common stock in Canada and accepting delivery of a purchase confirmation, a purchaser is representing to us and the dealer from whom the purchase confirmation is received that:

- the purchaser is entitled under applicable provincial securities laws to purchase the shares of our common stock without the benefit of a prospectus qualified under those securities laws as it is an “accredited investor” as defined under National Instrument 45-106 – *Prospectus Exemptions* or Section 73.3(1) of the *Securities Act* (Ontario), as applicable,
- the purchaser is a “permitted client” as defined in National Instrument 31-103—Registration Requirements, Exemptions and Ongoing Registrant Obligations,
- where required by law, the purchaser is purchasing as principal and not as agent and
- the purchaser has reviewed the text above under Resale Restrictions.

(C) Conflicts of Interest

Canadian purchasers are hereby notified that certain of the underwriters are relying on the exemption set out in section 3A.3 or 3A.4, if applicable, of National Instrument 33-105 – Underwriting Conflicts from having to provide certain conflict of interest disclosure in this document.

(D) Statutory Rights of Action

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if the prospectus (including any amendment thereto) such as this document contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser’s province or territory. The purchaser of these securities in Canada should refer to any applicable provisions of the securities legislation of the purchaser’s province or territory for particulars of these rights or consult with a legal advisor.

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(E) Enforcement of Legal Rights

All of our directors and officers as well as the experts named herein may be located outside of Canada and, as a result, it may not be possible for Canadian purchasers to effect service of process within Canada upon us or those persons. All or a substantial portion of our assets and the assets of those persons may be located outside of Canada and, as a result, it may not be possible to satisfy a judgment against us or those persons in Canada or to enforce a judgment obtained in Canadian courts against us or those persons outside of Canada.

(F) Taxation and Eligibility for Investment

Canadian purchasers of shares of common stock should consult their own legal and tax advisors with respect to the tax consequences of an investment in the shares of our common stock in their particular circumstances and about the eligibility of the shares of our common stock for investment by the purchaser under relevant Canadian legislation.

Australia

This prospectus is not a disclosure document for the purposes of Australia's Corporations Act 2001 (Cth) of Australia, or Corporations Act, has not been lodged with the Australian Securities & Investments Commission and is only directed to the categories of exempt persons set out below. Accordingly, if you receive this prospectus in Australia:

You confirm and warrant that you are either:

- a "sophisticated investor" under section 708(8)(a) or (b) of the Corporations Act;
- a "sophisticated investor" under section 708(8)(c) or (d) of the Corporations Act and that you have provided an accountant's certificate to the Company which complies with the requirements of section 708(8)(c)(i) or (ii) of the Corporations Act and related regulations before the offer has been made;
- a person associated with the Company under Section 708(12) of the Corporations Act; or
- a "professional investor" within the meaning of section 708(11)(a) or (b) of the Corporations Act.

To the extent that you are unable to confirm or warrant that you are an exempt sophisticated investor, associated person or professional investor under the Corporations Act any offer made to you under this prospectus is void and incapable of acceptance.

You warrant and agree that you will not offer any of the securities issued to you pursuant to this prospectus for resale in Australia within 12 months of those securities being issued unless any such resale offer is exempt from the requirement to issue a disclosure document under section 708 of the Corporations Act.

Hong Kong

No shares of our common stock have been offered or sold, and no shares of our common stock may be offered or sold, in Hong Kong, by means of any document, other than to persons whose ordinary business is to buy or sell shares or debentures, whether as principal or agent; or to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong, or the SFO, and any rules made under that Ordinance; or in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong, or the CO, or which do not constitute an offer or invitation to the public for the purpose of the CO or the SFO. No document, invitation or advertisement relating to the shares of our common stock has been issued or may be issued or may be in the possession of any person for the purpose of issue (in each case whether in Hong Kong or elsewhere), which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted under the securities laws of Hong Kong) other than with respect to shares of our common stock which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the SFO and any rules made under that Ordinance.

This prospectus has not been registered with the Registrar of Companies in Hong Kong. Accordingly, this prospectus may not be issued, circulated or distributed in Hong Kong, and the shares of our common stock may not be offered for subscription to members of the public in Hong Kong. Each person acquiring the shares of our common stock will be required, and is deemed by the acquisition of the shares of our common stock, to confirm that he is aware of the restriction on offers of the shares of our common stock described in this prospectus and the relevant offering documents and that he is not acquiring, and has not been offered any shares of our common stock in circumstances that contravene any such restrictions.

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Israel

This document does not constitute a prospectus under the Israeli Securities Law, 5728-1968, or the Securities Law, and has not been filed with or approved by the Israel Securities Authority. In Israel, this prospectus is being distributed only to, and is directed only at, and any offer of shares is directed only at, (i) a limited number of persons in accordance with the Israeli Securities Law and (ii) investors listed in the first addendum, or the Addendum, to the Israeli Securities Law, consisting primarily of joint investment in trust funds, provident funds, insurance companies, banks, portfolio managers, investment advisors, members of the Tel Aviv Stock Exchange, underwriters, venture capital funds, entities with equity in excess of NIS 50 million and "qualified individuals," each as defined in the Addendum (as it may be amended from time to time), collectively referred to as qualified investors (in each case, purchasing for their own account or, where permitted under the Addendum, for the accounts of their clients who are investors listed in the Addendum). Qualified investors are required to submit written confirmation that they fall within the scope of the Addendum, are aware of the meaning of same and agree to it.

Japan

The offering has not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948 of Japan, as amended), or FIEL, and the underwriters will not offer or sell any securities, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan (which term as used herein means any person resident in Japan, including any corporation or other entity organized under the laws of Japan), or to others for re-offering or resale, directly or indirectly, in Japan or to, or for the benefit of, any resident of Japan, except pursuant to an exemption from the registration requirements of, and otherwise in compliance with, the FIEL and any other applicable laws, regulations and ministerial guidelines of Japan.

Singapore

This prospectus has not been and will not be lodged or registered as a prospectus with the Monetary Authority of Singapore. Accordingly, this prospectus and any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the common stock may not be circulated or distributed, nor may the common stock be offered or sold, or be made the subject of an invitation for subscription or purchase, whether directly or indirectly, to persons in Singapore other than (i) to an institutional investor under Section 274 of the Securities and Futures Act, Chapter 289 of Singapore, or the SFA, (ii) to a relevant person pursuant to Section 275(1), or any person pursuant to Section 275(1A), and in accordance with the conditions specified in Section 275, of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares of our common stock are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

- a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or
- a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities (as defined in Section 239(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares of our common stock pursuant to an offer made under Section 275 of the SFA except:

- to an institutional investor or to a relevant person defined in Section 275(2) of the SFA, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;
- where no consideration is or will be given for the transfer;
- where the transfer is by operation of law;
- as specified in Section 276(7) of the SFA; or
- as specified in Regulation 32 of the Securities and Futures (Offers of Investments) (Shares and Debentures) Regulations 2005 of Singapore.

Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or the SIX, or on any other stock exchange or regulated trading facility in Switzerland. This prospectus has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this prospectus nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this prospectus nor any other offering or marketing material relating to the offering, us or the securities have been or will be filed with or approved by any Swiss regulatory authority. In particular, this prospectus will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or the CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

LEGAL MATTERS

The validity of the shares of common stock offered hereby is being passed upon for us by Wilmer Cutler Pickering Hale and Dorr LLP, Boston, Massachusetts. Cooley LLP, Washington, DC is acting as counsel for the underwriters in connection with this offering.

EXPERTS

The financial statements included in this prospectus have been audited by Deloitte & Touche LLP, an independent registered public accounting firm, as stated in their report appearing herein. Such financial statements have been so included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock we are offering to sell. This prospectus, which constitutes part of the registration statement, does not include all of the information contained in the registration statement or the exhibits, schedules and amendments to the registration statement. For further information with respect to us and our common stock, we refer you to the registration statement and to the exhibits and schedules to the registration statement. Statements contained in this prospectus about the contents of any contract, agreement or other document are not necessarily complete, and in each instance, we refer you to the copy of the contract, agreement or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by this reference to such contract, agreement or document.

Upon completion of this offering, we will be subject to the informational requirements of the Exchange Act and will file annual, quarterly and current reports, proxy statements and other information with the SEC. You can read our SEC filings, including the registration statement, at the SEC's website at www.sec.gov. We also maintain a website at <http://www.werewolftx.com> and upon completion of this offering, you may access, free of charge, our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and any amendments to those reports, as soon as reasonably practicable after such material is electronically filed with, or furnished to, the SEC. The information contained on, or that can be accessed through, our website is not a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and Board of Directors of Werewolf Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Werewolf Therapeutics, Inc. and its subsidiary (the "Company") as of December 31, 2019 and 2020, the related consolidated statements of operations, redeemable convertible preferred stock and stockholders' deficit, and cash flows, for the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2020, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Deloitte & Touche LLP

Boston, Massachusetts

February 26, 2021 (April 26, 2021, as to the effects of the reverse stock split described in Note 16)

We have served as the Company's auditor since 2020.

WEREWOLF THERAPEUTICS, INC.
Consolidated Balance Sheets
(in thousands, except share and per share amounts)

	AS OF DECEMBER 31,	
	2019	2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 17,896	\$ 92,570
Prepaid expenses and other current assets	167	344
Total current assets	18,063	92,914
Property and equipment, net	241	651
Restricted cash	208	207
Right of use	3,167	2,471
Deferred financing costs	—	155
Total assets	<u>\$ 21,679</u>	<u>\$ 96,398</u>
Liabilities, Redeemable Convertible Preferred Stock, and Stockholders' Deficit		
Current liabilities:		
Accounts payable	\$ 633	\$ 1,021
Accrued expenses	816	3,586
Lease liability	595	677
Total current liabilities	2,044	5,284
Preferred stock tranche liability	7,301	—
Lease liability, non-current	2,542	1,864
Other liabilities	23	31
Total liabilities	<u>11,910</u>	<u>7,179</u>
Commitments and contingencies		
Redeemable convertible preferred stock:		
Series A redeemable convertible preferred stock, par value \$0.0001 per share, 82,389,422 shares and 80,246,565 shares authorized as of December 31, 2019 and 2020, respectively, 48,675,140 shares and 80,246,565 shares issued and outstanding as of December 31, 2019 and 2020, respectively; liquidation preference of \$34,073 and \$69,012 as of December 31, 2019 and 2020, respectively	34,073	69,012
Series B redeemable convertible preferred stock, par value \$0.0001 per share, 0 shares and 78,222,173 shares authorized as of December 31, 2019 and 2020, respectively, 0 shares and 78,222,173 shares issued and outstanding as of December 31, 2019 and 2020, respectively; liquidation preference of \$0 and \$72,070 as of December 31, 2019 and 2020, respectively	—	72,070
Stockholders' deficit:		
Common stock, \$0.0001 par value, 105,000,000 shares and 193,500,000 shares authorized as of December 31, 2019 and 2020, respectively; 1,736,725 and 1,746,231 shares issued and outstanding as of December 31, 2019 and 2020, respectively	2	2
Additional paid-in capital	102	—
Accumulated deficit	(24,408)	(51,865)
Total stockholders' deficit	<u>(24,304)</u>	<u>(51,863)</u>
Total liabilities, redeemable convertible preferred stock, and stockholders' deficit	<u>\$ 21,679</u>	<u>\$ 96,398</u>

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

WEREWOLF THERAPEUTICS, INC.
Consolidated Statements of Operations
(in thousands, except share and per share amounts)

	YEAR ENDED DECEMBER 31,	
	2019	2020
Operating expenses:		
Research and development	\$ 6,340	\$ 16,641
General and administrative	3,596	5,763
Total operating expenses	<u>9,936</u>	<u>22,404</u>
Loss from operations	(9,936)	(22,404)
Other income (expense):		
Change in fair value of preferred stock tranche liability	487	7,301
Interest income (expense), net	(372)	101
Other expense, net	(57)	(38)
Change in fair value of warrant liabilities	(370)	—
Total other income (expense)	<u>(312)</u>	<u>7,364</u>
Net loss	(10,248)	(15,040)
Accretion of redeemable convertible preferred stock to redemption value	(7,981)	(13,177)
Net loss attributable to common stockholders	<u>\$ (18,229)</u>	<u>\$ (28,217)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (28.49)</u>	<u>\$ (28.09)</u>
Weighted-average common shares outstanding, basic and diluted	<u>639,888</u>	<u>1,004,691</u>
Pro forma net loss per share attributable to common stockholders, basic and diluted (unaudited)		<u>\$ (1.68)</u>
Pro forma weighted-average common shares outstanding, basic and diluted (unaudited)		<u>8,970,732</u>

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

WEREWOLF THERAPEUTICS, INC.

Consolidated Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit
(in thousands, except share amounts)

	SERIES A REDEEMABLE CONVERTIBLE PREFERRED STOCK		SERIES B REDEEMABLE CONVERTIBLE PREFERRED STOCK		COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' DEFICIT
	SHARES	AMOUNT	SHARES	AMOUNT	SHARES	AMOUNT			
Balances at December 31, 2018	—	\$ —	—	\$ —	639,969	\$ —	\$ 23	\$ (7,649)	\$ (7,626)
Reclassification of warrants	—	—	—	—	—	—	990	—	990
Issuance of Series A redeemable convertible preferred stock, net of issuance costs of \$193 and tranche liability of \$7,788	48,675,140	26,092	—	—	—	—	—	—	—
Accretion of redeemable convertible preferred stock to redemption value	—	7,981	—	—	—	—	(1,470)	(6,511)	(7,981)
Stock-based compensation expense	—	—	—	—	—	—	559	—	559
Issuances of restricted stock	—	—	—	—	1,219,413	2	—	—	2
Repurchases of restricted stock	—	—	—	—	(122,657)	—	—	—	—
Net loss	—	—	—	—	—	—	—	(10,248)	(10,248)
Balances at December 31, 2019	48,675,140	34,073	—	—	1,736,725	2	102	(24,408)	(24,304)
Issuance of Series A redeemable convertible preferred stock, net of issuance costs of \$31	31,571,425	22,069	—	—	—	—	—	—	—
Issuance of Series B redeemable convertible preferred stock, net of issuance costs of \$307	—	—	78,222,173	71,763	—	—	—	—	—
Accretion of redeemable convertible preferred stock to redemption value	—	12,870	—	307	—	—	(760)	(12,417)	(13,177)
Stock-based compensation expense	—	—	—	—	—	—	632	—	632
Stock option exercises	—	—	—	—	16,715	—	26	—	26
Repurchases of restricted stock	—	—	—	—	(7,209)	—	—	—	—
Net loss	—	—	—	—	—	—	—	(15,040)	(15,040)
Balances at December 31, 2020	80,246,565	\$ 69,012	78,222,173	\$ 72,070	1,746,231	\$ 2	\$ —	\$ (51,865)	\$ (51,863)

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

WEREWOLF THERAPEUTICS, INC.
Consolidated Statements of Cash Flows
(in thousands)

	YEAR ENDED DECEMBER 31,	
	2019	2020
Cash flows from operating activities:		
Net loss	\$ (10,248)	\$ (15,040)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	559	632
Depreciation	25	150
Noncash interest expense	512	—
Noncash lease expense	438	627
Change in fair value of warrant liabilities	370	—
Change in fair value of preferred stock tranche liability	(487)	(7,301)
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(131)	(177)
Accounts payable	116	388
Accrued expenses	(251)	2,616
Right of use assets and operating lease liability	(468)	(527)
Other liabilities	23	8
Net cash used in operating activities	<u>(9,542)</u>	<u>(18,624)</u>
Cash flows from investing activities:		
Acquisition of property and equipment	(266)	(560)
Net cash used in investing activities	<u>(266)</u>	<u>(560)</u>
Cash flows from financing activities:		
Proceeds from issuance of restricted stock	2	—
Deferred financing costs	—	(155)
Stock option exercise	—	26
Proceeds from issuance of Series A redeemable convertible preferred stock	22,100	22,100
Proceeds from issuance of Series B redeemable convertible preferred stock	—	72,070
Payment of equity issuance costs	(193)	(184)
Net cash provided by financing activities	<u>21,909</u>	<u>93,857</u>
Net increase in cash and cash equivalents	12,101	74,673
Cash and cash equivalents		
Cash, cash equivalents and restricted cash—beginning of period	6,003	18,104
Cash, cash equivalents and restricted cash—end of period	<u>\$ 18,104</u>	<u>\$ 92,777</u>
Supplemental disclosures of non-cash investing and financing activities:		
Non-cash accretion of Series A and Series B redeemable convertible preferred stock	\$ 7,981	\$ 13,177
Non-cash conversion of redeemable convertible notes and accrued interest	\$ 11,973	\$ —
Issuance of tranche liability in connection with Series A redeemable convertible preferred stock	\$ 7,788	\$ —
Right of use assets obtained in exchange for lease liabilities	\$ 3,546	\$ —
Change in classification of warrant liabilities	\$ 990	\$ —
Equity issuance costs in accrued expenses	\$ —	\$ 154

	AS OF DECEMBER 31,	
	2019	2020
Cash and cash equivalents	\$ 17,896	\$ 92,570
Restricted cash	208	207
Total cash, cash equivalents and restricted cash as shown in the consolidated statements of cash flows	<u>\$ 18,104</u>	<u>\$ 92,777</u>

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

WEREWOLF THERAPEUTICS, INC.

Notes to Consolidated Financial Statements
(in thousands, except share and per share amounts)

1. Description of Business, Organization, and Liquidity

Werewolf Therapeutics, Inc. ("Werewolf" or the "Company") was incorporated in the state of Delaware in October 2017. The Company is 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 headquarters are located in Cambridge, Massachusetts.

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

The Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date the financial statements are issued. The Company has incurred recurring losses since inception, including \$10,248 and \$15,040 for the years ended December 31, 2019 and 2020, respectively. As of December 31, 2020, the Company had an accumulated deficit of \$51,865. The Company expects to continue to generate operating losses and negative operating cash flows for the foreseeable future as it continues to develop its product candidates. Management believes that its cash and cash equivalents on hand as of December 31, 2020 of \$92,570 will be sufficient to continue funding the Company's increased research and development activities for more than 12 months from the date these financial statements are issued. However, additional funding will be necessary beyond this point to fund future clinical and pre-clinical activities. The Company may seek additional funding through public financings, debt financings, collaboration agreements, strategic alliances and licensing arrangements.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying financial statements have been prepared in accordance with United States generally accepted accounting principles ("GAAP"). Any reference in these notes to applicable guidance is meant to refer to the authoritative GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB"). The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the ordinary course of business.

In April 2012, the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act") was enacted. Section 107(b) of the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. The Company has irrevocably elected not to avail itself of this extended transition period, and, as a result, the Company will adopt new or revised accounting standards on the relevant dates on which adoption of such standards is required for other public companies.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, expenses and the related disclosure of

WEREWOLF THERAPEUTICS, INC.

Notes to Consolidated Financial Statements
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contingent assets and liabilities as of and during the reporting period. The Company bases its estimates and assumptions on historical experience when available and on various factors that it believes to be reasonable under the circumstances. Significant estimates and assumptions reflected in these financial statements include, but are not limited to, the fair values of common stock and redeemable convertible preferred stock, the fair value of the warrant liabilities, and the fair value of the preferred stock tranche rights. Actual results could differ materially from those estimates.

Fair Value of Financial Instruments

The Company discloses and recognizes the fair value of its assets and liabilities using a hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability (an exit price) in an orderly transaction between market participants at the reporting date. The hierarchy gives the highest priority to valuations based upon unadjusted quoted prices in active markets for identical assets or liabilities (Level 1 measurements) and the lowest priority to valuations based upon unobservable inputs that are significant to the valuation (Level 3 measurements). The guidance establishes three levels of the fair value hierarchy as follows:

- Level 1—Inputs that reflect unadjusted quoted prices in active markets for identical assets or liabilities that the Company has the ability to access at the measurement date.
- Level 2—Inputs other than quoted prices that are observable for the asset or liability either directly or indirectly, including inputs in markets that are not considered to be active.
- Level 3—Inputs are unobservable in which there is little or no market data available, which require the reporting entity to develop its own assumptions that are unobservable.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability.

Warrant Liabilities

The Company has determined that the Warrants (as defined below) issued in connection with its Convertible Notes (as defined below) represented a freestanding instrument. The resulting warrant liabilities were initially recorded at fair value, with gains and losses arising from changes in fair value recognized in other income (expense) in the consolidated statement of operations. The warrant liabilities were remeasured at each reporting period. In 2019, the warrant liabilities were modified and reclassified from liability to equity. The Warrants were marked-to-market immediately before and after the modification. Due to their reclassification from liability to equity in 2019, there will be no further remeasurement.

Preferred Stock Tranche Rights

The Company has determined that its obligation to issue, and its investors' obligation to purchase, additional shares of Series A redeemable convertible preferred stock upon the second closing represented a freestanding instrument. The resulting preferred stock tranche liability was initially recorded at fair value, with gains and losses arising from changes in fair value recognized in other income (expense) in the consolidated statements of operations. The preferred stock tranche liability was remeasured at each reporting period and upon the exercise or expiration of the obligation. The preferred stock tranche liability was valued using an option pricing model that utilized the fair value of the Series A redeemable convertible preferred stock, expected volatility and the expected term. As of December 31, 2020, all Series A redeemable convertible preferred stock closings have occurred and the associated tranche liability has been remeasured and reclassified to redeemable convertible preferred stock.

Cash and Cash Equivalents, and Restricted Cash

The Company's cash and cash equivalents consist of cash maintained within a standard checking account. The Company also maintains a cash sweep account in which cash from its main operating cash account is invested

WEREWOLF THERAPEUTICS, INC.**Notes to Consolidated Financial Statements**
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overnight in highly liquid, short-term investments. The Company considers all highly liquid investments with a maturity date of 90 days or less at the date of purchase to be cash equivalents.

The Company had restricted cash of \$208 and \$207 as of December 31, 2019 and 2020, respectively, related to a security deposit for the Company's leased office space in Cambridge, Massachusetts. The restricted cash is held in the form of a certificate of deposit.

Property and Equipment

Property and equipment are recorded at cost. Expenditures for repairs and maintenance are expensed as incurred. Depreciation is provided using the straight-line method over the estimated useful lives of the related assets as follows:

	ESTIMATED USEFUL LIFE
Computer equipment	3 years
Lab equipment	5 years
Office equipment	5 years
Leasehold improvements	7 years or the remaining term of the lease, if shorter

Upon retirement or sale of property and equipment, the cost and related accumulated depreciation are removed from the balance sheets and the resulting gain or loss is reflected in operations.

Impairment of Long-Lived Assets

Long-lived assets, which are comprised of property and equipment to be held and used, are tested for recoverability whenever events or changes in the business environment indicate that the carrying amount of the assets may not be fully recoverable. Factors considered by the Company when deciding when to perform an impairment review include significant underperformance of the business against expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows resulting from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows resulting from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its current fair value. To date, the Company has not recorded any impairment losses on long-lived assets.

Comprehensive Loss

The Company does not have items of other comprehensive loss for the years ended December 31, 2019 and 2020, and therefore does not present a consolidated statement of comprehensive loss. The Company's comprehensive loss equals its net loss.

Research and Development Expenses

Research and development costs are charged to expense as incurred. Research and development expenses include costs directly attributable to the conduct of research and development programs, including compensation costs, which includes salaries and benefits, stock-based compensation expense, depreciation on and maintenance of research equipment; the cost of services provided by outside contractors; and the allocable portions of facility costs, such as rent, utilities, insurance, and general support services. Costs for external development activities are recognized based on an evaluation of the progress to completion of specific tasks. Costs for certain research and development activities are recognized based on the pattern of performance of the individual arrangements, which may differ from the pattern of billings incurred, and are reflected in the consolidated financial statements as prepaid expenses or as accrued research and development expenses.

WEREWOLF THERAPEUTICS, INC.

Notes to Consolidated Financial Statements
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Redeemable Convertible Preferred Stock

The Company has classified redeemable convertible preferred stock outside of stockholders' deficit in the accompanying balance sheets because it becomes redeemable due to the passage of time. In absence of earlier conversion, which is outside the Company's control because the holders control the Company's board of directors, the redeemable convertible preferred stock will become redeemable upon the fifth anniversary of the original issue date. As a result of becoming redeemable due to the passage of time, the Company records changes in the redemption value and accretes the redeemable convertible preferred stock immediately to redemption value as it occurs. These increases are affected through charges against retained earnings, if any, and then to additional paid-in capital. In the absence of additional paid-in capital, the accretion is charged to accumulated deficit.

The preferred stock tranche liability relating to rights and obligations to participate in a subsequent issuance of redeemable convertible preferred stock is accounted for as a separate liability. This liability is required to be measured at fair value at issuance and remeasured at the end of each reporting period. To determine the fair value of these instruments, the Company utilized a market approach in which an option pricing model quantify and attribute value to the economic rights of preferred stock and common stock. Increases or decreases in fair value from initial measurement and each reporting period are recorded in the consolidated statements of operations as change in fair value of preferred stock tranche liability.

Stock-Based Compensation

The Company accounts for stock-based employee and nonemployee compensation awards in accordance with provisions of ASC 718, *Compensation—Stock Compensation* ("ASC 718"). ASC 718 requires the recognition of stock-based compensation expense, using a fair-value based method, for costs related to all stock-based compensation awards. ASC 718 requires companies to estimate the fair value of stock-based compensation awards on the date of grant using an option pricing or equity valuation model that is applied in a manner consistent with the fair value measurement objectives of ASC 718, is based on established principles of financial theory and reflects all of the substantive terms and conditions of the award. The Company uses the Black-Scholes option-pricing model ("Black-Scholes") and the fair value of the Company's common stock to determine the fair value of the stock option awards and restricted stock awards, respectively.

The Company's stock-based compensation awards are subject to either service or performance-based vesting conditions. Stock-based compensation expense related to awards to employees and non-employees with service-based vesting conditions is recognized on a straight-line basis based on the grant date fair value over the associated service period of the award, which is typically the vesting term. Stock-based compensation expense related to awards to employees with performance-based vesting conditions is recognized based on grant date fair value over the requisite service period using the accelerated attribution method to the extent achievement of the performance condition is probable. Non-employee option awards are measured at the earlier of the commitment date for performance by the counterparty or the date when the performance is complete, and compensation expense is recognized in the same manner as if the Company had paid cash for goods or services. The Company recognizes forfeitures as they occur for its stock-based compensation awards. The Company classifies stock-based compensation expense in its consolidated statements of operations in the same way the award recipient's payroll costs are classified or in which the award recipients' service payments are classified.

Black-Scholes requires inputs based on certain subjective assumptions, including (i) the expected stock price volatility, (ii) the expected term of the award, (iii) the risk-free interest rate and (iv) expected dividends. Due to the lack of a public market for the Company's common stock and lack of company-specific historical and implied volatility data, the Company has based its computation of expected volatility on the historical volatility of a representative group of public companies with similar characteristics to the Company, including stage of product development and life science industry focus. The historical volatility is calculated based on a period of time commensurate with expected term assumption. The Company uses the simplified method to calculate the expected term for stock options granted to employees whereby the expected term equals the arithmetic average of the vesting

WEREWOLF THERAPEUTICS, INC.

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term and the original contractual term of the stock options due to its lack of sufficient historical data. The risk-free interest rate is based on U.S. Treasury securities with a maturity date commensurate with the expected term of the associated award. The expected dividend yield is assumed to be zero as the Company has never paid dividends and has no current plans to pay any dividends on its common stock.

Due to the absence of an active market for the Company's common stock, the Company utilized methodologies in accordance with the framework of the American Institute of Certified Public Accountants Technical Practice Aid, Valuation of Privately-Held Company Equity Securities Issued as Compensation, to estimate the fair value of its common stock. In determining the exercise prices for stock options granted, the Company has considered the estimated fair value of the common stock as of the measurement date. The estimated fair value of the common stock has been determined at each grant date based upon a variety of factors, including the illiquid nature of the common stock, arm's-length sales of the Company's capital stock (including convertible preferred stock), the effect of the rights and preferences of the preferred stockholders and the prospects of a liquidity event. Among other factors are the Company's financial position and historical financial performance, the status of technological developments within the Company's research, the composition and ability of the current research and management team, an evaluation or benchmark of the Company's competition and the current business climate in the marketplace. Significant changes to the key assumptions underlying the factors used could result in different fair values of common stock at each valuation date.

Segment Reporting

Operating segments are identified as components of an enterprise for which separate discrete financial information is available for evaluation by the Company's Chief Operating Decision Maker ("CODM") to make decisions with respect to resource allocation and assessment of performance. The CODM is the Company's Chief Executive Officer. The CODM manages the Company's operations as a single segment for the purposes of assessing performance and making operating decisions. The Company's singular concentration is focused on the discovery and development of cancer therapeutics by advancing a novel class of conditionally activated proinflammatory immune modulators.

Leases

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the circumstances present. The Company accounts for a contract as a lease when it has the right to control the asset for a period of time while obtaining substantially all of the asset's economic benefits. The Company determines the initial classification and measurement of its operating right of use assets and operating lease liabilities at the lease commencement date, and thereafter if modified. The lease term includes any renewal options that the Company is reasonably assured to exercise. The Company's policy is to not record leases with a lease term of twelve months or less on its balance sheets. The Company's only existing lease is for office space.

The right of use asset represents the right to use the leased asset for the lease term. The lease liability represents the present value of the lease payments under the lease. The present value of lease payments is determined by using the interest rate implicit in the lease, if that rate is readily determinable; otherwise, the Company uses its estimated secured incremental borrowing rate for that lease term.

Lease expense for operating leases is recognized on a straight-line basis over the reasonably assured lease term based on the total lease payments and is included in operating expense in the consolidated statements of operations.

Net Loss per Common Share

Basic net loss per share is computed using the "two-class" method, which includes the weighted average number of shares of common stock outstanding during the period and other securities that participate in undistributed earnings (a participating security). The Company's redeemable convertible preferred stock and restricted stock awards are participating securities as defined by ASC 260-10, *Earnings per Share*. During the periods where the Company incurs net losses, the Company allocates no loss to participating securities because these securities have no contractual obligation to share in the losses of the Company. Under the two-class method, basic net loss per share

WEREWOLF THERAPEUTICS, INC.

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applicable to common stockholders is computed by dividing the net loss applicable to common stockholders by the weighted average number of common shares outstanding for the period. Diluted net loss per share is computed similar to basic net loss per share except that the denominator is increased to include the number of additional shares for the potential dilutive effects of warrants, redeemable convertible preferred stock and stock options outstanding during the period calculated in accordance with the treasury stock method, or the two-class method, whichever is more dilutive. The Company allocates net earnings on a *pari passu* (equal) basis to both common and preferred stockholders. Net losses are not allocated to preferred stockholders as they do not have an obligation to share in the Company's net losses. For all periods presented, basic and diluted net loss per share are the same, as any additional share equivalents would be anti-dilutive.

Unaudited Pro Forma Financial Information

The unaudited pro forma net loss per share is computed using the weighted-average number of shares of common stock outstanding after giving pro forma effect to the conversion of all issued and outstanding shares of convertible preferred stock during the year ended December 31, 2020 into shares of common stock as if such conversion had occurred at January 1, 2020 or date of issuance, if later.

Income Taxes

The Company accounts for income taxes in accordance with ASC 740, *Income Taxes* ("ASC 740"), which requires that deferred tax assets and liabilities be recognized using enacted tax rates for the effect of temporary differences between the book and tax bases of recorded assets and liabilities. Under ASC 740, the liability method is used in accounting for income taxes. Deferred tax assets and liabilities are determined based on the differences between financial reporting and the tax basis of assets and liabilities and are measured using the enacted tax rates and law that will be in effect when the differences are expected to reverse. ASC 740 also requires that deferred tax assets be reduced by a valuation allowance if it is more likely than not that some or all of the deferred tax assets will not be realized. The Company evaluates annually the realizability of the deferred tax assets by assessing the valuation allowance and by adjusting the amount of such allowance, if necessary. The factors used to assess the likelihood of realization include forecast of future taxable income and available tax planning strategies that could be implemented to realize the net deferred tax assets. In 2019 and 2020, the Company has recorded a full valuation allowance for the deferred tax assets based on the historical loss and the uncertainty regarding the ability to project future taxable income. In future periods if the Company is able to generate income, the Company may reduce or eliminate the valuation allowance.

The Company accounts for uncertain tax positions in accordance with ASC 740. ASC 740 prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax provision that an entity takes or expects to take in a tax return. Additionally, ASC 740 provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosures and transition. Under ASC 740, an entity may only recognize or continue to recognize tax positions that meet a "more likely than not" threshold. The Company recognizes accrued interest and penalties related to unrecognized tax benefits as a component of income tax.

Concentration of Credit Risk and Other Risks and Uncertainties

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist of cash and cash equivalents. Cash is held in a checking account at two financial institutions. At times, such deposits may be in excess of insured limits. The Company has not experienced any losses on its deposits of cash and cash equivalents. The Company has no significant off-balance sheet concentrations of credit risk, such as foreign currency exchange contracts, option contracts or other hedging arrangements.

The Company's future results of operations involve several risks and uncertainties. Factors that could affect the Company's future operating results and cause actual results to vary materially from expectations include, but are not limited to, rapid technological change, uncertainty of market acceptance of any products for which the Company may obtain marketing approval, competition from substitute products and larger companies, protection of proprietary technology, strategic relationships and dependence on key individuals.

WEREWOLF THERAPEUTICS, INC.

Notes to Consolidated Financial Statements
(in thousands, except share and per share amounts)

Products developed by the Company require approvals from the U.S. Food and Drug Administration or other international regulatory agencies prior to commercial sales. There can be no assurance the Company's future products will receive the necessary approvals. If the Company were to be denied approval, approval were to be delayed or it was unable to maintain approval, it could have a materially adverse impact on the Company.

The worldwide COVID-19 pandemic may affect the Company's ability to initiate and complete preclinical studies, delay the initiation of its future clinical trials, disrupt regulatory activities or have other adverse effects on its business, results of operations, financial condition and prospects. In addition, the pandemic has adversely impacted economies worldwide and may cause substantial disruption in the financial markets, both of which could adversely affect the Company's business, operations and ability to raise funds to support its operations.

To date, the Company has not experienced a material financial statement impact or business disruptions, including with its vendors, or impairments of any of its assets as a result of the pandemic. The Company is following, and plans to continue to follow, recommendations from federal, state and local governments regarding workplace policies, practices and procedures. The Company has taken temporary precautionary measures intended to help minimize the risk of the virus to its employees, including temporarily requiring certain of its employees to work remotely, suspending all non-essential travel worldwide for its employees and discouraging employee attendance at industry events and in-person work-related meetings, which could negatively affect its business. The Company expects to continue to take actions as may be required or recommended by government authorities or as it determines are in the best interests of its employees and other business partners. The Company is continuing to monitor the potential impact of the pandemic, but cannot be certain what the overall impact will be on its business, financial condition, results of operations and prospects.

Recent Accounting Pronouncements

In July 2017, the FASB issued ASU 2017-11, *I. Accounting for Certain Financial Instrument with Down Round Features II. Replacement of the Indefinite Deferral for Mandatorily Redeemable Financial Instruments of Certain nonpublic Entities and Certain Mandatorily Redeemable Noncontrolling Interests with a Scope Exception*. Part I of the ASU simplifies the accounting for certain equity-linked financial instruments and embedded features with down round features that reduce the exercise price when the pricing of a future round of financing is lower (down round protection). Current accounting guidance provides that instruments with down round protection be classified as derivative liabilities with changes in fair value recorded through earnings. The updated guidance provides that instruments with down round protection are no longer precluded from being classified as equity. This guidance is effective for fiscal years beginning after December 15, 2018. This guidance must be applied retrospectively. The Company adopted this guidance on January 1, 2019 and the adoption did not have a material impact on its financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement (Topic 820)*. This standard modifies disclosure requirements related to fair value measurement and is effective for all entities for fiscal years beginning after December 15, 2019. Among other things, ASU 2018-13 requires public entities to disclose the range and weighted average used to develop significant unobservable inputs for level 3 fair value measurements, while eliminating the requirement for public entities to disclose the amount of and reasons for transfers between level 1 and level 2 of the fair value hierarchy. Implementation on a prospective or retrospective basis varies by specific disclosure requirement. The standard also allows for early adoption of any removed or modified disclosures upon issuance while delaying adoption of the additional disclosures until their effective date. The Company adopted this guidance on January 1, 2020 and the adoption did not have a material impact on its financial statements.

In October 2020, the FASB issued ASU 2020-10, *Codification Improvements*, which updates various codification topics by clarifying or improving disclosure requirements to align with the SEC's regulations. The Company will adopt ASU 2020-10 as of the reporting period beginning January 1, 2021. The adoption of this update is not expected to have a material effect on the Company's financial statements.

WEREWOLF THERAPEUTICS, INC.

Notes to Consolidated Financial Statements
(in thousands, except share and per share amounts)

3. Financial Instruments and Fair Value Measurements

Financial assets and liabilities measured at fair value on a recurring basis are summarized below:

	AS OF DECEMBER 31, 2019			TOTAL
	QUOTED PRICE IN ACTIVE MARKETS (LEVEL 1)	SIGNIFICANT OTHER OBSERVABLE INPUTS (LEVEL 2)	SIGNIFICANT UNOBSERVABLE INPUTS (LEVEL 3)	
Assets:				
Money market funds	\$ 17,487	\$ —	\$ —	\$17,487
Total assets	<u>\$ 17,487</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$17,487</u>
Liabilities:				
Preferred stock tranche liability	\$ —	\$ —	\$ 7,301	\$ 7,301
Total liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 7,301</u>	<u>\$ 7,301</u>

	AS OF DECEMBER 31, 2020			TOTAL
	QUOTED PRICE IN ACTIVE MARKETS (LEVEL 1)	SIGNIFICANT OTHER OBSERVABLE INPUTS (LEVEL 2)	SIGNIFICANT UNOBSERVABLE INPUTS (LEVEL 3)	
Assets:				
Money market funds	\$ 92,397	\$ —	\$ —	\$92,397
Total assets	<u>\$ 92,397</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$92,397</u>
Liabilities:				
Preferred stock tranche liability	\$ —	\$ —	\$ —	\$ —
Total liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ —</u>

Cash Equivalents—Cash equivalents as of December 31, 2020 consisted of money market funds of \$92,397. Money market funds are classified within level 1 of the fair value hierarchy because they are valued using quoted market prices in active markets.

The following table sets forth a summary of the changes in fair value of the Level 3 liabilities for the years ended December 31, 2019 and 2020:

	WARRANT LIABILITIES	PREFERRED STOCK TRANCHE LIABILITY
Balance at December 31, 2018	\$ 620	\$ —
Value upon issuance of preferred stock tranche liability	—	7,788
Change in fair value of preferred stock tranche liability	—	(487)
Change in fair value of warrant liabilities	370	—
Change in classification of warrant liabilities	(990)	—
Balance at December 31, 2019	—	7,301
Change in fair value of preferred stock tranche liability	—	(7,301)
Balance at December 31, 2020	<u>\$ —</u>	<u>\$ —</u>

WEREWOLF THERAPEUTICS, INC.**Notes to Consolidated Financial Statements**
(in thousands, except share and per share amounts)

Preferred Stock Tranche Liability—During 2019, the Company issued 48,675,140 shares of Series A redeemable convertible preferred stock which contained the preferred stock tranche liability (see Note 8). The initial fair value of the preferred stock tranche liability was \$7,788. The preferred stock tranche liability was settled in June 2020 upon the closing of the second tranche of the Series A redeemable convertible preferred stock.

The preferred stock tranche liability was valued at issuance using a hybrid model. The hybrid model provides a probability weighting to various exit scenarios at the Company and determines the fair value of the preferred stock based the probability assigned to each scenario. The Company utilized the market approach to value the enterprise in one scenario, in which an option pricing model was used to attribute value to the economic rights of preferred stock and common stock. Additionally, the Company considered a scenario in which the Company would sell at or below liquidation preference of the preferred stock, with no exit option for the common stock. The Company remeasured the liability on each subsequent balance sheet date and prior to settlement and issuance of shares in connection with the Second Closing (see Note 8). Changes in fair value are recognized as a gain or loss within change in fair value of preferred stock tranche liability in the consolidated statements of operations.

The Company has estimated the fair value of the preferred stock tranche liability as of the grant date and December 31, 2019 using the Black-Scholes option pricing model with the following assumptions:

	AUGUST 2, 2019	DECEMBER 31, 2019
Stock price	\$ 0.54	\$ 0.56
Exercise price	\$ 0.70	\$ 0.70
Risk-free interest rate	1.7%	1.6%
Expected term (in years)	1.2	0.8
Expected volatility	87.0%	93.0%
Expected dividend yield	0.0%	0.0%

Warrant Liabilities—In 2017 and 2018, the Company issued the Warrants in connection with each of the Company's Convertible Notes issued (see Note 7).

On August 2, 2019, the Warrants were amended and reclassified from liability to equity. The Warrants were marked-to-market immediately before and after the Warrant Amendment (see Note 7). The inputs used to value the Warrants upon being reclassified from liability to equity are shown below. The Company recorded the change in the value of the Warrants to additional paid-in capital. There was no change between the inputs used to value the Warrants immediately before and after the Warrant Amendment.

	AUGUST 2, 2019
Stock price	\$ 2.77
Exercise price	\$ 0.09
Risk-free interest rate	1.8%
Expected term (in years)	7.0
Expected volatility	90.6%
Expected dividend yield	0.0%

WEREWOLF THERAPEUTICS, INC.**Notes to Consolidated Financial Statements**
(in thousands, except share and per share amounts)**4. Property and Equipment**

Property and equipment, net, consisted of the following:

	AS OF DECEMBER 31,	
	2019	2020
Lab equipment	\$ 252	\$ 606
Computer equipment	3	19
Office equipment	—	13
Leasehold improvements	11	188
Property and equipment, gross	266	826
Less: accumulated depreciation	(25)	(175)
Property and equipment, net	\$ 241	\$ 651

Depreciation expense for the years ended December 31, 2019 and 2020 was \$25 and \$150, respectively.

5. Accrued Expenses

Accrued expense consists of the following:

	AS OF DECEMBER 31,	
	2019	2020
Accrued manufacturing	\$ —	\$ 1,741
Accrued bonuses	543	990
Accrued professional fees	174	654
Accrued contract research	81	107
Other accrued	18	94
Total	\$ 816	\$ 3,586

6. Leases

In April 2019, the Company entered into an operating lease for 9,949 square feet of office and laboratory space in Cambridge, Massachusetts, that expires in March 2024. The Company's lease has established fixed payment terms, which increase each year throughout the term of the lease agreement.

The Company identified and assessed the following significant assumption in recognizing the right of use asset and corresponding liability:

Incremental borrowing rate

The Company derives its incremental borrowing rate from information available at the lease commencement date in determining the present value of lease payments. The incremental borrowing rate represents a collateralized rate of interest the Company would have to pay to borrow over a similar term an amount equal to the lease payments in a similar economic environment. The rate implicit on the Company's lease agreement is not reasonably determinable. As the Company did not have any external borrowings at the commencement date with comparable terms to its lease agreement, the Company estimated its incremental borrowing rate based on its credit quality, debt instruments, and by comparing interest rates available in the market for similar borrowings, and adjusting this amount based on the impact of collateral over the term of the lease.

WEREWOLF THERAPEUTICS, INC.**Notes to Consolidated Financial Statements**
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The Company is required to pay for operating costs, including insurance, maintenance and taxes, which are billed annually based on the Company's share of the total rentable square footage and applicable usage. These additional charges are considered variable lease cost and are recognized in the period in which the costs are incurred.

The components of lease expense were as follows:

	YEAR ENDED	
	DECEMBER 31,	
	2019	2020
Operating lease cost	\$ 658	\$ 877
Variable lease cost	174	208
Total lease cost	<u>\$ 832</u>	<u>\$ 1,085</u>
Weighted-average remaining lease term	4.25	3.25
Weighted-average discount rate	9.25%	9.25%

Cash paid for amounts included in the measurement of the lease liability was \$844 in 2020. There was no short term lease cost for the years ended December 31, 2019 and 2020.

As of December 31, 2020, the maturities of the Company's remaining operating lease liability were as follows:

	AS OF
	DECEMBER 31,
	2020
2021	\$ 870
2022	896
2023	923
2024	232
Thereafter	—
Present value adjustment	(380)
Present value of lease liabilities	<u>\$ 2,541</u>

7. Convertible Notes and Warrants

From inception through August 2018, the Company issued several convertible notes to related party investors ("Convertible Notes"). The Convertible Notes did not have a maturity date and accrued interest at 8.0% per annum until the entire outstanding amount was paid or converted into shares of the Company's preferred stock. The outstanding balance and accrued interest on each Convertible Note were due and payable on demand or upon an event of default. Upon the closing of an equity financing with aggregate proceeds of at least \$70.0 million (a "Qualified Financing"), the Convertible Notes were automatically convertible into the same class and series of the Company's preferred stock issued in the Qualified Financing and at the same price per share of preferred stock paid by the other investors in the Qualified Financing (the "Qualified Financing Price").

Upon the issuance of the Convertible Notes, the holder of each Convertible Note was issued a warrant to purchase shares of common stock at an exercise price of \$0.09 per share (each, a "Warrant" and, collectively, the "Warrants"). Each Warrant was originally exercisable for the number of shares of common stock equal to 20% of the original principal amount of the corresponding Convertible Note divided by the Qualified Financing Price, and were exercisable for seven years following the Qualified Financing.

WEREWOLF THERAPEUTICS, INC.**Notes to Consolidated Financial Statements**
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On August 2, 2019, the holders of the Convertible Notes agreed that the Company's issuance and sale of 27,999,996 shares of Series A redeemable convertible preferred stock at \$0.70 per share in the first tranche of the Company's Series A redeemable convertible preferred stock financing would be deemed to be a Qualified Financing under the Convertible Notes, and the Convertible Notes were converted into 17,103,716 shares of Series A redeemable convertible preferred stock. Simultaneously with the conversion of the Convertible Notes, the Warrants were amended such that each Warrant would be exercisable for the number of shares of common stock equal to 3.25% of the original principal amount of the corresponding Convertible Note divided by \$0.70, the purchase price per share of the Series A redeemable convertible preferred stock sold on August 2, 2019 (the "Warrant Amendment"). The Company determined that the conversion of the Convertible Notes into shares of Series A redeemable convertible preferred stock constituted an early extinguishment of debt.

Upon conversion of the Convertible Notes into shares of Series A redeemable convertible preferred stock and the Warrant Amendment, the number of shares to be issued upon exercise of the Warrants was fixed and knowable. Therefore, the Company reclassified the Warrants from liability to equity, as the Warrants were freestanding instruments which met the criteria prescribed in ASC 815 for equity classification. The Company recorded the Warrants at fair value on August 2, 2019 when they were reclassified from liability to equity.

8. Preferred Stock

The Company is authorized to issue up to 158,468,738 shares of convertible preferred stock with a par value of \$0.0001 per share, of which 80,246,565 shares have been designated as Series A redeemable convertible preferred stock, and 78,222,173 shares have been designated as Series B redeemable convertible preferred stock. On August 2, 2019, the Company issued 27,999,996 shares of Series A redeemable convertible preferred stock at a price of \$0.70 per share for aggregate proceeds of \$19,600, and 17,103,716 shares of Series A redeemable convertible preferred stock in connection with the conversion of the Convertible Notes with an aggregate carrying amount of \$11,973, including accrued interest. On November 1, 2019, the Company issued an additional 3,571,428 shares of Series A redeemable convertible preferred stock at a price of \$0.70 per share for aggregate proceeds of \$2,500, and on June 1, 2020, in connection with the Second Closing (as defined below), the Company issued 31,571,425 shares of Series A redeemable convertible preferred stock at a price of \$0.70 per share for aggregate proceeds of \$22,100.

On December 23, 2020, the Company issued 78,222,173 shares of Series B redeemable convertible preferred stock at a price of \$0.92 per share for aggregate proceeds of \$72,070.

As of December 31, 2020, preferred stock consisted of the following:

<u>CLASS OF PREFERRED</u>	<u>PREFERRED STOCK AUTHORIZED</u>	<u>PREFERRED STOCK ISSUED AND OUTSTANDING</u>	<u>CARRYING VALUE</u>	<u>LIQUIDATION PREFERENCE</u>	<u>COMMON STOCK ISSUABLE UPON CONVERSION</u>
Series A redeemable convertible preferred stock	80,246,565	80,246,565	\$ 69,012	\$ 69,012	9,256,620
Series B redeemable convertible stock	78,222,173	78,222,173	72,070	72,070	9,023,092
Total	<u>158,468,738</u>	<u>158,468,738</u>	<u>\$ 141,082</u>	<u>\$ 141,082</u>	<u>18,279,712</u>

Tranche Rights Issued with Series A Redeemable Convertible Preferred Stock

Included in the terms of the Series A redeemable convertible preferred stock purchase agreement (the "Series A Stock Purchase Agreement") were certain tranche rights (the "Tranche Rights"). The Tranche Rights obligated the

WEREWOLF THERAPEUTICS, INC.

Notes to Consolidated Financial Statements
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Series A redeemable convertible preferred stock investors to purchase, and the Company to sell, an additional 31,571,425 shares of Series A redeemable convertible preferred stock at \$0.70 per share (the "Second Closing") on November 1, 2020 or based on the election of each investor prior to the Second Closing. On May 12, 2020, the Series A Stock Purchase Agreement was amended such that the Second Closing would occur on June 1, 2020 or on an earlier date at the election of each investor.

The Company concluded that the Tranche Rights met the definition of a freestanding financial instrument, as the Tranche Rights were legally detachable and separately exercisable from the Series A redeemable convertible preferred stock. Therefore, the Company allocated the net proceeds between the Tranche Rights and the Series A redeemable convertible preferred stock. The trigger for the Second Closing was based on the passage of time or the election of the holders of Series A redeemable convertible preferred stock. Based on the contractual terms, and the fact that the issuance was based on an event that was not within the control of the Company (i.e., written consent or passage of time), the Tranche Rights imposed an obligation on the Company to issue shares. Since the Series A redeemable convertible preferred stock was contingently redeemable, the Tranche Rights were classified as a liability under ASC 480, *Distinguishing Liabilities from Equity*, and were initially recorded at fair value. The Tranche Rights were measured at fair value at each reporting period. Since the Tranche Rights were subject to fair value accounting, the Company allocated the proceeds to the Tranche Rights based on the fair value at the date of issuance with the remaining proceeds being allocated to the Series A redeemable convertible preferred stock.

The estimated fair value of the Tranche Rights was determined using a probability-weighted present value model that considered the probability of closing a tranche, the estimated future value of Series A redeemable convertible preferred stock at each closing and the investment required at each closing. Future values were converted to present value using a discount rate appropriate for probability-adjusted cash flows. The Tranche Rights were initially recorded as a liability of \$7,788. The Company remeasured the liability on each subsequent balance sheet date and prior to settlement and issuance of shares in connection with the Second Closing, which occurred on June 1, 2020.

Rights, preferences, privileges, and restrictions:

The holders of Series A redeemable convertible preferred stock and Series B redeemable convertible preferred stock (or collectively, the "Preferred Stock") have the rights, preferences, privileges, and restrictions as set forth below:

Dividends:

The holders of Series A redeemable convertible preferred stock and Series B redeemable convertible preferred stock are entitled to receive non-cumulative dividends when, as and if declared by the Company's Board of Directors at a rate of \$0.056 per share and \$0.0737 per share, respectively. The Company may not declare any dividends on the common stock unless the holders of Preferred Stock simultaneously receive dividends at the same rate and same time as the common stock, with the holders of Preferred Stock participating on an as-if converted basis. No dividends have been declared or paid as of December 31, 2020.

Voting Rights:

The holders of Preferred Stock are entitled to voting rights equal to the number of shares of common stock into which the shares of Preferred Stock can be converted. As long as at least 15,000,000 shares of Preferred Stock remain outstanding, the holders of Series A redeemable convertible preferred stock, exclusively and as a separate class, are entitled to elect four members of the Company's Board of Directors, and the holders of Series B redeemable convertible preferred stock, exclusively and as a separate class, are entitled to elect two members of the Company's Board of Directors. If the holders of the Preferred Stock fail to elect a sufficient number of directors to fulfill directorships for which they are entitled to elect directors, then any directorship shall remain vacant until the holders of Preferred Stock elect a person. The holders of common stock, and any other class or series of voting stock (including Preferred Stock) exclusively and voting together as a single class, shall be entitled to elect the balance of the total number of directors of the Company.

WEREWOLF THERAPEUTICS, INC.

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Liquidation Rights:

In the event of any liquidation, dissolution or winding up of the Company, whether voluntary or involuntary, the holders of Preferred Stock have liquidation preferences, before any distribution or payment is made to holders of any common stock, in an amount per share equal to the greater of (i) the original issue price of \$0.70 per share for Series A redeemable convertible preferred stock and the original issue price of \$0.92 per share for Series B redeemable convertible preferred stock, respectively, or (ii) an amount per share that would have been payable had, in the case of the Series A redeemable convertible preferred stock, all shares of Series A redeemable convertible preferred stock and, in the case of the Series B redeemable convertible preferred stock, Series B redeemable convertible preferred stock been converted to common stock. If the assets and funds to be distributed among the holders of Preferred Stock are insufficient to permit the payment to such holders, then the entire assets and funds of the Company legally available for distribution will be distributed ratably among the holders of Preferred Stock in proportion to the preferential amount each such holder is otherwise entitled to receive.

Upon completion of the payment of the full liquidation preference of Preferred Stock, the remaining assets of the Company, if any, shall be distributed among the holders of common stock, pro rata based on the number of shares held by each common stockholder.

Conversion:

Each share of Preferred Stock is convertible into shares of common stock, at the option of the holder, at any time after date of issuance. Each share of Preferred Stock automatically converts to the number of shares of common stock determined in accordance with the conversion rate upon the earlier of (i) the closing of a public offering, in which the gross cash proceeds are at least \$75,000 and the initial offering price to the public is at least \$24.01 per share (as adjusted for any stock splits, stock dividends, combinations, subdivisions, recapitalizations, reorganizations, reclassifications or the like) or (ii) the occurrence of an event, specified by vote or written consent of the Preferred Holders.

Redemption:

The Preferred Stock is not currently redeemable. Upon certain change in control events that are outside of the Company's control, including liquidation, sale or transfer of control of the Company, the Preferred Stock is contingently redeemable. In addition, the Preferred Stock is redeemable at any time on or after the fifth anniversary of the original issue date. The Preferred Stock shall be redeemed by the Company at a price equal to the greater of (i) the original issue price of \$0.70 per share for Series A redeemable convertible preferred stock and the original issue price of \$0.92 per share for Series B redeemable convertible preferred stock, respectively, or (ii) the fair market value of the Series A redeemable convertible preferred stock and Series B redeemable convertible preferred stock, as applicable, as of the redemption request date. As the Preferred Stock becomes redeemable due to the passage of time, the Company records changes in the redemption value and accretes the Preferred Stock immediately to redemption value as it occurs.

Protective Provisions:

As long as at least 20,000,000 shares of Preferred Stock are outstanding, as adjusted for any stock splits, stock dividends, combinations, subdivisions, recapitalizations, reorganizations, reclassifications or the like, the Company shall not, either directly or by amendment, merger, consolidation, reclassification or otherwise, do any of the following without the approval of the holders of a majority of the shares of outstanding Preferred Stock, including at least 67% of the then-outstanding shares of Series B redeemable convertible preferred stock: (i) effect the consummation of a liquidation event or any other merger or consolidation, (ii) amend, alter or repeal any provision of the Company's certificate of incorporation or bylaws in a manner that adversely affects the powers, preferences or rights of the Preferred Stock, (iii) create, or authorize the creation of, or obligate the Company to issue any equity security unless such security is junior to the Preferred Stock, (iv) subject to certain exceptions, purchase or redeem, or pay or declare or make any distribution on, any shares of the capital stock, (v) create, or authorize the creation of, or issue, or authorize the issuance of certain debt securities, (vi) change the authorized number of directors of the Company, (vii) increase the number of authorized shares of Preferred Stock, (viii) alter or change the powers,

WEREWOLF THERAPEUTICS, INC.

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preferences or rights of the Preferred Stock, (ix) create, or hold capital stock in, any subsidiary that is not wholly owned or (x) enter into any transactions between the Company and any Company affiliate.

9. Term Loan

In May 2020, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with Pacific Western Bank ("PWB"). Under the terms of the Loan Agreement, PWB made available a term loan up to \$6,000 ("Term Loan A"). Based on the satisfaction of certain conditions defined in the Loan Agreement, PWB is also obligated to make available an additional term loan in the amount of up to \$8,000 ("Term Loan B", or collectively with Term Loan A, the "Term Loans"). The Company satisfied the conditions to draw Term Loan B in June 2020. Although Term Loan A was made available to the Company at the closing date, the Company elected to forgo making a draw, thereby incurring a delayed draw fee of \$25 with PWB. As of December 30, 2020, the Company had not drawn down any Term Loans and had no outstanding borrowings under the Loan Agreement.

The Term Loans will bear interest on the outstanding daily balance at a floating annual rate equal to greater of: (i) 1.75% above the prime rate then in effect or (ii) 5.00%. 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 Loan Agreement is computed on a 360-day year for the actual number of days elapsed, with interest payable monthly.

The Company is obligated to pay PWB a fee of 5.00% of the amount drawn under the Term Loans upon the occurrence of the Company achieving certain conditions defined in the Loan Agreement (the "Success Fee"). The Success Fee will survive ten years from the date of payment of the Term Loan in full, such that, if the Loan Agreement is terminated prior to the payment of the Success Fee the Company will remain obligated to pay the Success Fee upon the occurrence of a Success Fee Event.

The Company determined that the Success Fee constitutes a freestanding financial instrument and should be accounted for as a liability in connection with ASC 480—*Distinguishing Liabilities from Equity*. The Company determined that the fair value of the Success Fee was immaterial at both issuance and as of December 31, 2020.

Borrowings under the Loan Agreement are secured by the Company's 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 obligated to pay a fee equal to 5.0% of such unpaid amounts. In connection with the Loan Agreement, the Company is required to comply with certain covenants, which among other things, restrict the Company from (i) effectuating a merger or consolidation with or into any other business organization, (ii) paying dividends or making certain other distributions and (iii) making investments in any entities or instruments other than certain investments specified in the Loan Agreement. In addition, the Loan Agreement 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 state of formation. The Company is also required to maintain unrestricted cash balances of at least 2.5 times its monthly cash burn, and has covenanted not to make any capital expenditures in excess of \$350 in the aggregate in any fiscal year without the prior written consent of PWB. In December 2020, the Loan Agreement was amended to allow the Company to make investments in its subsidiary, Werewolf Therapeutics Mass Securities, Inc., subject to certain conditions described in the Loan Agreement. In February 2021, the Loan Agreement was amended such that the Company may not make any capital expenditures in excess of \$2,000 in the aggregate in 2021 and \$500 in the aggregate in any fiscal year thereafter without the prior written consent of PWB.

PWB has the right to accelerate all obligations of the Company in the event of a material adverse effect on (i) the operations, business or financial condition of the Company (ii) the Company's ability to repay any portion of the Term Loans or perform any of its other obligations under the Loan Agreement and (iii) the Company's interest in, or the value, perfection or priority of PWB's security interest in the collateral. As of December 31, 2020, the Company had \$14,000 available to draw on the Term Loans and had no outstanding principal.

WEREWOLF THERAPEUTICS, INC.**Notes to Consolidated Financial Statements**
(in thousands, except share and per share amounts)**10. Common Stock**

Common stockholders are entitled to dividends if and when declared by the Company's Board of Directors subject to the rights of the preferred stockholders. As of December 31, 2020, no dividends on common stock had been declared by the Company.

The Company had reserved shares of common stock for issuance as follows:

	AS OF DECEMBER 31,	
	2019	2020
Redeemable convertible preferred stock outstanding	5,614,780	18,279,712
Options issued and outstanding	172,878	2,058,964
Warrants issued and outstanding	58,904	58,904
Total	<u>5,846,562</u>	<u>20,397,580</u>

11. Stock-based Compensation

In 2017, the Company adopted the 2017 Stock Incentive Plan (the "Plan"). As of December 31, 2020, the maximum number of shares of common stock authorized to be issued under the Plan was 3,480,522 shares. Any award that expires, is terminated, forfeited, surrendered, or canceled without having been fully exercised, will be returned to the overall pool available for grant. The Company had a total of 172,878 and 926,768 of stock options and restricted stock awards outstanding and a total of 2,058,964 and 562,049 of stock options and restricted stock awards as of December 31, 2019 and 2020, respectively.

Under the Plan, the Company may grant incentive stock options, nonqualified stock options, restricted stock, restricted stock units, stock appreciation rights and other stock-based awards. The exercise price of stock options must be no less than 100% of the grant date fair market value of the stock option award. The maximum term of the stock option awards cannot exceed 10 years from the date of grant. To date, the Company has granted stock options and restricted stock to both employees and nonemployees.

Service-based stock option and restricted stock awards generally vest 25% on the 1-year anniversary of the applicable vesting commencement date, and an additional 1/48th on a monthly basis thereafter for three years.

Stock-based Payment

The following table summarizes restricted stock activity for employees and non-employees during the year ended December 31, 2020:

	SHARES/UNITS	WEIGHTED-AVERAGE GRANT DATE FAIR VALUE PER SHARE
Unvested at December 31, 2019	926,768	\$ 1.54
Granted	—	—
Vested	(357,510)	\$ 1.54
Forfeited	(7,209)	\$ 1.56
Unvested at December 31, 2020	<u>562,049</u>	\$ 1.54

During the year ended December 31, 2020, the total fair value of restricted stock vested was \$551. At December 31, 2020, total unrecognized stock-based compensation expense related to unvested restricted stock was \$867, which the Company expects to recognize over a weighted-average period of 2.3 years.

WEREWOLF THERAPEUTICS, INC.**Notes to Consolidated Financial Statements**
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During the year ended December 31, 2019, the Company granted 927,688 shares of restricted stock to employees, of which 60.5% did not contain vesting conditions predicated upon satisfaction of a performance condition, and 39.5% vested upon the Second Closing of the Company's Series A redeemable convertible preferred stock financing. Management recognized stock-based compensation expense of \$116 associated with 60.5% of the restricted stock awards that were not predicated upon the satisfaction of a performance condition. However, management determined the Second Closing was a type of liquidity event that was not to be considered probable until the Second Closing occurred. As such, the Company did not recognize any stock-based compensation expense for the year ended December 31, 2019 associated with the restricted stock awards that vests only upon the completion of the Second Closing. Management determined that occurrence of the Second Closing in June 2020 satisfied the performance conditions associated with Series A redeemable convertible preferred stock and, as such, the Company recorded a cumulative catch up stock-based compensation expense of \$56 related to these restricted stock awards in 2020.

Stock Options

	OPTIONS OUTSTANDING		
	NUMBER OF OPTIONS	WEIGHTED AVERAGE EXERCISE PRICE	WEIGHTED-AVERAGE REMAINING CONTRACTUAL LIFE (IN YEARS)
Balances, December 31, 2019	172,878	\$ 1.56	9.95
Options granted	1,907,412	\$ 3.96	
Options exercised	(16,715)	\$ 1.56	
Options forfeited	(4,611)	\$ 1.56	
Balances, December 31, 2020	2,058,964	\$ 3.79	9.76
Exercisable at December 31, 2020	35,240	\$ 1.61	8.97
Vested and expected to vest at December 31, 2020	2,058,964	\$ 3.79	9.76

The weighted-average grant date fair value of stock options granted was \$1.08 and \$2.73 during the years ended December 31, 2019 and 2020, respectively. There were 172,878 stock options granted at an aggregate fair value of \$186 for the year ended December 31, 2019 and 1,907,412 stock options granted at an aggregate fair value of \$5,209 for the year ended December 31, 2020. The total grant-date fair value of service-based stock options vested was \$3 and \$54 during the years ended December 31, 2019 and 2020, respectively. There were no stock options exercised during the year ended December 31, 2019. During the year ended December 31, 2020, there were 16,715 stock options exercised with an aggregate grant date fair value of \$18. As of December 31, 2020, the total unrecognized stock-based compensation expense related to unvested stock option awards was approximately \$5,187, which the Company expects to recognize over a weighted-average period of approximately 3.8 years.

WEREWOLF THERAPEUTICS, INC.**Notes to Consolidated Financial Statements**
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The fair value of stock options was estimated using the following assumptions:

	YEAR ENDED DECEMBER 31, 2020
Stock price	\$1.56 - \$4.77
Exercise price	\$1.56 - \$4.77
Risk-free interest rate	0.3% - 0.9%
Expected term (in years)	5.9 - 6.1
Dividend yield	0%
Expected volatility	80.3% - 95.2%

Expected Term: The Company uses the simplified method to calculate expected term described in the Securities and Exchange Commission's Staff Accounting Bulletin No. 107, which takes into account vesting term and expiration date of the options.

Volatility: Volatility is based on an average of the historical volatilities of comparable publicly traded companies for the expected term.

Risk Free Interest Rate: The risk-free rate is based on the U.S. Treasury yields in effect at the time of grant for periods corresponding with the expected term of the option.

Dividend Yield: The Company has never declared or paid any cash dividends and does not plan to pay cash dividends in the foreseeable future, and therefore, used an expected dividend yield of zero in the valuation model.

Total Stock-Based Compensation Expense

Total stock-based compensation expense recorded under ASC 718 related to stock options and restricted stock awards granted to employees and nonemployees was allocated to research and development and general and administrative expense as follows:

	YEAR ENDED DECEMBER 31,	
	2019	2020
Research and development	\$ 239	\$ 192
General and administrative	320	440
Total stock-based compensation	<u>\$ 559</u>	<u>\$ 632</u>

12. License Agreements**Harpoon License**

In March 2018, the Company entered into a Patent Assignment and License Agreement (the "Harpoon Agreement") with Harpoon Therapeutics ("Harpoon"), a clinical-stage immune-oncology company developing a novel class of T-cell engagers to fight cancer and other diseases. Under the terms of the Harpoon Agreement, Harpoon granted the Company a license to use its intellectual property, solely to make, have made, use, sell, offer for sale and import covered products in the licensed field and Harpoon sold, assigned and transferred other specific patents to the Company (the "Harpoon License").

On October 19, 2018, the Company and Harpoon entered into the First Amended and Restated Assignment and License Agreement which amended certain terms of the original agreement, but did not change the terms of the

WEREWOLF THERAPEUTICS, INC.

Notes to Consolidated Financial Statements
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license to the Company, patent assignments between the parties or payments due to Harpoon. Further, on December 20, 2019, the companies entered into the Second Amended and Restated Assignment and License Agreement, which also amended certain terms of the original agreement to expand the licenses and assignments for specific patents granted to the Company or by the Company to Harpoon. In exchange for these additional terms, Harpoon agreed to reimburse up to \$75 of the Company's legal costs. Additionally, the Company agreed to pay to Harpoon royalties on future net sales and pay minimum annual royalties of \$250 upon achievement of its first commercial sale.

Under the terms of the Harpoon License, the Company paid an upfront fee of \$500 in 2018 and is obligated to reimburse Harpoon for certain legal costs incurred by Harpoon. In addition, the Company is obligated to pay Harpoon royalties based on future net sales and has agreed to pay a minimum annual royalty payment at an amount in the low hundreds of thousands of dollars upon achievement of its first commercial sale. In 2018, the Company recorded the upfront fee as research and development expense upon payment as the intellectual property was acquired prior to regulatory approval and does not have an alternative future use. The royalty payments are contingent upon sales and, as such, the royalty payments made to Harpoon will be considered probable and estimable and treated as cost of sales when incurred. Accordingly, at the commencement of sales, the Company will account for the royalty payments as cost of sales equal to the greater of a percentage in the low-single digits of the net sales of the patent-covered products or a minimum annual royalty payment at an amount in the low hundreds of thousands of dollars. Any legal fees incurred in connection with the Harpoon Agreement will be expensed as incurred.

The Harpoon License will expire on a country-by-country basis upon the expiration of the last to expire patent or patent application included in the licensed patents within the applicable country. The Company has the right to terminate the Harpoon License upon 30 days prior written notice to Harpoon, and either party may terminate for a material breach if such breach is not cured within a specified number of days.

Adimab License

In March 2018, the Company entered into a Development and Option Agreement (the "Adimab Agreement") with Adimab LLC ("Adimab"), a company specializing in antibody discovery, humanization and optimization. Under the terms of the Adimab Agreement, Adimab granted the Company the rights to initiate certain research initiatives on a specified number of targets. Adimab also granted to the Company a license to certain Adimab core technologies, antibodies and products applicable to certain targets ("Adimab License").

In August 2020 the Company and Adimab entered into Amendment One to the Development and Option Agreement, which extended the period of time for the Company to evaluate candidate antibodies in advance of electing to exercise the option to acquire exclusive rights to licensed antibodies (the "Evaluation Term"), but did not otherwise change the terms of the Adimab License. The Evaluation Term was then further extended in December 2020 by entering into Amendment Two to the Development and Option Agreement, through delivery of a non-refundable payment of \$100 by the Company to Adimab, which was creditable toward the option fee. The non-refundable payment was recorded immediately as research and development expense in the consolidated statements of operations.

Under the terms of the Adimab License, the Company must pay both an upfront fee and final fee of \$200 for all research programs. The Company must also pay Adimab milestone fees with respect to each research program ranging from \$150 to \$200 based on the achievement of technical milestones by Adimab for the applicable research program. In order to exercise any options in the Adimab Agreement, the Company must pay a \$500 fee for each target option exercised.

For each target option exercised, the Company is also obligated to pay certain milestones ranging from \$1,000 to \$4,000 for certain clinical and commercialization achievements. Additionally, for licensed products sold during the applicable royalty term, the Company must pay Adimab royalties at percentages in the low-to-mid single digits.

WEREWOLF THERAPEUTICS, INC.**Notes to Consolidated Financial Statements**
(in thousands, except share and per share amounts)

The Adimab Agreement will expire upon the expiration of any options or if an option is exercised, on a country-by-country and licensed product-by-licensed product basis on the expiration of the last royalty term for a licensed product in the particular country. As of December 31, 2020, the Company has not exercised any target options or recorded any milestone or royalty payments pursuant to the Adimab Agreement.

13. Income Taxes

During the years ended December 31, 2019 and 2020, the Company recorded no current or deferred income tax expenses or benefits as the Company has incurred losses since inception and has provided a full valuation allowance against its deferred tax assets.

A reconciliation of the expected income tax (benefit) computed using the federal statutory income tax rate to the Company's effective income tax rate is as follows:

	YEAR ENDED DECEMBER 31,	
	2019	2020
Income tax computed at federal statutory rate	21.0%	21.0%
State taxes, net of federal benefit	6.7	9.9
Change in valuation allowance	(26.5)	(42.0)
R&D credit carryovers	0.7	1.7
Interest expense	(1.0)	0.0
Stock-based compensation	(1.1)	(0.8)
Cancellation of tranche rights	0.0	10.2
Permanent differences	0.2	0.0
Effective income tax rate	<u>0.0%</u>	<u>0.0%</u>

The Company's deferred tax assets consist of the following:

	AS OF DECEMBER 31,	
	2019	2020
Deferred tax assets:		
Net operating losses	\$ 4,363	\$ 10,363
Tax credit carryforwards	566	1,021
Lease liability	910	731
Capitalized costs—net of amortization	135	124
Reserves and accruals	—	264
Other	1	—
Deferred tax assets	<u>5,975</u>	<u>12,503</u>
Valuation allowance	(5,069)	(11,776)
Deferred tax assets recognized	<u>906</u>	<u>727</u>
Deferred tax liabilities:		
Right of use asset	(899)	(711)
Fixed assets and depreciation	(7)	(12)
Other	—	(4)
Deferred tax liabilities	<u>(906)</u>	<u>(727)</u>
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

WEREWOLF THERAPEUTICS, INC.

Notes to Consolidated Financial Statements
(in thousands, except share and per share amounts)

The Company evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets as of December 31, 2019 and 2020. Management considered the Company's cumulative net losses and concluded as of December 31, 2019 and 2020, that it was more likely than not that the Company would not realize the benefits of the deferred tax assets. Accordingly, a full valuation allowance was established against the net deferred tax assets as of December 31, 2019 and 2020. The valuation allowance increased by \$2,895 and \$6,707 for the years ended December 31, 2019 and 2020, respectively, primarily as a result of operating losses generated with no corresponding financial statement benefit.

The Company has incurred net operating losses ("NOL") since inception. As of December 31, 2019 and 2020, the Company had federal net operating loss carryforwards of \$15,046 and \$35,898, respectively, available to reduce future federal taxable income. The carryforward generated in 2017 expire in 2037. \$35,764 of carryforwards generated post 2017 do not expire. The Tax Cuts and Jobs Act enacted on December 22, 2017 limits a taxpayer's ability to utilize NOL deduction in a year to 80% taxable income for federal net operating losses arising in tax years beginning after 2017. The Coronavirus Aid, Relief, and Economic Security Act enacted on March 27, 2020 removes the 80% taxable income limitation for NOL deductions in taxable years beginning prior to January 1, 2021. As of December 31, 2019 and 2020, the Company had state net operating loss carryforwards of \$15,045 and \$35,301, respectively, available to reduce future state taxable income, which expire at various dates beginning in 2037.

As of December 31, 2019 and 2020, the Company had federal research and development tax credit carryforwards of \$355 and \$613, respectively, available to reduce future federal tax liabilities, which expire at various dates beginning in 2038. The Company also had state research and development tax credit carryforwards as of December 31, 2019 and 2020 of \$212 and \$408, respectively, available to reduce future state tax liabilities, which expire at various dates beginning in 2033.

Utilization of the Company's net operating loss carryforwards and research and development tax credit carryforwards may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 due to ownership changes that have occurred previously or that could occur in the future. These ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of certain shareholders or public groups in the stock of a corporation by more than 50% over a three-year period. The Company has not conducted a study to assess whether a change of control has occurred or whether there have been multiple changes of control since inception due to the significant complexity and cost associated with such a study. If the Company has experienced a change of control, as defined by Section 382, at any time since inception, utilization of the net operating loss carryforwards or research and development tax credit carryforwards would be subject to an annual limitation under Section 382, which is determined by first multiplying the value of the Company's stock at the time of the ownership change by the applicable long-term tax-exempt rate, and then could be subject to additional adjustments, as required. Any limitation may result in expiration of a portion of the net operating loss carryforwards or research and development tax credit carryforwards before utilization. Further, until a study is completed, and any limitation is known, no amounts are being presented as an uncertain tax position.

The Company has not recorded any reserves for uncertain tax positions as of December 31, 2019 and 2020. The Company has not yet conducted a study of research and development credit carryforwards; however, until a study is completed, and any adjustment is known, no amounts are being presented as an uncertain tax position. A full valuation allowance has been provided against the Company's research and development credits and, if an adjustment is required, this adjustment would be offset by an adjustment to the valuation allowance. Thus, there would be no impact.

The Company files tax returns as prescribed by the tax laws of the jurisdictions in which it operates. In the normal course of business, the Company is subject to examination by federal and state jurisdictions, where applicable. There are currently no pending tax examinations. The Company's tax years are still open under statute from inception to the present.

WEREWOLF THERAPEUTICS, INC.**Notes to Consolidated Financial Statements**
(in thousands, except share and per share amounts)**14. Net Loss per Share and Unaudited Pro Forma Net Loss Per Share**

The following outstanding potentially dilutive common stock equivalents have been excluded from the calculation of diluted net loss per share attributable to common stockholders for the periods presented due to their antidilutive effect:

	AS OF DECEMBER 31,	
	2019	2020
Redeemable convertible preferred stock (as converted)	5,614,780	18,279,712
Options issued and outstanding	172,878	2,058,964
Warrants to purchase common stock	58,904	58,904
Total	<u>5,846,562</u>	<u>20,397,580</u>

The basic and diluted net loss per share attributable to common stockholders has been prepared as follows:

	YEAR ENDED DECEMBER 31,	
	2019	2020
Net loss	\$ (10,248)	\$ (15,040)
Accretion of redeemable convertible preferred stock to redemption value	(7,981)	(13,177)
Net loss attributable to common stockholders	<u>\$ (18,229)</u>	<u>\$ (28,217)</u>
Weighted-average common shares outstanding—basic and diluted	<u>639,888</u>	<u>1,004,691</u>
Net loss per share attributable to common stockholders—basic and diluted	<u>\$ (28.49)</u>	<u>\$ (28.09)</u>

Unaudited Pro Forma Financial Information

The unaudited pro forma net loss per share is computed using the weighted-average number of shares of common stock outstanding after giving pro forma effect to the conversion of all issued and outstanding shares of convertible preferred stock during the year ended December 31, 2020, into shares of common stock as if such conversion had occurred on January 1, 2020 or the dates those convertible preferred stock were issued; whichever is later.

	YEAR ENDED DECEMBER 31, 2020
Net loss attributable to common stockholders	\$ (28,217)
Adjust: Remove impact of accretion of preferred stock—Pro Forma	13,177
Net loss attributable to common stockholders	<u>\$ (15,040)</u>
Weighted-average common shares—basic and diluted	1,004,691
Adjust: Assumed weighted-average effect of conversion of convertible preferred stock (unaudited)	7,966,041
Pro Forma weighted-average common shares outstanding—basic and diluted	<u>8,970,732</u>
Pro Forma net loss per share attributable to common stockholders—basic and diluted	<u>\$ (1.68)</u>

15. Related Parties

The Company issued the Convertible Notes to investors from December 2017 until August 2018 (see Note 7). On December 5, 2017, the Company entered into a royalty transfer agreement, which was amended and restated on

WEREWOLF THERAPEUTICS, INC.

Notes to Consolidated Financial Statements
(in thousands, except share and per share amounts)

August 2, 2019, with MPM Oncology Charitable Foundation, an entity affiliated with MPM Capital, which is an investor in the Company, and UBS Optimus Foundation, an entity affiliated with UBS Oncology Impact Fund, L.P., which is an investor in the Company, for the transfer of one percent of all future global net sales to the MPM Oncology Charitable Foundation and UBS Optimus Foundation. During the years ended December 31, 2019 and 2020, MPM Capital provided management services to the Company. For the year ended December 31, 2019, the Company incurred \$195 of general and administrative expense and \$64 of research and development expense in the accompanying consolidated statements of operations related to the MPM Capital management services. For the year ended December 31, 2020, the Company recorded \$31 of general and administrative expense in the accompanying consolidated statements of operations related to the MPM Capital management services. As of December 31, 2019, and 2020, the Company recorded amount in accounts payable of \$21 and \$8, respectively, in the accompanying consolidated balance sheets related to the MPM Capital management services.

In March 2018, the Company entered into the Harpoon Agreement with Harpoon, an affiliate of an investor (see Note 12). For the years ended December 31, 2019 and 2020, respectively, the Company did not incur any expenses related to the Harpoon Agreement. During the year ended December 31, 2019, the Company incurred certain legal expenses which were agreed to be reimbursed by Harpoon. As of December 31, 2019, the Company recorded a receivable of \$75 for legal fees in Other Current Assets on its balance sheet with a corresponding reduction to general and administrative expenses with respect to these reimbursable expenses.

In December 2019, the Company entered into a consulting agreement with Briggs Morrison, M.D., a member of the Company's board of directors, for the provision of consulting, advisory and related services. Pursuant to the consulting agreement, in December 2019, the Company issued Dr. Morrison a stock option for 46,570 shares of our common stock at an aggregate grant date fair value of \$50, and agreed to reimburse certain of Dr. Morrison's expenses in connection with the performance of services under the agreement. The stock option has an exercise price of \$1.56 per share and is scheduled to vest with respect to 2.0833% of the shares underlying the stock option in equal monthly installments over four years following November 2019, subject to continuous service. The Company recognized \$2 and \$13 of expense related to this award in the research and development line in the consolidated statements of operations for the years ended December 31, 2019 and 2020, respectively.

16. Subsequent Events

Subsequent events have been evaluated through February 26, 2021, which is the date of the consolidated financial statements were available to be issued and April 26, 2021 as to the reverse stock split referenced below.

Reverse Stock Split

In connection with preparing for its initial public offering, the Company's board of directors and stockholders approved an amendment to the Company's certificate of incorporation, which became effective on April 23, 2021. The amendment, among other things, effected a 1-for-8.6691 reverse stock split of the Company's common stock and a proportional adjustment to the conversion price for each series of preferred stock and to the exercise prices and number of shares of common stock underlying the outstanding stock options, and modified the requirements for the automatic conversion of all outstanding shares of preferred stock.

All share and per share amounts in the consolidated financial statements and notes thereto have been retroactively adjusted for all periods presented to give effect to the reverse stock split, including reclassifying an amount equal to the reduction in par value of common stock to additional paid-in capital.

7,500,000 Shares



Common Stock

PROSPECTUS

Jefferies

SVB Leerink

Evercore ISI

H.C. Wainwright & Co.

April 29, 2021
